

[Table of Contents](#)

Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-233604

PROSPECTUS

7,142,858 Shares



Common Stock

This is the initial public offering of shares of common stock of Vir Biotechnology, Inc.

We are offering 7,142,858 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is \$20.00.

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “VIR.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See the section titled “[Risk Factors](#)” beginning on page 11.

	Per Share	Total
Initial public offering price	\$ 20.00	\$ 142,857,160.00
Underwriting discounts and commissions(1)	\$ 1.40	\$ 10,000,001.20
Proceeds to us before expenses	\$ 18.60	\$ 132,857,158.80

(1) See the section titled “Underwriting” for additional information regarding compensation payable to the underwriters.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

We have granted the underwriters an option for a period of 30 days to purchase up to 1,071,428 additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on October 16, 2019.

Goldman Sachs & Co. LLC

J.P. Morgan

Cowen

Barclays

Prospectus dated October 10, 2019

[Table of Contents](#)

TABLE OF CONTENTS

	<u>Page</u>
Prospectus Summary	1
Risk Factors	11
Special Note Regarding Forward-Looking Statements	63
Market and Industry Data	64
Use of Proceeds	65
Dividend Policy	66
Capitalization	67
Dilution	69
Selected Consolidated Financial Data	71
Management's Discussion and Analysis of Financial Condition and Results of Operations	73
Business	94
Management	159
Executive and Director Compensation	168
Certain Relationships and Related Party Transactions	186
Principal Stockholders	192
Description of Capital Stock	195
Shares Eligible for Future Sale	201
Material U.S. Federal Income Tax Consequences for Non-U.S. Holders	204
Underwriting	208
Legal Matters	214
Experts	214
Where You Can Find Additional Information	214
Index to Consolidated Financial Statements	F-1

“Vir Biotechnology,” “Vir Bio,” “Vir.Bio,” the Vir logo and other trademarks, trade names or service marks of Vir Biotechnology, Inc. appearing in this prospectus are the property of Vir Biotechnology, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside the United States.

Unless the context otherwise requires, the terms “Vir,” “the company,” “we,” “us,” “our” and similar references in this prospectus refer to Vir Biotechnology, Inc. and its consolidated subsidiaries.

[Table of Contents](#)

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus. You should carefully consider, among other things, the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus.

Our Mission Is to Create a World Without Infectious Disease

We are a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are one of the leading causes of death worldwide and cause hundreds of billions of dollars of economic burden each year. We believe that now is the time to apply the recent and remarkable advances in immunology to combat infectious diseases. Our approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. We then bring to bear powerful technologies that we believe, individually or in combination, will lead to effective therapies.

We have assembled four technology platforms, focused on antibodies, T cells, innate immunity and small interfering ribonucleic acid, or siRNA, through internal development, collaborations and acquisitions. Our current development pipeline consists of product candidates targeting hepatitis B virus, or HBV, influenza A, human immunodeficiency virus, or HIV, and tuberculosis, or TB. VIR-2218, an HBV-targeting siRNA, is in an ongoing Phase 1/2 clinical trial and initial data have demonstrated substantial reduction of hepatitis B virus surface antigen, or HBsAg. Based on initial data, VIR-2218 has been generally well-tolerated. Additionally, we have initiated a Phase 1/2 clinical trial for VIR-2482, a monoclonal antibody, or mAb, designed for the prevention of influenza A. We have built an industry-leading team that has deep experience in immunology, infectious diseases and product development. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

Our Technology Platforms

Our four current technology platforms are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. We are using our platforms to advance our current product candidates and generate additional product candidates for multiple indications.

Antibody Platform: We have established a robust method for capitalizing on unusually successful immune responses naturally occurring in people who are protected from, or have recovered from, infectious diseases. We identify rare antibodies from survivors that have the potential to treat and prevent rapidly evolving and/or previously untreatable pathogens via direct pathogen neutralization and immune system stimulation. We engineer the fully-human antibodies that we discover to enhance their therapeutic potential.

T Cell Platform: We are exploiting the unique immunology of human cytomegalovirus, or HCMV, a commonly occurring virus in humans, as a vaccine vector to potentially treat and prevent infection by pathogens refractory to current vaccine technologies. This approach is based on fundamental observations made in non-human primates, or NHPs, with rhesus cytomegalovirus, or RhCMV. We believe that this platform may also have applicability beyond infectious diseases, to areas such as cancer.

Innate Immunity Platform: Moving beyond more traditional approaches that are used to evoke adaptive immunity or that directly target pathogens, where the development of resistance can occur, we plan to target host proteins as a means of creating host-directed therapies with high barriers to resistance. We believe that by leveraging the power of innate immunity, we can create medicines that break the “one-drug-for-one-bug” paradigm to produce “one-drug-for-multiple-bugs.”

Table of Contents

siRNA Platform: We are harnessing the power of siRNA to inhibit pathogen replication, eliminate key host factors necessary for pathogen survival and remove microbial immune countermeasures. Our collaboration with Alnylam Pharmaceuticals, Inc., or Alnylam, includes VIR-2218 for HBV and up to four additional programs in infectious diseases.

Our Development Pipeline

Our current product candidates are summarized in the chart below:

Indication	Product Candidate	Treatment/ Prophylaxis	Platform	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator	Anticipated Milestones
HBV	VIR-2218	Treatment	siRNA						Additional Phase 2 data in 1H 2020
	VIR-3434	Treatment	Antibody						CTA 1H 2020
Influenza A	VIR-2482	Prophylaxis	Antibody						Initial Phase 1/2 data in 2H 2020
HIV	VIR-1111 *	Prophylaxis	T cell						IND 1H 2020
TB	VIR-2020	Prophylaxis	T cell						IND 1H 2021

IND = Investigational New Drug Application; CTA = Clinical Trial Application.

* VIR-1111 is a vaccine designed to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans. Ultimately any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.

HBV: Approximately 290 million people globally are chronically infected with HBV and approximately 900,000 of them die from HBV-associated complications each year. There is a significant unmet medical need for more effective therapies.

We are developing VIR-2218 and VIR-3434 for the functional cure of HBV, meaning life-long control of the virus after a finite duration of therapy. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. While monotherapy with each of these agents may provide a functional cure in some patients, we believe combination therapy will be necessary for many patients. We are planning trials that combine VIR-2218 with VIR-3434, which we believe have the potential to act in concert by removing potentially tolerogenic HBV proteins and stimulating new HBV specific T cells. We are planning additional trials that combine VIR-2218 with other immunotherapy agents and direct acting antiviral agents. We anticipate that the initial registration population for these product candidates will be patients chronically infected with HBV.

VIR-2218 is a subcutaneously administered HBV-targeting siRNA that is currently in a Phase 1/2 clinical trial. VIR-2218 is the first siRNA in the clinic to include ESC+ technology, which has the potential to enhance the therapeutic index. As of September 18, 2019, 37 healthy volunteers have received VIR-2218 and 12 healthy volunteers have received placebo. 23 patients with chronic HBV have received VIR-2218 and eight patients with chronic HBV have received placebo. Initial data suggest that VIR-2218 is generally well-tolerated in healthy volunteers given as a single dose up to 600 mg and in patients given as two doses of 20 mg, 50 mg, 100 mg or 200 mg each dose. Initial data also demonstrate substantial reductions in HBsAg in patients at doses ranging from 20 mg to 200 mg. VIR-2218 is the first asset in our collaboration with Alnylam to enter clinical trials. We anticipate additional clinical data for this trial to be available in the first half of 2020.

[Table of Contents](#)

VIR-3434 is a subcutaneously administered HBV-neutralizing mAb for which we plan to submit a CTA in the first half of 2020 and thereafter commence a Phase 1 clinical trial. By targeting a conserved region of HBsAg, it is designed to block entry of all 10 genotypes of HBV into liver cells called hepatocytes and reduce the level of virions and subviral particles in the blood. We have also engineered VIR-3434 to have an extended half-life and to potentially function as a T cell vaccine against HBV in infected patients. We anticipate clinical data from a Phase 1 clinical trial to be available in the first half of 2021.

Influenza: On average, each year the influenza virus infects 5% to 10% of the world's population and results in an estimated 500,000 deaths. In the 2017-2018 flu season, approximately 80,000 people died from influenza in the United States alone. Influenza vaccines have historically had limited success, with an average efficacy of 40%, resulting from incomplete coverage against seasonal strains and reliance on a person to generate an effective immune response. We are developing VIR-2482 as a universal prophylaxis for influenza A and have designed it to overcome the limitations of flu vaccines and lead to meaningfully higher levels of protection. We anticipate that the initial registration population for VIR-2482 will be individuals at high risk of influenza A complications, such as the elderly with chronic lung disease.

VIR-2482 is an intramuscularly administered influenza A-neutralizing mAb. In August 2019, we initiated dosing in a Phase 1/2 clinical trial for VIR-2482. In vitro, VIR-2482 has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. We believe that VIR-2482 has the potential to provide superior protection to flu vaccines and be able to be used year after year because it has broad strain coverage as opposed to the limited strain coverage generated by vaccines. We also believe that it provides passive immunity rather than relying on a person to generate a functional immune response. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long. We anticipate clinical data from the first flu season of a Phase 1/2 clinical trial to be available in the second half of 2020 and from the second flu season of this trial to be available in the first half of 2021.

HIV: Each year there are approximately 1.8 million new cases of HIV and approximately 1.0 million HIV-related deaths globally. Current prevention approaches such as behavioral modification and pharmacological intervention have had only a modest effect on HIV transmission globally, leaving a high unmet medical need for a safe and effective vaccine for the billions of individuals who are or may become sexually active. VIR-1111 is a proof of concept HIV vaccine designed to elicit a type of immune response that is different from other vaccines. We anticipate the initial registration population for our eventual HIV vaccine will be individuals at high risk of contracting HIV.

VIR-1111 is a subcutaneously administered HIV T cell vaccine based on HCMV for which we plan to submit an IND in the first half of 2020 and thereafter commence a Phase 1 clinical trial. VIR-1111 has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of NHPs from simian immunodeficiency virus, or SIV, the NHP equivalent of HIV. VIR-1111 is a vaccine designed solely to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans.

TB: Globally, nearly 1.7 billion people are latently infected with TB, and each year there are approximately 10 million new active cases of TB and approximately 1.6 million TB-related deaths. There is a high unmet medical need for a safe and effective vaccine that prevents active pulmonary TB in adolescents and adults, as they represent the key sources of TB transmission and are the primary contributors to overall disease burden. VIR-2020 is a vaccine designed to provide a type of immune response that is different from other vaccines and lead to meaningful levels of protection from active TB. We anticipate that the initial registration population for VIR-2020 will be people at high risk of developing active TB, such as those who have latent TB infection.

[Table of Contents](#)

VIR-2020 is a subcutaneously administered TB T cell vaccine based on HCMV for which we plan to submit an IND in the first half of 2021 and thereafter commence a Phase 1 clinical trial. VIR-2020 is designed to stimulate T cells that reside in the lung and to recognize TB epitopes that are different from those recognized by prior TB vaccines. In preclinical studies, a T cell vaccine based on rhesus cytomegalovirus, or RhCMV, has been shown to provide protection of NHPs from TB.

Our Strategy

The core elements of our business strategy include:

- **Rapidly advancing our pipeline.** We have commenced a Phase 1/2 clinical trial for each of VIR-2218 and VIR-2482. We anticipate moving multiple preclinical candidates into the clinic in the next 12-18 months and initiating combination trials where applicable.
- **Expanding our pipeline using our current technology platforms.** We are leveraging our four current technology platforms to discover and develop novel product candidates for HBV, influenza A, HIV and TB, as well as additional viral, bacterial, fungal and parasitic infections, and potentially cancers.
- **Acquiring new technology platforms and assets.** We continually evaluate external technology platforms and assets that may help us develop therapies to treat and prevent serious infectious diseases.
- **Scaling our capabilities.** We are investing in our people, processes and systems across all functions of our company to ensure that we are able to take full advantage of our multiple technology platforms and multiple product candidates.
- **Enabling global access to our future medicines.** We have established relationships with organizations seeking to make a global impact like the Bill & Melinda Gates Foundation and the National Institutes of Health to further enable and facilitate access to our future medicines and to support our clinical development efforts. We will continue to pursue additional relationships like these moving forward.

Our Corporate History and Team

We were founded in 2016 with the mission of creating a world without infectious disease. We are taking a multi-program, multi-technology platform approach, assembled through internal development, collaborations and acquisitions.

We have an industry-leading management team, board of directors and scientific advisors with significant experience in immunology and infectious diseases, and progressing product candidates from early stage research to clinical trials, regulatory approval and ultimately commercialization.

Our team is further supported by a committed group of investors including a subsidiary of the Abu Dhabi Investment Authority, ARCH Venture Partners, the Alaska Permanent Fund, Baillie Gifford, the Bill & Melinda Gates Foundation, the SoftBank Vision Fund, Temasek and others.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability.

Table of Contents

- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Even after this offering, we will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.
- Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- We intend to rely on third parties to produce clinical and commercial supplies of our product candidates.
- We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We also intend to explore additional strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

Our Corporate Information

We were incorporated under the laws of the State of Delaware on April 7, 2016. Our principal executive offices are located at 499 Illinois Street, Suite 500, San Francisco, California 94158, and our telephone number is (415) 906-4324. Our corporate website address is www.vir.bio. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this prospectus or the registration statement of which it forms a part. We have included our website in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and we may remain an emerging growth company for up to five years following the completion of this offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding

[Table of Contents](#)

executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We would cease to be an “emerging growth company” upon the earliest to occur of: (i) the last day of the fiscal year in which we have \$1.07 billion or more in annual revenue; (ii) the date on which we first qualify as a large accelerated filer under the rules of the U.S. Securities and Exchange Commission, or the SEC; (iii) the date on which we have, in any three-year period, issued more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of this offering. We may choose to take advantage of some but not all of these reduced reporting burdens.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

[Table of Contents](#)**The Offering**

Common stock to be offered by us	7,142,858 shares
Underwriters' option to purchase additional shares	1,071,428 shares
Common stock to be outstanding immediately after this offering	109,397,196 shares (or 110,468,624 shares if the underwriters exercise in full their option to purchase additional shares)
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$127.4 million (or approximately \$147.3 million if the underwriters exercise in full their option to purchase up to 1,071,428 additional shares of common stock), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, to fund the research and development of our product candidates and development programs, including to complete our ongoing VIR-2218 Phase 1/2 clinical trial and fund related manufacturing needs, to advance VIR-3434 through our planned Phase 1 clinical trial, to advance VIR-2482 through our ongoing Phase 1/2 clinical trial, as well as preparation for a potential registrational clinical trial, and the remainder to fund any potential future combination or other clinical trials and preclinical programs, and for working capital and other general corporate purposes.</p> <p>The intended uses set forth above include any related milestone payments that may be due from us under the applicable license and collaboration agreements. In addition, we expect that the current grants from the Bill & Melinda Gates Foundation will fund the manufacture and early clinical development of VIR-1111 and VIR-2020.</p> <p>See the section titled "Use of Proceeds" for additional information.</p>
Risk factors	You should read the section titled "Risk Factors" for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	"VIR"

The number of shares of our common stock to be outstanding after this offering is based on 102,254,338 shares of common stock (including (i) 88,112,733 shares issuable upon the conversion of all outstanding shares

[Table of Contents](#)

of our convertible preferred stock and (ii) 4,418,767 shares of unvested restricted common stock) outstanding as of June 30, 2019, and excludes:

- 5,544,976 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2019, with a weighted-average exercise price of \$2.36 per share;
- 1,031,758 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to June 30, 2019, with an exercise price of \$10.40 per share;
- 244,444 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2019, with an exercise price of \$4.50 per share, which warrant is exercisable to purchase shares of our Series A-1 convertible preferred stock and will automatically convert to a warrant to purchase an equivalent number of shares of our common stock upon the completion of this offering;
- up to 1,111,111 shares of our common stock issuable to Alnylam upon the achievement of a development milestone pursuant to a collaboration and license agreement with Alnylam, or the Alnylam Agreement (see “Business—Our Collaboration, License and Grant Agreements—Collaboration and License Agreement with Alnylam” for additional information);
- 5,800,000 shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2019 Plan (of which options to purchase an aggregate of 306,441 shares of our common stock were granted to certain of our employees and certain non-employee directors of our board of directors at the time of effectiveness of the 2019 Plan with an exercise price equal to the initial public offering price per share); and
- 1,280,000 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan, or ESPP, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our ESPP.

Unless otherwise indicated, all information contained in this prospectus, including the number of shares of common stock that will be outstanding after this offering, assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation immediately after the completion of this offering and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- the conversion of all outstanding shares of our convertible preferred stock as of June 30, 2019 into an aggregate of 88,112,733 shares of our common stock upon the completion of this offering;
- a 1-for-4.5 reverse stock split of our common stock and convertible preferred stock effected on September 27, 2019;
- no exercise of the outstanding options and outstanding warrant described above; and
- no exercise by the underwriters of their option to purchase up to 1,071,428 additional shares of our common stock.

[Table of Contents](#)

Summary Consolidated Financial Data

The following tables set forth our summary consolidated statements of operations data for the years ended December 31, 2017 and 2018, which have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The following summary consolidated statements of operations data for the six months ended June 30, 2018 and 2019 and the summary consolidated balance sheet data as of June 30, 2019 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The unaudited condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2019. You should read the following summary consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:				
Revenue:				
Grant revenue	\$ 2,559	\$ 9,800	\$ 3,909	\$ 5,605
Contract revenue	149	868	748	103
Total revenue	2,708	10,668	4,657	5,708
Operating expenses:				
Research and development	62,512	100,229	48,419	55,677
General and administrative	21,693	29,131	13,788	16,570
Total operating expenses	84,205	129,360	62,207	72,247
Loss from operations	(81,497)	(118,692)	(57,550)	(66,539)
Other income (expense):				
Interest income	638	2,540	1,207	4,552
Other income (expense), net	83	(212)	(192)	(592)
Total other income (expense), net	721	2,328	1,015	3,960
Loss before benefit from (provision for) income taxes	(80,776)	(116,364)	(56,535)	(62,579)
Benefit from (provision for) income taxes	10,924	480	500	(19)
Net loss	\$ (69,852)	\$ (115,884)	\$ (56,035)	\$ (62,598)
Net loss per share, basic and diluted(1)	\$ (32.45)	\$ (15.12)	\$ (8.04)	\$ (6.83)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted(1)	2,152,273	7,666,463	6,973,460	9,165,311
Pro forma net loss per share, basic and diluted (unaudited)(1)		\$ (1.52)		\$ (0.64)
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited)(1)		76,050,495		96,912,507

[Table of Contents](#)

- (1) See Notes 2 and 13 to each of our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares outstanding used in the computation of the per share amounts.

	As of June 30, 2019		
	Actual	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾
(in thousands)			
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 356,547	\$ 356,547	\$ 486,813
Working capital ⁽³⁾	336,679	336,679	466,945
Total assets	456,849	456,849	584,206
Convertible preferred stock warrant liability	1,808	—	—
Convertible preferred stock	636,612	—	—
Accumulated deficit	(256,434)	(256,434)	(256,434)
Total stockholders' (deficit) equity	(236,967)	401,453	528,810

- (1) The pro forma column reflects: (i) the conversion of all of the outstanding shares of our convertible preferred stock into an aggregate of 88,112,733 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the completion of this offering; (ii) the automatic conversion of a warrant to purchase an aggregate of 244,444 shares of our Series A-1 convertible preferred stock outstanding as of June 30, 2019 into a warrant to purchase an equivalent number of shares of our common stock, and the related reclassification of convertible preferred stock warrant liability to additional paid-in-capital, a component of stockholders' (deficit) equity, upon the completion of this offering; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately after the completion of this offering.
- (2) The pro forma as adjusted column reflects: (i) the pro forma adjustments set forth in footnote (1) above; and (ii) the sale of 7,142,858 shares of our common stock in this offering at the initial public offering price of \$20.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

[Table of Contents](#)

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability.

Since inception in April 2016, we have incurred significant net losses and have never generated any revenue from product sales. Our net loss was \$69.9 million and \$115.9 million for the years ended December 31, 2017 and 2018, respectively, and \$62.6 million for the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of \$256.4 million. We expect to continue to incur significant expenses and increasing net losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. To date, we have never obtained regulatory approval for, or commercialized, any products. It could be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of our product candidates;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any current or future product candidate for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- continue to build a portfolio of product candidates through the acquisition or in-license of products, product candidates or technologies;
- maintain, protect and expand our intellectual property portfolio;
- make milestone payments if we successfully achieve certain predetermined milestones under existing or future agreements;
- hire additional clinical, regulatory and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities,

[Table of Contents](#)

including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, procuring commercial-scale manufacturing, marketing and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is sufficient to offset our expenses and achieve profitability.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage company founded in April 2016 and our operations to date have been largely focused on identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. As an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We currently have four technology platforms and five product candidates in our development pipeline. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Even after this offering, we will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

As of June 30, 2019, we had cash, cash equivalents and short-term investments of \$356.5 million. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of the date of this prospectus, will fund our current operating plans through at least the next 18 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;

Table of Contents

- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts, which may adversely affect our business, financial condition, results of operations and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, including investors in this offering, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and collaborations and strategic alliances, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations or strategic alliances, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

[Table of Contents](#)**Risks Related to the Development and Commercialization of Our Product Candidates**

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.

We have invested a significant portion of our time and financial resources in the development of VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-2020. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We may face unforeseen challenges in our product development strategy, and we can provide no assurances that our product candidates will be successful in clinical trials or will ultimately receive regulatory approval.

We have only recently initiated clinical trials for one product candidate. We have not obtained regulatory approval for any product candidate, and it is possible that any product candidates we may seek to develop in the future will not obtain regulatory approval. Neither we nor any current or future collaborator is permitted to market any product candidates in the United States or abroad until we receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or applicable foreign regulatory agency. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable and typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program, requiring their alteration.

Of the large number of products in development, only a small percentage successfully complete the FDA's or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, biologics license application, or BLA, or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of

[Table of Contents](#)

our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities. If we are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to replicate our approach for other diseases.

A core element of our business strategy is to expand our product pipeline. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenue for many reasons, including the following:

- the methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

We are developing, and in the future may develop, other product candidates in combination with other therapies, which exposes us to additional risks.

We are developing VIR-2218 and VIR-3434 for the functional cure of hepatitis B virus, or HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. Monotherapy with each of these agents may provide a functional cure in some patients, while combination therapy may be necessary for others. We are planning trials that combine VIR-2218 with VIR-3434, as well as combine VIR-2218 with other immunotherapy agents and direct acting antiviral agents. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination

Table of Contents

with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and Phase 1 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, making the trial results less reliable than trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct clinical trials with a small number of patients, we may not achieve a statistically significant result or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or other comparable regulatory authority, and we may never receive such approvals. It is

[Table of Contents](#)

impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following:

- delays in reaching a consensus with regulatory authorities on the design or implementation of our clinical trials;
- regulators or institutional review boards and ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays or failures by our manufacturing partners to comply with current good manufacturing practices, or cGMP;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may fail to recruit suitable patients to participate in a trial;
- clinical trials of our product candidates may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

[Table of Contents](#)

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Furthermore, our product candidates are based on certain innovative technology platforms, which makes it even more difficult to predict the time and cost of product candidate development and obtaining regulatory approval, particularly for our small interfering ribonucleic acid, or siRNA, and cytomegalovirus, or CMV, vector technologies. Relatively few siRNA product candidates have ever been tested in humans and to date, we are only aware of one siRNA, ONPATRO (*patisiran*) in 2018 (developed by Alnylam Pharmaceuticals, Inc., or Alnylam), that has received regulatory approval. In addition, the compounds we are developing may not demonstrate in patients the chemical and pharmacological properties ascribed to them in preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways.

As part of our T cell platform, our approach is to use human cytomegalovirus, or HCMV, as a vaccine vector to potentially treat and prevent pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. Safety and toxicity studies for this technology have so far only been conducted in animal species, in which HCMV has limited ability to replicate. If our first clinical trial for VIR-1111 or VIR-2020 causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidates and any other potential products based on HCMV-vector technology may be significantly limited or become impossible. Also, because our HCMV-vector technology is novel, regulatory agencies may lack experience with product candidates such as VIR-1111 and VIR-2020, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. In addition, our HCMV-vector technology utilizes live-attenuated, genetically-modified organisms for which the FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities and other public health authorities, such as the Centers for Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates.

Further, we, the FDA, a foreign regulatory authority or an institutional review board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with

[Table of Contents](#)

regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA or foreign regulatory authority finds deficiencies in our investigational new drug applications, or INDs, or clinical trial applications, or CTAs, respectively, or the conduct of these trials. Moreover, we may not be able to file INDs to commence additional clinical trials on the timelines we expect because our filing schedule is dependent on further preclinical and manufacturing progress. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We are developing VIR-2218 and VIR-3434 for the treatment of HBV, VIR-2482 for the prevention of influenza A, VIR-1111 for the prevention of human immunodeficiency virus, or HIV, and VIR-2020 for the prevention of tuberculosis, or TB. In particular, clinical trials for prophylaxes tend to require enrollment of a larger number of subjects than clinical trials for treatments. We may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects or patients. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, financial condition, results of operations and prospects.

[Table of Contents](#)

Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, “top-line” or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We also intend to explore additional strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates.

We are a party to various strategic collaboration and license agreements that are important to our business and to our current and future product candidates. For example, we license a number of technologies to form our antibody platform, including technology from the Institute for Research in Biomedicine, or IRB, The Rockefeller University, or Rockefeller, and Xencor, Inc., or Xencor, pursuant to our exclusive license agreement with IRB, or the IRB Agreement, our exclusive license agreement with Rockefeller, or the Rockefeller Agreement, and our patent license agreement with Xencor, or the Xencor Agreement. We also license technology from Oregon Health & Science University, or OHSU, pursuant to our master exclusive license agreement with OHSU, or the OHSU Agreement, to form our T cell platform. In addition, the technology we use in our siRNA technology platform is licensed from Alnylam pursuant to a collaboration and license agreement, or the Alnylam Agreement. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved.

Our agreements with Alnylam, OHSU, MedImmune, LLC, or MedImmune, Rockefeller and Xencor include the following milestone payment obligations: up to \$1.3 billion in milestone payments under the Alnylam Agreement, up to \$1.3 million in milestone payments per product and up to \$2.0 million in the aggregate for all products under the OHSU Agreement, up to \$343.3 million in milestone payments under the 2018 MedImmune Agreement, up to \$48.5 million in milestone payments per product under the Rockefeller Agreement and up to \$155.5 million in milestone payments for all licensed products under the Xencor Agreement. We may in the future be required to make these payments, which could adversely affect our financial condition. In addition, upon the achievement of a certain development milestone, we will be required to issue Alnylam shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone is achieved.

Furthermore, pursuant to the Alnylam Agreement, Alnylam granted us an exclusive option for each of the infectious disease siRNA programs directed to our selected targets, to obtain a worldwide, exclusive license to develop, manufacture, and commercialize siRNA products directed to the target of each such program. Our options are each exercisable during a specified period following selection of candidates for each program, or two years following the initiation of certain activities under an agreed upon development plan, if earlier. On a product-by-product basis for each product arising from the HBV and, following our option exercise, the infectious disease programs, Alnylam has an option, exercisable during a specified period during development of each such product, to negotiate and enter into a profit-sharing agreement for such product. If we do not exercise our options with respect to a particular program in a timely manner or at all, Alnylam will retain such rights and may offer such exclusive rights to other third parties. If Alnylam exercises its profit-sharing option for a product, including VIR-2218, we will be required to negotiate the terms of a profit-sharing agreement with Alnylam,

[Table of Contents](#)

which will include sharing equally with Alnylam the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances. Because of the uncertainty associated with Alnylam's decision to exercise its profit-sharing option for VIR-2218, we are unable to accurately predict the timing or amount of expenses related to the development of VIR-2218 after the specified period that Alnylam is allowed to exercise its option. Furthermore, if Alnylam does not exercise its profit-sharing option, it could damage public perceptions of VIR-2218, which could have a substantial adverse effect on the price of our common stock.

In addition, in May 2018, we entered into an option and license agreement, or the Brie Agreement, with Brie Biosciences Limited (previously named BiiG Therapeutics Limited), or Brie Bio Parent, and Brie Biosciences Offshore Limited, or Brie Bio, pursuant to which we granted to Brie Bio, with respect to up to four of our programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau, or collectively the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. In partial consideration for the options granted by us to Brie Bio, Brie Bio Parent and Brie Bio granted us, with respect to up to four of Brie Bio Parent's or Brie Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brie Bio programs in the United States for the Field of Use. Neither we nor Brie Bio has exercised an option under the Brie Agreement. We cannot be certain that, following the exercise of an option by Brie Bio or by us, we will achieve any benefits from our collaboration with Brie Bio. For more information on the Brie Agreement, see the sections titled "Business—Our Collaboration, License and Grant Agreements—Collaboration and License Agreement with Brie Bio."

A core element of our business strategy also includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources.

At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business;

[Table of Contents](#)

- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

If the market opportunities for our product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our product development on product candidates for the treatment and prevention of serious infectious diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be receptive to treatment with our product candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

[Table of Contents](#)

We face substantial competition, which may result in others developing or commercializing products before or more successfully than us.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. In addition, regulatory incentives to develop products for treatment of infectious diseases have increased interest and activity in this area and may lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

As a result of these factors, our competitors may achieve patent protection or obtain regulatory approval of their products before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our product candidates obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

For additional information regarding our competition for each of our target indications, see the section titled "Business—Competition."

Even if any product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if any product candidates receive marketing approval, they may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the effectiveness of sales and marketing efforts;

Table of Contents

- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complex and distinctive nature of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business.

For example, we are developing VIR-2482 as a universal prophylaxis for influenza A. VIR-2482 is designed to overcome the limitations of influenza vaccines and lead to meaningfully higher levels of protection. In order for VIR-2482 to be successful, not only will it need to be approved for commercial sale, but it will also need to demonstrate a higher efficacy compared to influenza vaccines and be offered at a competitive price in order to receive favorable coverage and reimbursement from third-party payors and in order for physicians to prescribe the product in lieu of the standard of care treatment.

Even if we obtain regulatory approvals for our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the product. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, biopharmaceutical manufacturers and their facilities are subject to ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;

Table of Contents

- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA, BLA or comparable foreign marketing application or any supplements thereto submitted by us or our partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biologic products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the executive orders, will be implemented and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business, financial condition, results of operations and prospects may be negatively impacted.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing them, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability, and have no experience as a company in commercializing products. Establishing sales and marketing capabilities will be particularly important to the commercial success of our product candidates that target diseases with large patient populations throughout the world. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on

[Table of Contents](#)

favorable terms, if at all. If any current or future collaborators do not commit sufficient time or resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside the United States, which would limit our market opportunities.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for our product candidates in the European Union, or EU, from the European Commission following the opinion of the EMA if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Approval of certain product candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States will be particularly important to the commercial success of such product candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. On March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty, scheduled to be effective March 29, 2019. To date, no formal withdrawal agreement has been reached between the United Kingdom and the EU, despite the passage of the date on which it was expected that the United Kingdom's membership in the EU would terminate. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek

[Table of Contents](#)

regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business, financial condition, results of operations and prospects.

If we commercialize our product candidates outside the United States, a variety of risks associated with international operations could harm our business.

We intend to seek approval to market our product candidates outside the United States, and may also do so for future product candidates. If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their products in foreign countries to be challenging.

Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The clinical and commercial success of our product candidates will depend in part on public acceptance of the use of new technologies for the prevention or treatment of human diseases. For example, we use CMV, a commonly occurring virus in humans, as a vaccine vector to prevent and treat pathogens refractory to current vaccine technologies. We also use CRISPR gene-editing technology as a research tool to systematically identify human genes that control infection.

Public perception may be influenced by claims that CMV technology is unsafe and products incorporating this technology may not gain the acceptance of the public or the medical community, or that CRISPR gene-editing technology is unethical or immoral. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials for our product candidates.

[Table of Contents](#)

Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our product candidates or demand for such product candidates. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could negatively impact our business, financial condition, results of operations and prospects.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Regulatory Compliance

If any of our future small molecule product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a

[Table of Contents](#)

generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our future small molecule product candidates are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

Any biologic, or large molecule, product candidates for which we intend to seek approval may face competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate faster than our competitors, such product candidates may face competition from biosimilar products. In the United States, large molecule product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical studies. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

[Table of Contents](#)

If competitors are able to obtain marketing approval for biosimilars referencing our large molecule product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare

[Table of Contents](#)

clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf;

- the Federal Food Drug or Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data).

We may also be subject to other laws, such federal laws as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibit, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

[Table of Contents](#)

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs and biological products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Healthcare legislative reform measures may have a negative impact on our business, financial condition, results of operations and prospects.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there

[Table of Contents](#)

have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, the CMS, published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable

[Table of Contents](#)

feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, which will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biological product pricing, reduce the cost of prescription drugs and biological products under government payor programs and review the relationship between pricing and manufacturer patient programs. At the federal level, for example, on January 31, 2019, The U.S. Department of Health and Human Services Office of Inspector General proposed modifications to U.S. federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug and biological products to consumers. In addition, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. The U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug and biological product costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs, biological products and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

[Table of Contents](#)

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could have an adverse effect on demand for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. For additional information on healthcare reform, see the section titled “Business—Government Regulation and Product Approval.”

We are subject to anti-corruption, anti-bribery, anti-money laundering, and similar laws, and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities.

While we have policies and procedures to address compliance with such laws in the United States, we cannot assure you that all of our employees and agents will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Detecting, investigating and resolving actual or alleged violations can require a significant diversion of time, resources and attention from senior management. In addition, noncompliance with anti-corruption, anti-bribery or anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, financial condition, results of operations and prospects could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management’s attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We intend to rely on third parties to produce clinical and commercial supplies of our product candidates.

We are currently manufacturing material for product candidates of three different modalities: monoclonal antibodies, or mAbs, HCMV-based vaccines and siRNAs. Except for limited process development and quality

[Table of Contents](#)

control testing capabilities in certain of our facilities, we do not own or operate facilities for product manufacturing, storage and distribution, or testing. We are dependent on third parties to manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple contract development and manufacturing organizations, or CDMOs, that have produced material to support our preclinical, Phase 1 and Phase 2 clinical trials. We have not yet manufactured our product candidates on a commercial scale, and we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates. Certain of our product candidates may have to compete with existing and future products, such as the annual flu vaccine, that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of our product candidates. If we are not able to meet market demand for any approved product or if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, we currently rely on foreign CDMOs, including a CDMO in China, and will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, or delay the procurement of such material. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China which could have an adverse effect on our business, financial condition, results of operations and prospects.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our third-party manufacturers to execute our manufacturing procedures and other logistical support requirements appropriately;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;

Table of Contents

- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for product components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- lack of ownership to the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We cannot be sure that single source suppliers for our product components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these components for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results.

Furthermore, there are a limited number of manufacturers that supply synthetic siRNAs. Alnylam is currently supplying clinical material for our VIR-2218 Phase 1/2 clinical trial through its CDMOs. We will assume responsibility for technology transfer and manufacturing ahead of any Phase 3 clinical trials for VIR-2218. Alnylam currently relies on a limited number of CDMOs for our supply of synthetic siRNAs. There are risks inherent in pharmaceutical manufacturing that could affect the ability of Alnylam and Alnylam's CDMOs to meet our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs. Included in these risks are potential synthesis and purification failures and/or contamination during the manufacturing process, as well as other issues with the CDMO's facility and ability to comply with the applicable manufacturing requirements, including use of the proper raw material components, which could result in unusable product. This would cause delays in our manufacturing timelines and ultimately delay our clinical trials and potentially put at risk commercial supply, as well as result in additional expense to us. To fulfill our siRNA requirements, we may need to secure alternative suppliers of synthetic siRNAs and such alternative suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner.

In addition, manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our HCMV vector-based product candidates. The challenges to HCMV-based vaccine manufacturing include the large size of the virus, which precludes terminal sterile filtration, and the attenuation of the engineered human virus, which dramatically reduces high growth yields during manufacturing. To address these challenges, we have made significant internal investments in process development and scale-up, largely funded by grants from the Bill & Melinda Gates Foundation. We have established a cGMP process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred and executed at two CDMOs specializing in live vaccine manufacturing (IDT Biologika and Advanced Bioscience Laboratories, Inc.). However, the existing process will require scale-up for later stages of clinical development and commercial supply.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production.

[Table of Contents](#)

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;

[Table of Contents](#)

- fail to comply with contractual obligations;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. While we will have agreements governing their activities, our CROs will not be our employees and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our relationship with any of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition, results of operations and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Risks Related to Our Intellectual Property

If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.

We license a number of technologies to form our antibody platform and T cell platform, and the technology we use in our siRNA platform is licensed from Alnylam. We have also developed certain product candidates using intellectual property licensed from third parties. A core element of our business strategy includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases.

If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such

[Table of Contents](#)

agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. For more information on our license agreements, see the section titled “Business—Our Collaboration, License and Grant Agreements.”

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the license agreement and other issues relating to interpretation of the relevant agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license granted to us;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, on the one hand, and us and our sublicensees, on the other hand.

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the U.S. Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if

[Table of Contents](#)

approved. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to

[Table of Contents](#)

comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations could be adversely affected.

Given the amount of time required for the development, testing and regulatory review of our product candidates, such as VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-2020, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Hatch-Waxman Act permits a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Numerous U.S. and

[Table of Contents](#)

foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate or technology platform infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could

[Table of Contents](#)

be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities.

[Table of Contents](#)

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned to a first inventor to file system in which,

[Table of Contents](#)

assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

[Table of Contents](#)***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Since we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. We also enter into invention or patent assignment agreements with our employees, advisors and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

In addition, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations and prospects.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

[Table of Contents](#)

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- others may be able to develop technologies that are similar to our technology platforms but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

[Table of Contents](#)

The exercise by the Bill & Melinda Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.

We entered into a letter agreement with the Bill & Melinda Gates Foundation, or the Gates Agreement, in December 2016 in connection with the Bill & Melinda Gates Foundation's investment in us through the purchase of \$20.0 million of shares of our convertible preferred stock. We are obligated to use the proceeds of the Bill & Melinda Gates Foundation's investment in furtherance of its charitable purposes to (i) conduct our programs to develop products to treat or prevent infectious disease caused by HIV and TB, respectively, with at least 50% of the funds to be used for such programs, and (ii) develop our HCMV-based vaccine technology platform in a manner reasonably expected to result in the generation of products for the treatment or prevention of other specified infectious diseases, in each case for use in specified developing countries. We agreed to use reasonable efforts to achieve specified research and development milestones with respect to our HIV program and TB program and, if requested by the Bill & Melinda Gates Foundation, to work with the Bill & Melinda Gates Foundation on an additional mutually agreeable infectious disease program. Additionally, we agreed to specified global access commitments including a commitment to provide any products developed using the proceeds of the Bill & Melinda Gates Foundation's investment at an affordable price to the people most in need within the specified developing countries, not to exceed a specified percentage over our fully burdened manufacturing and sales costs.

If we fail to comply with (i) our obligations to use the proceeds of the Bill & Melinda Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a Specified Default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Bill & Melinda Gates Foundation under the Gates Agreement, at the Bill & Melinda Gates Foundation's request, at a price equal to the greater of (1) the original purchase price plus 5% compounding interest or (2) the fair market value as determined by an independent third-party, which amount may increase in the event of certain underwritten public offerings of our common stock or a sale of our company or all of our material assets relating to the Gates Agreement. Additionally, if a Specified Default occurs or if we are unable or unwilling to continue the HIV program, TB program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the Bill & Melinda Gates Foundation will have the right to exercise a non-exclusive, fully-paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the Bill & Melinda Gates Foundation's charitable purpose.

The exercise by the Bill & Melinda Gates Foundation of any of its non-exclusive licenses to certain of our intellectual property (or its right to obtain such licenses), and its development and commercialization of product candidates and products that we are also developing and commercializing, could have an adverse impact on our market position. The Gates Agreement is described further in "Business—Collaboration, License and Grant Agreements—Letter Agreement with the Bill & Melinda Gates Foundation."

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, Dr. Scangos. Our key personnel may currently terminate their employment with us at any time and will continue to be able to do so after the closing of this offering. The loss of the services of either of these persons could impede the achievement of our research, development and commercialization objectives.

[Table of Contents](#)

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We have in the past and may in the future acquire or invest in other companies or technologies, which could divert our management’s attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We have in the past and may in the future seek to acquire or invest in additional businesses and/or technologies that we believe complement or expand our product candidates, enhance our technical capabilities or otherwise offer growth opportunities in the United States and internationally. The pursuit of potential acquisitions and investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

For example, we acquired TomegaVax, Inc., or TomegaVax, in September 2016, Humabs BioMed SA, or Humabs, in August 2017, Agenovir Corporation, or Agenovir, in January 2018 and Statera Health, LLC, or Statera, in February 2018. Realizing the benefits of these acquisitions will depend upon the successful integration of the acquired technology into our existing and future product candidates. Furthermore, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not realize the anticipated benefits from any acquired business. The risks we face in connection with acquisitions and investments, whether or not consummated, include:

- unanticipated costs or liabilities associated with the acquisition;
- diversion of management’s attention from other business concerns;
- adverse effects to our existing strategic collaborations as a result of the acquisition;
- assimilation of operations, intellectual property and products of an acquired company;
- the potential loss of key employees;

[Table of Contents](#)

- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- the assumption of additional indebtedness or contingent or unknown liabilities, or adverse tax consequences or unfavorable accounting treatment;
- claims and disputes by stockholders and third parties, including intellectual property claims and disputes;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- increased operating expenses and cash requirements;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations and prospects.

In addition, our acquisitions of TomegaVax, Humabs and Agenovir included the following future contingent payments: up to \$30.0 million in milestone payments related to the TomegaVax acquisition, up to \$240.0 million in milestones payments related to the Humabs acquisition, and up to \$270.0 million in milestones related to the Agenovir acquisition. Upon the completion of this offering, the milestone payments related to the TomegaVax acquisition will be dependent on the per share price of our publicly traded common stock. We may in the future be required to make these payments, which could adversely affect our financial condition. For more information on the future payments related to the TomegaVax, Humabs and Agenovir acquisitions, see the section titled “Business—Our Acquisition Agreements.”

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition, results of operations and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations and prospects.

We expect to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of August 31, 2019, we had 206 full-time employees. As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, we also expect to hire additional personnel in order to operate as a public company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, we must effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture. The expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

[Table of Contents](#)

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMO, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop our product candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our internal computer systems, or those of our collaborators, service providers or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively, and adversely affect our business, financial condition, results of operations and prospects.

Our internal computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other contractors or consultants are potentially vulnerable to malware, computer viruses, data corruption, cyber-based attacks, natural disasters, terrorism, war and telecommunication and electrical failures that may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. We have in the past experienced security breaches of our information technology systems. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

In addition, our internal computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other contractors or consultants are potentially vulnerable to data security breaches, whether by employees, contractors, consultants, malware, phishing attacks or other cyber-attacks, that may expose confidential information, intellectual property, proprietary business information or personal information to unauthorized persons. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber-attacks in the future. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. If a data security breach affects our systems, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. These may include state breach notification laws, and the GDPR. Accordingly, a data

[Table of Contents](#)

security breach or privacy violation that leads to unauthorized access to, disclosure or modification of personal information (including protected health information), that prevents access to personal information or materially compromises the privacy, security, or confidentiality of the personal information, could result in fines, increased costs or loss of revenue and we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Furthermore, federal, state and international laws and regulations, such as the GDPR, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail.

We receive, process, store and use personal information and other data, which subjects us to governmental regulation and other legal obligations, liability and risks related to privacy, security, and data protection, and our actual or perceived failure to comply with such obligations could harm our business.

We receive, process, store and use personal information and other data about our patients, employees, partners and others. We must comply with numerous foreign and domestic laws and regulations regarding privacy and the storing, sharing, use, processing, disclosure, security, and protection of personal information and other data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. We strive to comply with all applicable requirements and obligations; however new laws, policies, codes of conduct and legal obligations may arise, continue to evolve, be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and conflict with one another. Any failure or perceived failure by us or third parties working on our behalf to comply with applicable laws and regulations, any privacy and data security obligations pursuant to contract, our stated privacy or security policies or obligations to third parties may result in governmental enforcement actions (including fines, penalties, judgments, settlements, imprisonment of company officials and public censure), civil claims, litigation, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, operations and financial performance. With substantial uncertainty over the interpretation and application of these laws, regulations and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in our efforts to do so.

The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. For example, in May 2018 the GDPR went into effect in the EU. The GDPR imposes stringent data protection requirements for processing the information of EU subjects, including clinical trial data, and to date, has increased compliance burdens on us, including by mandating burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR also provides for more robust regulatory enforcement and greater penalties for noncompliance than previous data protection laws, including fines of up to €20 million or 4% of global annual revenue of any noncompliant company for the preceding financial year, whichever is higher. Further, following a referendum in June 2016 in which voters in the United Kingdom approved an exit from the EU, the government of the United Kingdom has initiated a process to leave the EU, or Brexit, which has created uncertainty with regard to the regulation of data protection in the United Kingdom, including with respect to whether laws or regulations will apply to us consistent with the GDPR in the future and how data transfers to and from the United Kingdom will be regulated. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity. In the United States, on June 28, 2018, California adopted the California Consumer Privacy Act of 2018, or CCPA, which will take effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right

[Table of Contents](#)

of action for data breaches that is expected to increase litigation involving misuse of personal information of California residents. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend of states adopting more stringent privacy legislation in the United States, which could increase our compliance costs, potential liability and adversely affect our business. Similar privacy legislation has been proposed in a number of states.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

The Tax Cuts and Jobs Act, or the Tax Act, could adversely affect our business and financial condition.

In December 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (with certain exceptions, including for certain small businesses), (iii) limitation of the deduction for post-2017 net operating losses, or NOLs, to 80% of current-year taxable income and elimination of net operating loss carrybacks for post-2017 NOLs, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time and (vi) modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”). We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business, financial condition, results of operations and prospects could be adversely affected. We urge our stockholders, including purchasers of common stock in this offering, to consult

[Table of Contents](#)

with their legal and tax advisors with respect to the Tax Act and the tax consequences of investing in our common stock.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of this offering and/or subsequent changes in our stock ownership (some of which shifts are outside our control). In addition, Agenovir has experienced at least one ownership change in the past resulting in a limitation under Section 382 of the Code, which has been accounted for in calculating our available NOL carryforwards. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

The Tax Act, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. For NOLs arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer’s ability to utilize NOL carryforwards to 80% of taxable income. In addition, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and 20-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods, as well as the new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

Risks Related to This Offering and Ownership of Our Common Stock

No public market for our common stock currently exists, and a public market may not develop or be sustained, or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common stock. Although our common stock has been approved for listing on The Nasdaq Global Select Market, an active trading market may never develop following the completion of this offering, or, if developed, may not be sustained. If an active trading market for our common stock does not develop or is not sustained following this offering, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration. The initial public offering price of our common stock was determined by negotiations between us and representatives of the underwriters and may not be indicative of the market prices of our common stock that will prevail in the trading market.

Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict.

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

[Table of Contents](#)

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, the market price for our common stock may be influenced by the following:

- the commencement, enrollment or results of our planned or future preclinical studies or clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate supply for any approved product or inability to do so at acceptable prices;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved product;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors’ general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management’s attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Table of Contents

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon shares of our common stock outstanding as of September 15, 2019, upon the completion of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately 56.1% of our outstanding common stock. If our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

Participation in this offering by our directors, officers or affiliates would reduce the available public float of our shares.

If any of our directors, officers or affiliates purchase shares in this offering, such purchases would reduce the available public float of our common stock because such purchasers would be restricted from selling such shares during the 180-day period following this offering and thereafter would be subject to volume limitations pursuant to restrictions under applicable securities laws. As a result, any purchase of shares by our directors, officers or affiliates in this offering will reduce the liquidity of our common stock relative to what it would have been had these shares been purchased by investors that were not directors, officers or our affiliates.

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. Equity research analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock as of June 30, 2019. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share immediately after this offering. Based on the initial public offering price of \$20.00 per share, you will experience immediate dilution of \$15.65 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price per share. After this offering, we will also have outstanding options and a warrant to purchase common stock with exercise prices lower than the initial public offering price. To the extent these outstanding options or warrant are exercised, there will be further dilution to investors in this offering. See the section titled “Dilution” for additional information.

[Table of Contents](#)

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock in this offering.

We have broad discretion in the use of our cash, cash equivalents and short-term investments, including the net proceeds from this offering, and may use them ineffectively, in ways with which you do not agree or in ways that do not increase the value of your investment.

Our management will have broad discretion in the application of our cash, cash equivalents and short-term investments, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in additional operating losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and short-term investments, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled “Use of Proceeds” for additional information.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding 109,397,196 shares of common stock based on the number of shares outstanding as of June 30, 2019, and assuming no exercise by the underwriters’ option to purchase additional shares. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining 102,254,338 shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the sections titled “Shares Eligible for Future Sale” and “Underwriting.” Moreover, upon the completion of this offering, holders of an aggregate of approximately 88.2 million shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We further intend to register all shares of common stock that we may issue in the future or have issued to date under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the sections titled “Shares Eligible for Future Sale” and “Underwriting.”

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not EGCs, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;

Table of Contents

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. We may take advantage of some or all of these reporting exemptions until we are no longer an EGC. We will remain an EGC until the earlier of (i) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the date on which we first qualify as a large accelerated filer under the rules of the U.S. Securities and Exchange Commission, or the SEC, and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, EGCs can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not EGCs.

As a public company, we will be subject to more stringent federal and state law requirements.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations. Despite reforms made possible by the JOBS Act, compliance with these rules and regulations will nonetheless increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results.

As a result of disclosure of information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business, results of operations, financial condition and prospects could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our brand and reputation, business, results of operations, financial condition and prospects.

We also expect that being a public company and the associated rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, California Governor Jerry Brown signed into law Senator Bill 826, which generally requires public companies

[Table of Contents](#)

with principal executive offices in California to have a minimum number of females on the company's board of directors. By December 31, 2019, each public company with principal executive offices in California is required to have at least one female on its board of directors. By December 31, 2021, each public company is required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. If we fail to comply with this new law, we could be fined by the California Secretary of State, with a \$100,000 fine for the first violation and a \$300,000 for each subsequent violation, and our reputation may be adversely affected.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Our previous acquisitions and strategic transactions and resulting international operations have increased the complexity of our accounting, and additional acquisitions and transactions and further geographic expansion will likely increase this complexity and the related accounting challenges. Any failure to

[Table of Contents](#)

maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, or FASB, or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws that will become effective upon the completion of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 $\frac{2}{3}$ % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns 15% or more of our

[Table of Contents](#)

outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

[Table of Contents](#)**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our strategy, future financial condition, future operations, research and development, planned clinical trials and preclinical studies, technology platforms, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, the potential benefits of collaborations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Other sections of this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

[Table of Contents](#)

MARKET AND INDUSTRY DATA

Certain market, industry and competitive data included in this prospectus were obtained from our own internal estimates and research, as well as from publicly available information, reports of governmental agencies and industry publications and surveys. In some cases, we do not expressly refer to the sources from which this data is derived. All of the market and industry data used in this prospectus is inherently subject to uncertainties and involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

[Table of Contents](#)

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$127.4 million (or approximately \$147.3 million if the underwriters exercise in full their option to purchase up to 1,071,428 additional shares of common stock), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, establish a public market for our common stock and to facilitate future access to the public equity markets by us, our employees and our stockholders, obtain additional capital to support our operations and increase our visibility in the marketplace.

As of June 30, 2019, we had cash, cash equivalents and short-term investments of \$356.5 million. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately \$45.0 million to complete our ongoing VIR-2218 Phase 1/2 clinical trial and fund related manufacturing needs;
- approximately \$30.0 million to advance VIR-3434 through our planned Phase 1 clinical trial;
- approximately \$75.0 million to advance VIR-2482 through our ongoing Phase 1/2 clinical trial, as well as preparation for a potential registrational clinical trial; and
- the remainder to fund any potential future combination or other clinical trials and preclinical programs, and for working capital and other general corporate purposes.

The estimated amounts set forth above include any related milestone payments that may be due from us under the applicable license and collaboration agreements. In addition, we expect that the current grants from the Bill & Melinda Gates Foundation will fund the manufacture and early clinical development of VIR-1111 and VIR-2020.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the drug development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes.

Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions and the amount of cash obtained through current and any future collaborations.

The expected net proceeds from this offering, together with our cash, cash equivalents and short-term investments, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaborations, and license and development agreements. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

[Table of Contents](#)

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

[Table of Contents](#)

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments, and our capitalization as of June 30, 2019 on:

- an actual basis;
- a pro forma basis, to reflect: (i) the conversion of all of the outstanding shares of our convertible preferred stock as of June 30, 2019 into an aggregate of 88,112,733 shares of common stock upon the completion of this offering and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the completion of this offering; (ii) the automatic conversion of a warrant to purchase an aggregate of 244,444 shares of our Series A-1 convertible preferred stock outstanding as of June 30, 2019 into a warrant to purchase an equivalent number of shares of our common stock, and the related reclassification of convertible preferred stock warrant liability to additional paid-in-capital, a component of stockholders' (deficit) equity, upon the completion of this offering; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately after the completion of this offering; and
- a pro forma as adjusted basis, giving effect to the pro forma adjustments discussed above, and giving further effect to the sale of 7,142,858 shares of our common stock in this offering at the initial public offering price of \$20.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of June 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Cash, cash equivalents and short-term investments	\$ 356,547	\$ 356,547	\$ 486,813
Convertible preferred stock warrant liability	\$ 1,808	\$ —	\$ —
Convertible preferred stock, \$0.0001 par value per share; 421,450,000 shares authorized, 88,112,733 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	636,612	—	—
Stockholders' (deficit) equity:			
Preferred stock, \$0.0001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted			—
Common stock, \$0.0001 par value per share; 558,350,000 shares authorized, 9,722,838 shares issued and outstanding, actual; 300,000,000 shares authorized and 97,835,571 shares issued and outstanding, pro forma; 300,000,000 shares authorized and 104,978,429 shares issued and outstanding, pro forma as adjusted	1	10	10
Additional paid-in capital	19,226	657,637	784,994
Accumulated other comprehensive loss	240	240	240
Accumulated deficit	(256,434)	(256,434)	(256,434)
Total stockholders' (deficit) equity	(236,967)	401,453	528,810
Total capitalization	<u>\$ 401,453</u>	<u>\$ 401,453</u>	<u>\$ 528,810</u>

[Table of Contents](#)

The number of shares of our common stock to be outstanding after this offering reflected in the table above is based on 97,835,571 shares of common stock outstanding (including 88,112,733 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock) as of June 30, 2019, and excludes:

- 5,544,976 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2019, with a weighted-average exercise price of \$2.36 per share;
- 1,031,758 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to June 30, 2019, with an exercise price of \$10.40 per share;
- 4,418,767 shares of our unvested restricted common stock as of June 30, 2019;
- 244,444 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2019, with an exercise price of \$4.50 per share, which warrant is exercisable to purchase shares of our Series A-1 convertible preferred stock and will automatically convert to a warrant to purchase an equivalent number of shares of our common stock upon the completion of this offering;
- up to 1,111,111 shares of our common stock issuable to Alnylam, upon the achievement of a development milestone pursuant to the Alnylam Agreement (see “Business—Our Collaboration, License and Grant Agreements—Collaboration and License Agreement with Alnylam” for additional information);
- 5,800,000 shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2019 Plan (of which options to purchase an aggregate of 306,441 shares of our common stock were granted to certain of our employees and certain non-employee directors of our board of directors at the time of effectiveness of the 2019 Plan with an exercise price equal to the initial public offering price per share); and
- 1,280,000 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan, or ESPP, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our ESPP.

[Table of Contents](#)

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book deficit as of June 30, 2019 was \$(293.1) million, or \$(20.73) per share of our common stock. Our historical net tangible book deficit represents our total tangible assets (net of deferred offering costs) less total liabilities and convertible preferred stock. Historical net tangible book deficit per share is our historical net tangible book deficit divided by the number of shares of our common stock (including 4,418,767 shares of unvested restricted common stock) outstanding as of June 30, 2019.

Our pro forma net tangible book value as of June 30, 2019 was \$345.3 million, or \$3.38 per share of our common stock, based on the total number of shares of our common stock outstanding as of June 30, 2019. Pro forma net tangible book value per share represents our total tangible assets (net of deferred offering costs) less our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to (i) the conversion of all of the outstanding shares of our convertible preferred stock as of June 30, 2019 into an aggregate of 88,112,733 shares of common stock upon the completion of this offering and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the completion of this offering and (ii) the automatic conversion of a warrant to purchase an aggregate of 244,444 shares of our Series A-1 convertible preferred stock outstanding as of June 30, 2019 into a warrant to purchase an equivalent number of shares of our common stock, and the related reclassification of convertible preferred stock warrant liability to additional paid-in-capital, a component of stockholders' (deficit) equity, upon the completion of this offering.

After giving effect to the sale of 7,142,858 shares of common stock in this offering at the initial public offering price of \$20.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been \$475.6 million, or \$4.35 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.97 per share to our existing stockholders and an immediate dilution of \$15.65 per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share	\$ 20.00
Historical net tangible book deficit per share as of June 30, 2019	\$(20.73)
Pro forma increase in net tangible book value per share as of June 30, 2019 attributable to the pro forma transactions described above	24.11
Pro forma net tangible book value per share as of June 30, 2019	3.38
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	0.97
Pro forma as adjusted net tangible book value per share after this offering	4.35
Dilution per share to new investors participating in this offering	<u>\$ 15.65</u>

If the underwriters exercise in full their option to purchase up to 1,071,428 additional shares of common stock from us, the pro forma as adjusted net tangible book value per share after giving effect to this offering would be \$4.49 per share, representing an immediate increase to existing stockholders of \$1.11 per share, and dilution to new investors participating in this offering of \$15.51 per share.

The following table summarizes on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us on an as converted basis, the total consideration paid and the weighted-average price per share paid to us by existing stockholders and by investors purchasing shares in this offering at

[Table of Contents](#)

the initial public offering price of \$20.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us:

	Total Shares		Total Consideration ⁽¹⁾		Weighted-Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders	102,254,338	93.5%	\$651,184,445	82.0%	\$ 6.37
New investors	7,142,858	6.5	142,857,160	18.0	\$ 20.00
Total	<u>109,397,196</u>	<u>100.0%</u>	<u>\$794,041,605</u>	<u>100.0%</u>	

(1) Including non-cash consideration of \$14,753,615.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own 92.6% and our new investors would own 7.4% of the total number of shares of our common stock outstanding upon the completion of this offering.

The foregoing discussion and tables above are based on 102,254,338 shares of common stock (including (i) 88,112,733 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock and (ii) 4,418,767 shares of unvested restricted common stock) outstanding as of June 30, 2019, and excludes:

- 5,544,976 shares of our common stock issuable upon the exercise of outstanding stock options as of June 30, 2019, with a weighted-average exercise price of \$2.36 per share;
- 1,031,758 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to June 30, 2019, with an exercise price of \$10.40 per share;
- 244,444 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2019, with an exercise price of \$4.50 per share, which warrant is exercisable to purchase shares of our Series A-1 convertible preferred stock and will automatically convert to a warrant to purchase an equivalent number of shares of our common stock upon the completion of this offering;
- up to 1,111,111 shares of our common stock issuable to Alnylam, upon the achievement of a development milestone pursuant to the Alnylam Agreement (see “Business—Our Collaboration, License and Grant Agreements—Collaboration and License Agreement with Alnylam” for additional information);
- 5,800,000 shares of our common stock reserved for future issuance under the 2019 Plan, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2019 Plan (of which options to purchase an aggregate of 306,441 shares of our common stock were granted to certain of our employees and certain non-employee directors of our board of directors at the time of effectiveness of the 2019 Plan with an exercise price equal to the initial public offering price per share); and
- 1,280,000 shares of our common stock reserved for future issuance under our ESPP, which became effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our ESPP.

To the extent that any outstanding options or the outstanding warrant are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional equity or convertible debt securities in the future, there will be further dilution to new investors participating in this offering.

[Table of Contents](#)

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated statements of operations data for the years ended December 31, 2017 and 2018, and our selected consolidated balance sheet data as of December 31, 2017 and 2018, which have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The following selected consolidated statements of operations data for the six months ended June 30, 2018 and 2019 and the selected consolidated balance sheet data as of June 30, 2019 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The unaudited condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2019. You should read the following selected consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:				
Revenue:				
Grant revenue	\$ 2,559	\$ 9,800	\$ 3,909	\$ 5,605
Contract revenue	149	868	748	103
Total revenue	2,708	10,668	4,657	5,708
Operating expenses:				
Research and development	62,512	100,229	48,419	55,677
General and administrative	21,693	29,131	13,788	16,570
Total operating expenses	84,205	129,360	62,207	72,247
Loss from operations	(81,497)	(118,692)	(57,550)	(66,539)
Other income (expense):				
Interest income	638	2,540	1,207	4,552
Other income (expense), net	83	(212)	(192)	(592)
Total other income (expense), net	721	2,328	1,015	3,960
Loss before benefit from (provision for) income taxes	(80,776)	(116,364)	(56,535)	(62,579)
Benefit from (provision for) income taxes	10,924	480	500	(19)
Net loss	\$ (69,852)	\$ (115,884)	\$ (56,035)	\$ (62,598)
Net loss per share, basic and diluted(1)	\$ (32.45)	\$ (15.12)	\$ (8.04)	\$ (6.83)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted(1)	2,152,273	7,666,463	6,973,460	9,165,311
Pro forma net loss per share, basic and diluted (unaudited)(1)		\$ (1.52)		\$ (0.64)
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited)(1)		76,050,495		96,912,507

Table of Contents


(1) See Notes 2 and 13 to each of our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares outstanding used in the computation of the per share amounts.

	As of December 31,		As of June 30,
	2017	2018 (in thousands)	2019
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 187,918	\$ 98,443	\$ 356,547
Working capital(1)	179,912	77,875	336,679
Total assets	251,566	191,596	456,849
Convertible preferred stock warrant liability	929	1,024	1,808
Convertible preferred stock	292,525	309,137	636,612
Accumulated deficit	(77,952)	(193,836)	(256,434)
Total stockholders' deficit	(68,916)	(179,177)	(236,967)

(1) We define working capital as current assets less current liabilities. See our consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

You should read the following discussion and analysis of our financial condition and results of operations together with the section titled “Selected Consolidated Financial Data” and our consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section titled “Risk Factors” and elsewhere in this prospectus. Please also see the section titled “Special Note Regarding Forward-Looking Statements.”

Our current product candidates are summarized in the chart below:

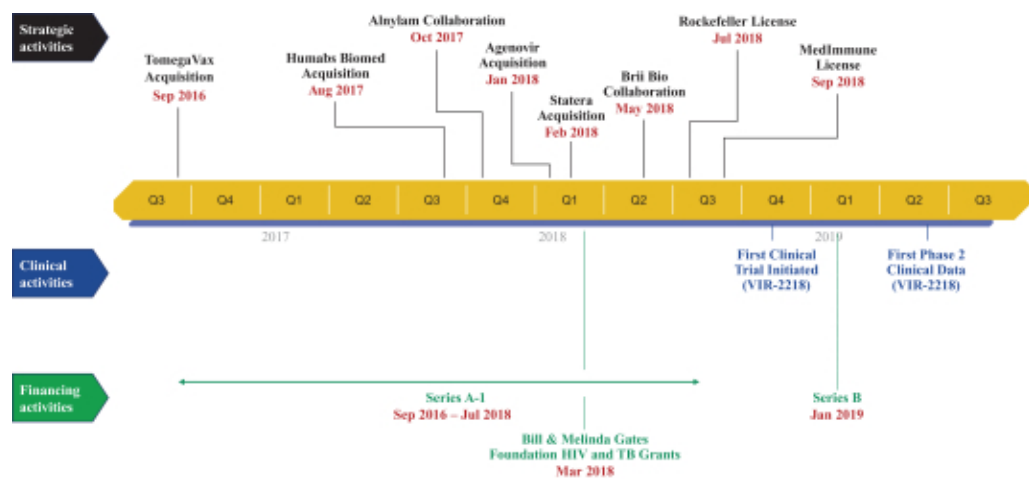
Indication	Product Candidate	Treatment/ Prophylaxis	Platform	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator	Anticipated Milestones
HBV	VIR-2218	Treatment	sRNA	<div><div></div></div>				 Alnylam	Additional Phase 3 data in 1H 2020
	VIR-3434	Treatment	Antibody	<div><div></div></div>					CTA 1H 2020
Influenza A	VIR-2482	Prophylaxis	Antibody	<div><div></div></div>					Initial Phase 1/2 data in 2H 2020
HIV	VIR-1111 [*]	Prophylaxis	T cell	<div><div></div></div>				Bill & MELINDA GATES <i>Foundation</i>	IND 1H 2020
TB	VIR-2020	Prophylaxis	T cell	<div><div></div></div>				Bill & MELINDA GATES <i>Foundation</i>	IND 1H 2021

<https://www.sec.gov/Archives/edgar/data/1706431/000119312519266864/d755217d424b4.htm>[10/15/2019 10:21:00 AM]

Table of Contents

We were incorporated in April 2016 and commenced principal operations later that year. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials. We have funded our operations to date primarily from the issuance and sale of convertible preferred stock, and to a lesser extent from revenue from grant agreements with government-sponsored and private organizations, as well as research and development services. From our inception through June 30, 2019, we have raised aggregate net cash proceeds of \$630.7 million from the sale of our convertible preferred stock. As of June 30, 2019, we had \$356.5 million in cash, cash equivalents and short-term investments. Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of the date of this prospectus will enable us to fund our operating expenses and capital expenditure requirements through at least the next 18 months from the date of this offering.

Here are some of the significant milestones we have achieved since commencing our operations:



We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. We do not have any products approved for sale, we have not generated any revenue from the sale of products, and we do not expect to generate revenue from the sale of our product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever. Our net losses were \$69.9 million and \$115.9 million for the years ended December 31, 2017 and 2018, respectively, and \$56.0 million and \$62.6 million for the six months ended June 30, 2018 and 2019, respectively. As of June 30, 2019, we had an accumulated deficit of \$256.4 million. Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We expect to continue to incur net operating losses for at least the next several years. In particular, we expect our expenses and losses to increase as we continue our research and development efforts, advance our product candidates through preclinical and clinical development, seek regulatory approval, prepare for commercialization, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

[Table of Contents](#)

We are currently manufacturing product candidates from three different platforms: antibodies, T cells and siRNAs. We have established our own internal chemistry, manufacturing and control, or CMC, capabilities and are working with CDMOs to supply our early stage product candidates in the near-term. We have completed our internal capacity build in process development, analytical development, quality, manufacturing and supply chain. Specifically, our San Francisco, California and Portland, Oregon facilities include laboratories that support process development, production of HCMV research viral seed stock and selected quality control testing for our product candidates. We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1 and Phase 2 clinical trials. Material for Phase 3 clinical trials and commercial supply will require large-volume, low-cost-of-goods production, and we are in discussions with additional large-scale CDMOs to plan for future scale-up and capacity.

Our License, Collaboration and Grant Agreements

We have entered into grant, license and collaboration arrangements with various third parties as summarized below. For further details regarding these and other agreements, see the section titled “Business—Our Collaboration, License and Grant Agreements” and Note 6 to each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus.

Alnylam

In October 2017, we entered into the Alnylam Agreement for the development of siRNA therapeutic products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA therapeutic products directed to up to four other infectious disease targets selected by us. The technology licensed under the Alnylam Agreement forms the basis of our siRNA technology platform.

Pursuant to the Alnylam Agreement, we obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such as excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to our selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA therapeutics directed to the target of each such program for all uses and purposes other than the Excluded Fields. On a product-by-product basis for each product arising from the HBV and, following our option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

Pursuant to the Alnylam Agreement, we paid Alnylam an upfront fee of \$10.0 million and issued to Alnylam 1,111,111 shares of our common stock. Both the upfront fee and the estimated fair value of our common stock were recognized as research and development expenses for the year ended December 31, 2017. During the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, we incurred \$1.1 million, \$8.3 million, \$5.5 million and \$3.1 million, respectively, for the joint funding of development activities for POC study relating to this collaboration. Under this agreement, we may also owe Alnylam milestone payments upon the achievement of certain development, regulatory and commercial milestones, of up to a maximum of \$1.3 billion in the aggregate, as well as royalties on the net sales of licensed products ranging from high-single-digit to sub-teen double-digit percentages. Upon the achievement of a certain development milestone, we will also issue shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone is achieved, which milestone has not yet been achieved. Additionally, the receipt of consideration from Bii, as discussed below, triggered a requirement under this agreement to transfer a portion of the consideration, consisting of equity in Bii, to Alnylam. Accordingly, we have recognized a liability of \$0.8 million to Alnylam as of December 31, 2018 and a corresponding charge to research and development expenses. The liability of \$0.8 million remained outstanding as of June 30, 2019.

[Table of Contents](#)

We and Alnylam are jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept studies. Prior to the exercise of our option for each other siRNA program directed to one of our selected infectious disease targets, Alnylam is responsible for conducting all development activities, at our expense, in accordance with an agreed upon development plan. Following our exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, we are solely responsible, at our expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program.

MedImmune

In September 2018, we entered into the 2018 MedImmune Agreement pursuant to which we obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, we made an upfront payment to MedImmune of \$10.0 million. The upfront fee was recognized as research and development expenses in the year ended December 31, 2018.

We will be obligated to make development, regulatory, and commercial milestone payments of up to \$343.3 million in the aggregate relating to influenza A and influenza B products. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits.

Rockefeller University

In July 2018, we entered into the Rockefeller Agreement, which was amended in May 2019. Pursuant to the Rockefeller Agreement, Rockefeller granted us a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases.

Under this agreement, we paid Rockefeller an upfront fee of \$0.3 million and are required to pay annual license maintenance fees of up to \$1.0 million, which will be creditable against royalties following commercialization. In addition, for achievement of specified development and regulatory milestone events, we will be required to pay up to \$8.5 million with respect to the first infectious disease product for the HIV indication, up to \$7.0 million with respect to each of the first four other infectious disease products with specified projected peak worldwide annual net sales and up to \$3.6 million with respect to any other infectious disease product. Following regulatory approval, we will be required to pay commercial success milestones of up to \$40.0 million in the aggregate for the achievement of specified aggregate worldwide annual net sales of the first infectious disease product for the HIV indication and the first four infectious disease products with specified projected peak worldwide annual net sales. We will also be required to pay to Rockefeller a tiered royalty of up to a low single digit percentage on net sales of licensed products, subject to certain adjustments.

We recognized \$1.0 million for the annual license maintenance fee as research and development expense during the six months ended June 30, 2019.

[Table of Contents](#)

Brii

In May 2018, we entered into the Brii Agreement with respect to up to four of our programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau, or collectively the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection. Each party has the option to acquire an exclusive license to develop and commercialize products based on the other party's intellectual property on a collaboration program-by-collaboration program basis for a specific target market, namely the United States for us and greater China territory for Brii. Each party can exercise license options up to four times at an exercise price which varies from \$5.0 million to \$50.0 million, depending on the commercial potential of each program. Subsequent to the exercise of each license option, the option holder will be required to make certain potential milestone and royalty payments. As of June 30, 2019, no license option has been exercised.

As partial consideration for our entry into the Brii Agreement, upon closing of Brii Bio Parent's Series A preferred stock financing, we received ordinary shares of Brii Bio Parent equal to 9.9% of the outstanding shares in Brii Bio Parent. We also received an option to purchase additional ordinary shares of Brii Bio Parent at a purchase price of \$0.0001 per share in connection with additional Series A issuances by Brii Bio Parent and an option to acquire Brii Bio Parent's Series B preferred shares upon occurrence of the Series B financing at the same purchase price paid by the other Series B investors.

Brii Bio Parent and its wholly owned subsidiary Brii Bio are considered variable interest entities due to their reliance on future financing and insufficient equity at risk. However, we do not have the power to direct activities which most significantly impact the economic success of these entities and are not the primary beneficiary of these entities, and therefore we do not consolidate Brii Bio Parent or Brii Bio. We also determined that we do not exercise significant influence over Brii Bio Parent or Brii Bio. The investment in Brii Bio Parent was recorded at its initial estimated fair value of \$6.6 million within other assets on the consolidated balance sheet and is subsequently accounted for under the cost method. We also recorded a contract liability of \$6.6 million within deferred revenue which represents the four options that we granted to Brii Bio.

Bill & Melinda Gates Foundation

Campylo/EPEC/EAEC Grant

As part of our acquisition of Humabs in August 2017, we acquired a grant agreement with the Bill & Melinda Gates Foundation, or the 2017 Grant Agreement, pursuant to which we were awarded a grant totaling up to \$4.7 million. The 2017 Grant Agreement supported our discovery, characterization and selection of human mAbs with preclinical efficacy against three enteric pathogens responsible for life-threatening diarrhea in neonates. The 2017 Grant Agreement expired on May 31, 2019.

Pursuant to the 2017 Grant Agreement, we recognized grant revenue of \$0.8 million and \$2.0 million for the years ended December 31, 2017 and 2018, respectively, and \$0.7 million and \$0.9 million for the six months ended June 30, 2018 and 2019, respectively.

HIV Grant

In January 2018, we entered into a grant agreement with the Bill & Melinda Gates Foundation, or the HIV Grant Agreement, pursuant to which we were awarded a grant totaling up to \$12.2 million for our HIV program. The HIV Grant Agreement will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation.

Pursuant to the HIV Grant Agreement, we recognized grant revenue of \$4.4 million for the year ended December 31, 2018, and \$2.0 million and \$2.9 million for the six months ended June 30, 2018 and 2019, respectively.

[Table of Contents](#)

TB Grant

In March 2018, we entered into a grant agreement with the Bill & Melinda Gates Foundation for the development of a TB vaccine, under which we were awarded a grant totaling up to \$14.9 million, or the TB Grant Agreement. Unless terminated earlier by the Bill & Melinda Gates Foundation, this agreement will continue in effect until June 30, 2020.

Pursuant to the TB Grant Agreement, we recognized grant revenue of \$2.3 million for the year ended December 31, 2018, and \$0.5 million and \$1.3 million for the six months ended June 30, 2018 and 2019, respectively.

National Institutes of Health

As part of our acquisition of TomegaVax in September 2016, we acquired grant agreements relating to TomegaVax's research effort in infectious diseases and cancer that entitled them to several awards under the Small Business Innovative Research Program from the NIH. These grants are cost plus fixed fee agreements in which we are reimbursed for our direct and indirect costs. Only costs that are allowable under certain government regulations and NIH's supplemental policy and procedure manual may be claimed for reimbursement, subject to government audit.

Through June 30, 2019, we have acquired or been awarded grants from the NIH totaling \$4.1 million. We recognized \$1.8 million, \$1.1 million, \$0.7 million and \$0.5 million in grant revenue for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019, respectively, related to the NIH grants.

Our Acquisitions

We have completed the acquisitions summarized below. For further details regarding these acquisitions, see Note 4 to each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus.

TomegaVax

In September 2016, we acquired all of the outstanding equity of TomegaVax, a private preclinical biotechnology company whose primary asset was a CMV vector-based vaccine platform for use in HBV, HIV and TB.

The transaction was accounted for as an asset acquisition with a purchase price of \$5.2 million. As consideration, we issued 1,555,550 shares of our Series A-2 convertible preferred stock, valued at \$3.6 million as of the date of the transaction, to former TomegaVax stockholders. In addition, we paid liabilities of \$1.1 million and incurred transaction costs of \$0.5 million related to the TomegaVax acquisition. The purchase price of \$5.2 million was included in research and development expenses in our consolidated statement of operations for the year ended December 31, 2016. The former TomegaVax stockholders are entitled to future milestone payments of up to \$30.0 million upon the achievement of certain specified milestone events relating to asset disposition, merger and equity transfer activities and the share price of our publicly traded common stock. These milestone payment rights expire in September 2024. None of the milestones had been achieved as of June 30, 2019, and therefore no related amounts were recognized during the years ended December 31, 2017 or 2018, or the six months ended June 30, 2019.

Humabs

In August 2017, we acquired all of the outstanding equity of Humabs, a private Swiss company which discovers and develops monoclonal antibodies derived from individuals whose immune systems have

[Table of Contents](#)

successfully responded to major diseases. We acquired all of Humabs' rights, title and interest in and to substantially all of the assets of Humabs except for rights under certain license agreements with third-parties. We are obligated to pass-through to the former Humabs shareholders any amounts received by Humabs under such license agreements, net of any program expenses.

The transaction was accounted for as an acquisition of a business with total consideration of \$42.3 million. As consideration, we paid \$30.0 million in cash and issued 1,666,656 shares of our common stock, valued at \$2.5 million as of the date of the transaction, to former Humabs shareholders. We also agreed to pay additional amounts in cash upon the achievement of specified milestone events: (i) up to \$135.0 million upon the achievement of clinical, regulatory and commercial milestones for an HBV product; and (ii) up to \$105.0 million upon the achievement of clinical, regulatory and commercial milestones for another product. The estimated fair value of this contingent consideration was \$6.3 million as of the date of acquisition. Payments will vary based on milestones that are reached. The final component of the total consideration was for acquired net working capital of \$3.6 million.

The acquired developed technologies that have associated patents issued are classified as finite-lived intangible assets and are amortized on a straight-lined basis over their estimated remaining useful lives, generally between seven to twelve years. The amortization expense for the years ended December 31, 2017 and 2018 was \$0.2 million and \$0.5 million, respectively. These assets will not be amortized until regulatory approval is obtained in a major market. At that time, we will determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned, the related in-process research and development assets will be written-off and an impairment charge recorded. As of June 30, 2019, there have been no such impairments. The estimated fair value of the intangible assets was determined using the replacement cost method. The excess of the purchase price over the estimated fair value of the net assets acquired was recorded as goodwill. None of the goodwill is expected to be deductible for income tax purposes. As of June 30, 2019, no goodwill impairment was identified.

We incurred \$0.7 million of transaction costs related to the Humabs acquisition. These costs were included in general and administrative expense in our consolidated statement of operations for the year ended December 31, 2017.

Agenovir

In January 2018, we acquired all of the outstanding equity of Agenovir, a private company whose primary assets were in-process research and development programs in HPV and HBV using CRISPR/Cas9.

The transaction was accounted for as an asset acquisition with a purchase price of \$15.3 million. As consideration, we issued 555,537 shares of our Series A-2 convertible preferred stock, valued at \$1.8 million as of the date of the transaction and agreed to pay cash of \$11.5 million to the former Agenovir stockholders. We also assumed certain liabilities of \$1.3 million and incurred transaction costs of \$0.7 million. The purchase price was allocated between acquired tangible assets of \$0.8 million and acquired in-process research and development assets of \$14.5 million, which was included in research and development expenses in our consolidated statement of operations for the year ended December 31, 2018. We had retained \$2.0 million of the cash purchase price as holdback to satisfy claims for indemnification, which was recorded in our consolidated balance sheet as restricted cash, current as of December 31, 2018. In April 2019, we paid \$1.8 million of the holdback to the former Agenovir stockholders.

The former Agenovir stockholders are entitled to future milestone payments of up to \$270.0 million upon the achievement of specified milestone events: (i) up to \$45.0 million upon the achievement of clinical and regulatory milestones for an HBV product; (ii) up to \$45.0 million upon the achievement of clinical and regulatory milestones for an HPV product; (iii) up to \$90.0 million upon the achievement of commercial milestones for an HBV product; and (iv) up to \$90.0 million upon the achievement of commercial milestones for an HPV product. None of the milestones had been achieved as of June 30, 2019, and therefore no related amounts were recognized during the year ended December 31, 2018 or the six months ended June 30, 2019.

[Table of Contents](#)

Statera

In February 2018, we acquired all of the outstanding equity of Statera Health, Inc., or Statera, a private company whose primary asset was a cloud-based predictive analytics platform that translates clinical data into casual hypotheses of disease pathophysiology.

The transaction was accounted for as an asset acquisition with a purchase price of \$1.7 million. As consideration, we paid cash of \$0.9 million, issued 188,333 shares of our Series A-2 convertible preferred stock, valued at \$0.6 million as of the date of the transaction, to the former Statera stockholders and incurred transaction costs of \$0.2 million. The cloud-based predictive analytics platform was accounted for as developed technology and is classified as finite-lived intangible assets and amortized on a straight-lined basis over an estimated useful life of three years.

Components of Operating Results

Revenue

We do not have any products approved for sale, we have not generated any revenue from the sale of our products, and we do not expect to generate revenue from the sale of our product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever.

Our revenue consists of: (i) grant revenue; and (ii) contract revenue. Grant revenue is comprised of revenue derived from grant agreements with government-sponsored and private organizations. Contract revenue is comprised of revenue generated from research and development services through Humabs, our Swiss subsidiary.

Operating Expenses

Research and Development

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. We do not track research and development expenses by product candidate.

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses related to license and collaboration agreements;
- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel contributing to research and development activities;
- expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants;
- clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and
- other allocated expenses, including expenses for rent and facilities maintenance, and depreciation and amortization.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our

[Table of Contents](#)

product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our clinical development costs may vary significantly based on factors such as:

- whether a collaborator is paying for some or all of the costs;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses for personnel in executive, finance and other administrative functions, facilities and other allocated expenses, transaction costs associated related to acquisitions and other expenses for outside professional services, including legal, audit and accounting services, and insurance costs. Personnel-related expenses consist of salaries, benefits and stock-based compensation.

We expect our general and administrative expenses to increase substantially in absolute dollars for the foreseeable future as we continue to support our continued research and development activities, grow our business and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

[Table of Contents](#)
Interest Income

Interest income consists of interest earned on our cash and cash equivalents and short-term investments.

Other Income (Expense), Net

Other income (expense), net consists of foreign currency transaction gains and losses and remeasurement gains and losses related to the convertible preferred stock warrant liability. We will continue to record adjustments to the estimated fair value of the convertible preferred stock warrant until such time as this instrument is exercised, expired or converted into a warrant to purchase shares of our common stock.

Benefit from (Provision for) Income Taxes

Benefit from income taxes consists of the partial release of the valuation allowance on net deferred tax assets triggered by the deferred tax liabilities recorded as a result of the acquisitions of Humabs in 2017 and Statera in 2018. Provision for income taxes in 2019 consisted of immaterial state income tax.

Results of Operations
Comparison of the Six Months Ended June 30, 2018 and 2019

The following table summarizes our results of operations for the periods presented:

	Six Months Ended June 30,		
	2018	2019	Change
	(in thousands)		
Revenue:			
Grant revenue	\$ 3,909	\$ 5,605	\$ 1,696
Contract revenue	748	103	(645)
Total revenue	<u>4,657</u>	<u>5,708</u>	<u>1,051</u>
Operating expenses:			
Research and development	48,419	55,677	7,258
General and administrative	13,788	16,570	2,782
Total operating expenses	<u>62,207</u>	<u>72,247</u>	<u>10,040</u>
Loss from operations	(57,550)	(66,539)	(8,989)
Other income (expense):			
Interest income	1,207	4,552	3,345
Other income (expense), net	(192)	(592)	(400)
Total other income (expense), net	<u>1,015</u>	<u>3,960</u>	<u>2,945</u>
Loss before benefit from (provision for) income taxes	(56,535)	(62,579)	(6,044)
Benefit from (provision for) income taxes	500	(19)	(519)
Net loss	<u><u>\$ (56,035)</u></u>	<u><u>\$ (62,598)</u></u>	<u><u>\$ (6,563)</u></u>

Revenue

Total revenue was \$4.7 million and \$5.7 million for the six months ended June 30, 2018 and 2019, respectively. This \$1.0 million increase was primarily due to an increase in revenue recognized under HIV and TB grants of \$0.9 million and \$0.8 million, respectively as the grants were awarded in the first quarter of 2018.

[Table of Contents](#)
Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Six Months Ended June 30,		Change
	2018	2019	
	(in thousands)		
Licenses and collaborations	\$22,696	\$ 350	\$ (22,346)
Personnel	10,080	20,117	10,037
Contract manufacturing	3,207	12,794	9,587
Clinical costs	356	2,173	1,817
Other	12,080	20,243	8,163
Total research and development	<u>\$48,419</u>	<u>\$55,677</u>	<u>\$ 7,258</u>

Research and development expenses were \$48.4 million and \$55.7 million for the six months ended June 30, 2018 and 2019, respectively. This \$7.3 million increase was primarily due to:

- personnel-related expenses increased by \$10.0 million, which was primarily attributable to an increase in our headcount;
- contract manufacturing expenses increased by \$9.6 million, which was primarily attributable to production of clinical materials for use in our preclinical studies and clinical trials;
- other research and development expenses increased by \$8.2 million, which was attributable to increases of \$5.6 million in external research costs, \$1.7 million in the allocation of facilities costs, and \$0.8 million in supplies and equipment costs to support an increase in our headcount; and
- clinical costs increased \$1.8 million, which was primarily attributable to initiation of our first HBV clinical trial in November 2018 and preparation for our influenza A clinical trial.

This increase was partially offset by a decrease of \$22.3 million in licenses and collaborations expense. For the six months ended June 30, 2018, our licenses and collaborations expenses primarily consisted of \$14.5 million related to the Agenovir acquisition, which was accounted for as an asset acquisition, \$3.8 million related to the collaboration with Alnylam, \$2.2 million related to a collaboration, license and option agreement, or the Visterra Agreement, with Visterra, Inc., or Visterra, and \$2.0 million for the change in fair value of the contingent consideration from the Humabs acquisition. For the six months ended June 30, 2019, our licenses and collaborations expenses consisted only of \$0.4 million for the change in fair value of the contingent consideration from the Humabs acquisition.

General and Administrative Expenses

General and administrative expenses were \$13.8 million and \$16.6 million for the six months ended June 30, 2018 and 2019, respectively. This \$2.8 million increase was primarily due to an increase in personnel-related expenses related to additional headcount and professional fees.

Interest Income

Interest income was \$1.2 million and \$4.5 million for the six months ended June 30, 2018 and 2019, respectively. This \$3.3 million increase was due to higher cash, cash equivalents and short-term investment balances in the six months ended June 30, 2019 compared to the prior period.

[Table of Contents](#)
Other Income (Expense), Net

Other income (expense), net was \$(0.2) million and \$(0.6) million for the six months ended June 30, 2018 and 2019, respectively. Other income (expense), net in the six months ended June 30, 2018 was comprised of a \$0.2 million loss on disposal of property and equipment. Other income (expense), net in the six months ended June 30, 2019 was primarily comprised of a \$0.8 million loss from revaluation of convertible preferred stock warrant liability.

Comparison of the Years Ended December 31, 2017 and 2018

The following table summarizes our results of operations for the periods presented:

	Year Ended December 31,		
	2017	2018	Change
	(in thousands)		
Revenue:			
Grant revenue	\$ 2,559	\$ 9,800	\$ 7,241
Contract revenue	149	868	719
Total revenue	2,708	10,668	7,960
Operating expenses:			
Research and development	62,512	100,229	37,717
General and administrative	21,693	29,131	7,438
Total operating expenses	84,205	129,360	45,155
Loss from operations	(81,497)	(118,692)	(37,195)
Other income (expense):			
Interest income	638	2,540	1,902
Other income (expense), net	83	(212)	(295)
Total other income (expense), net	721	2,328	1,607
Loss before benefit from income taxes	(80,776)	(116,364)	(35,588)
Benefit from income taxes	10,924	480	(10,444)
Net loss	<u>\$ (69,852)</u>	<u>\$ (115,884)</u>	<u>\$ (46,032)</u>

Revenue

Total revenue was \$2.7 million and \$10.7 million for the years ended December 31, 2017 and 2018, respectively. This \$8.0 million increase was primarily due to revenue recognized under new HIV and TB grants awarded in 2018 of \$4.4 million and \$2.3 million, respectively.

[Table of Contents](#)
Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Year Ended December 31,		Change
	2017	2018	
	(in thousands)		
Licenses and collaborations	\$ 41,117	\$ 31,695	\$ (9,422)
Personnel	7,182	24,550	17,368
Contract manufacturing	457	13,486	13,029
Clinical costs	27	1,275	1,248
Other	13,729	29,223	15,494
Total research and development expenses	<u>\$ 62,512</u>	<u>\$ 100,229</u>	<u>\$ 37,717</u>

Research and development expenses were \$62.5 million and \$100.2 million for the years ended December 31, 2017 and 2018, respectively. This \$37.7 million increase was primarily due to:

- personnel-related expenses increased by \$17.4 million, which was attributable to an increase in our headcount;
- other research and development expenses increased by \$15.5 million, which was attributable to increases of \$6.8 million in external research costs, \$3.8 million in supplies and equipment costs to support an increase in our headcount, \$3.8 million due to expansion of our research facility and \$1.1 million relating to amortization of acquired assets;
- contract manufacturing expenses increased by \$13.0 million, which was primarily attributable to production of clinical materials for use in our preclinical studies and clinical trials; and
- clinical costs increased \$1.2 million, which was primarily attributable to initiation of our first HBV clinical trial.

This increase was partially offset by a decrease of \$9.4 million in licenses and collaborations expense which was attributable to the timing of payments under certain of these arrangements, the change in fair value of the contingent consideration from the Humabs acquisition and one-time payments made to collaborators in the year ended December 31, 2017. Specifically, in the year ended December 31, 2017, our licenses and collaborations expenses primarily consisted of \$25.9 million as a result of entering into the Visterra Agreement, \$12.4 million for the Alnylam Agreement, and \$2.8 million for the change in fair value of the contingent consideration from the Humabs acquisition. In the year ended December 31, 2018, our licenses and collaborations expenses primarily consisted of \$14.5 million related to the Agenovir acquisition, which was accounted for as an asset acquisition, \$10.0 million relating to the 2018 MedImmune Agreement, \$4.2 million related to the collaboration with Alnylam and \$2.6 million related to the Visterra Agreement.

General and Administrative Expenses

General and administrative expenses were \$21.7 million and \$29.1 million for the years ended December 31, 2017 and 2018, respectively. This \$7.4 million increase was primarily due to an increase of \$7.0 million in personnel-related expenses related to additional headcount.

Interest Income

Interest income was \$0.6 million and \$2.5 million for the years ended December 31, 2017 and 2018, respectively. This \$1.9 million increase was due to investing our cash in higher-interest earning cash equivalents and short-term investments in 2018.

[Table of Contents](#)***Other Income (Expense), Net***

Other income (expense), net was \$0.1 million and \$(0.2) million for the years ended December 31, 2017 and 2018, respectively. Other income (expense), net in the year ended December 31, 2017 comprised of a \$0.1 million gain from revaluation of convertible preferred stock warrant liability. Other income (expense), net in the year ended December 31, 2018 was primarily comprised of a \$0.1 million loss from revaluation of convertible preferred stock warrant liability.

Liquidity, Capital Resources and Capital Requirements***Sources of Liquidity***

Since our inception, we have funded our operations primarily through the sale and issuance of convertible preferred stock, and to a lesser extent from revenue from grant agreements with government-sponsored and private organizations, as well as research and development services. From our inception through June 30, 2019, we have raised aggregate net cash proceeds of \$630.7 million from the sale of our convertible preferred stock. As of June 30, 2019, we had \$356.5 million in cash, cash equivalents and short-term investments. Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and early clinical trials, and to a lesser extent, general and administrative expenditures.

Future Funding Requirements

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments as of the date of this prospectus, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 18 months from the date of this offering. However, even after this offering, we will need to raise substantial additional capital to fund the development of our product candidates. We anticipate raising additional capital through the sale of our equity securities, incurring debt, entering into collaboration, licensing or similar arrangements with third parties, or receiving research contributions, grants or other sources of financing to fund our operations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;

[Table of Contents](#)

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including the timing and amount of any future milestone, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2017	2018	2018	2019
	(in thousands)			
Net cash provided by (used in):				
Operating activities	\$ (66,381)	\$ (94,096)	\$ (29,984)	\$ (53,792)
Investing activities	(29,994)	(60,441)	(94,914)	(229,681)
Financing activities	271,182	24,978	12,328	317,412
Net increase (decrease) in cash and cash equivalents and restricted cash and cash equivalents	<u>\$ 174,807</u>	<u>\$ (129,559)</u>	<u>\$ (112,570)</u>	<u>\$ 33,939</u>

Operating Activities

During the six months ended June 30, 2019, net cash used in operating activities was \$53.8 million. This consisted primarily of a net loss of \$62.6 million, partially offset by a decrease in our net operating assets of \$2.9 million and non-cash charges of \$5.9 million. The decrease in our net operating assets of \$2.9 million was primarily due to an increase in deferred revenue of \$2.9 million related to upfront payments received from the Bill & Melinda Gates Foundation grants. The non-cash charges of \$5.9 million primarily consisted of \$3.9 million for stock-based compensation expense and \$1.5 million for depreciation and amortization expense.

During the six months ended June 30, 2018, net cash used in operating activities was \$30.0 million. This consisted primarily of a net loss of \$56.0 million, partially offset by a decrease in our net operating assets of \$19.1 million and non-cash charges of \$7.0 million. The decrease in our net operating assets of \$19.1 million was primarily due to an increase in deferred revenue of \$13.1 million related to upfront payments received from the Bill & Melinda Gates Foundation grants and increases in accounts payable, accrued liabilities and other long-term liabilities of \$6.4 million as we expanded our operations. The non-cash charges of \$7.0 million primarily

[Table of Contents](#)

consisted of \$2.7 million for stock-based compensation expense, \$2.0 million for change in fair value of contingent consideration and \$1.8 million for the preferred stock issued in connection with our acquisition of Agenovir.

During the year ended December 31, 2018, net cash used in operating activities was \$94.1 million. This consisted primarily of a net loss of \$115.9 million, partially offset by a decrease in our net operating assets of \$12.5 million and non-cash charges of \$9.3 million. The decrease in our net operating assets of \$12.5 million was primarily due to an increase in deferred revenue of \$7.9 million related to upfront payments received from the Bill & Melinda Gates Foundation grants and increases in accounts payable, accrued liabilities and other long-term liabilities of \$8.6 million as we expanded our operations, partially offset by an increase in prepaid expenses and other current assets of \$4.2 million. The non-cash charges of \$9.3 million primarily consisted of \$5.1 million for stock-based compensation expense and \$2.8 million for depreciation and amortization expense.

During the year ended December 31, 2017, cash used in operating activities was \$66.4 million. This consisted primarily of a net loss of \$69.9 million and a change in deferred income taxes of \$10.9 million related to the deferred tax liability resulting from the Humabs acquisition, partially offset by other non-cash charges of \$9.5 million and a decrease in our net operating assets of \$4.9 million. The other non-cash charges of \$9.5 million primarily consisted of \$4.8 million for stock-based compensation expense and \$2.8 million related to the change in fair value of contingent consideration. The decrease in our net operating assets of \$4.9 million was primarily due to increases in accounts payable, accrued liabilities and other long-term liabilities of \$6.8 million as we expanded our operations, partially offset by an increase in prepaid expenses and other current assets of \$2.6 million.

Investing Activities

During the six months ended June 30, 2019, cash used in investing activities was \$229.7 million. This consisted of purchases of short-term investments of \$360.0 million and purchases of property and equipment of \$6.1 million, partially offset by \$136.5 million in proceeds received from short-term investments which matured during the period.

During the six months ended June 30, 2018, cash used in investing activities was \$94.9 million. This consisted primarily of purchases of short-term investments of \$100.3 million and purchases of property and equipment of \$3.9 million, partially offset by \$11.0 million in proceeds received from short-term investments which matured during the period.

During the year ended December 31, 2018, cash used in investing activities was \$60.4 million. This consisted primarily of purchases of short-term investments of \$123.1 million and purchases of property and equipment of \$8.2 million, partially offset by \$72.6 million in proceeds received from short-term investments which matured during the period.

During the year ended December 31, 2017, cash used in investing activities was \$30.0 million. This consisted primarily of cash consideration paid for the acquisition of Humabs, net of cash acquired, of \$27.3 million and purchases of property and equipment of \$2.7 million.

Financing Activities

During the six months ended June 30, 2019, cash provided in financing activities was \$317.4 million. This consisted primarily of net proceeds received from the issuance of our Series B convertible preferred stock of \$317.3 million in January 2019.

During the six months ended June 30, 2018, cash provided in financing activities was \$12.3 million. This consisted primarily of net proceeds received from the issuance of our Series A-1 convertible preferred stock of \$12.3 million.

[Table of Contents](#)

During the year ended December 31, 2018, cash provided in financing activities was \$25.0 million. This consisted primarily of net proceeds received from the issuance of our Series A-1 convertible preferred stock of \$14.3 million and advance cash payment of \$10.1 million for the issuance of our Series B convertible preferred stock, which closed in January 2019.

During the year ended December 31, 2017, cash provided in financing activities was \$271.2 million. This consisted of net proceeds received from the issuance of our Series A-1 convertible preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2018:

	Payments Due by Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
	(in thousands)				
Operating leases(1)	\$ 3,436	\$ 10,868	\$ 7,559	\$ —	\$ 21,863

- (1) This table does not include the additional space in the amended operating lease we entered into in April 2019 for our San Francisco facility, which has a total minimum lease payment of \$0.8 million over the eleven-month term. In addition, this table does not include the noncancellable operating lease for our South San Francisco facility we entered into in June 2019. The additional minimum lease payments for the South San Francisco lease over the eleven-month term total \$0.3 million.

Under our collaboration, license and acquisition agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements. As of December 31, 2018, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. For additional information regarding these agreements, including our payment obligations thereunder, see the sections titled “Business—Our Collaboration, License and Grant Agreements” and “Business—Our Acquisition Agreements,” as well as Notes 4 and 6 to each of our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

We enter into agreements in the normal course of business with contract manufacturing organizations and contract research organizations for clinical trials, preclinical studies, manufacturing, and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are also not included in the table above.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the SEC. Bii Bio Parent and its wholly owned subsidiary Bii are variable interest entities due to their reliance on future financing and insufficient equity at risk. However, we do not have the power to direct activities which most significantly impact the economic success of these entities and are not the primary beneficiary, and therefore we do not consolidate Bii Bio Parent or Bii.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

Interest Rate Risk

We had cash and cash equivalents and restricted cash and cash equivalents of \$93.3 million as of June 30, 2019, which consisted of bank deposits and money market funds. We also had short-term investments of

Table of Contents

\$275.9 million as of June 30, 2019. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of June 30, 2019.

Foreign Currency

The functional currency of our foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of our foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. As of the date of this prospectus, we are exposed to foreign currency risk related to the operations of our Swiss subsidiary and consequently the Swiss Franc. Transaction gains and losses are included in other income (expenses), net on the consolidated statements of operations and were not material for the years ended December 31, 2017 and 2018 and for the six months ended June 30, 2018 and 2019.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to get comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements requires us to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the related disclosures. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. The critical accounting policies, estimates and judgments that we believe to have the most significant impacts to our consolidated financial statements are described below.

Research and Development Expenses

We expense all research and development costs in the periods in which they are incurred. We estimate preclinical and clinical expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies and clinical trials and research services on our behalf. We record the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets. We have not experienced any material differences between accrued costs and actual costs incurred. However, the status and

[Table of Contents](#)

timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations.

Business Combinations

Accounting for business combinations requires us to make significant estimates and assumptions, especially at the acquisition date with respect to tangible and intangible assets acquired and liabilities assumed and pre-acquisition contingencies. We use our best estimates and assumptions to accurately assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date as well as the useful lives of those acquired intangible assets. Examples of critical estimates in valuing certain of the intangible assets and goodwill we have acquired include but are not limited to developed technologies and in-process research and development. Our estimates may also impact our deferred income tax assets and liabilities. Unanticipated events and circumstances may occur that may affect the accuracy or validity of such assumptions, estimates or actual results.

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant, and we recognize forfeitures as they occur. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service period, which is typically the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Fair Value of Common Stock*—See the subsection titled “—Common Stock Valuations” below.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.
- *Expected Volatility*—Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 12 to each of our audited consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option-pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2017 and 2018 and the six months ended June 30, 2019. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

[Table of Contents](#)

Stock-based compensation expense was \$4.8 million and \$5.1 million during the years ended December 31, 2017 and 2018, respectively, and \$2.7 million and \$3.9 million during the six months ended June 30, 2018 and 2019, respectively. As of June 30, 2019, we had \$10.1 million of total unrecognized stock-based compensation costs which we expect to recognize over a weighted-average period of 2.8 years. These amounts reflect our reassessment of the fair value of our common stock in the second half of 2018 and the first half of 2019.

The intrinsic value of all outstanding options as of June 30, 2019 was approximately \$97.8 million, based on the initial public offering price of \$20.00 per share, of which approximately \$21.7 million is related to vested options and approximately \$76.1 million is related to unvested options.

Common Stock Valuations

Historically, for all periods prior to this initial public offering, since there has been no public market of our common stock to date, the fair value of the shares of common stock underlying our share-based awards was estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, input from management, valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant, and factors that may have changed from the date of the most recent valuation through the date of the grant. These factors include, but are not limited to:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to its business;
- progress of our research and development activities;
- our business conditions and projections;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices at which we sold shares of our convertible preferred stock to outside investors in arms-length transactions;
- the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for our securityholders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

For our valuations performed prior to December 31, 2018, we used the option pricing method, or OPM, backsolve method. In an OPM framework, the backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. This method was selected as management concluded that the contemporaneous financing transaction was an arms-length transaction. Furthermore, as of the valuation date prior to December 31, 2018, we were at an early stage of development and future liquidity events were difficult to forecast.

[Table of Contents](#)

For our valuations performed on or subsequent to December 31, 2018, we used a hybrid method of the OPM and the Probability-Weighted Expected Return Method, or PWERM. PWERM considers various potential liquidity outcomes. Our approach included the use of different timing of initial public offering scenarios and a scenario assuming continued operation as a private entity. Under the hybrid OPM and PWERM method, the per share value calculated under the OPM and PWERM are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share value of the common stock before a discount for lack of marketability is applied.

In the course of preparing our consolidated financial statements with a retrospective view, we have reassessed the fair value of our common stock in the second half of 2018 and the first quarter of 2019 solely for accounting purposes. For purposes of this determination, we assumed that the reassessed fair value of the common stock increased on a linear basis between the dates of our third-party valuation reports. We believe that a linear interpolation is appropriate as no single event caused the valuation of our common stock to fluctuate.

Following the closing of this offering, our board of directors will determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Recently Adopted and Recent Accounting Pronouncements

See Note 2 to our audited consolidated financial statements included elsewhere in this prospectus for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

[Table of Contents](#)

BUSINESS

Overview

Our mission is to create a world without infectious disease.

We are a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are one of the leading causes of death worldwide and cause hundreds of billions of dollars of economic burden each year. We believe that now is the time to apply the recent and remarkable advances in immunology to combat infectious diseases. Our approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. We then bring to bear powerful technologies that we believe, individually or in combination, will lead to effective therapies.

We have assembled four technology platforms, focused on antibodies, T cells, innate immunity and small interfering ribonucleic acid, or siRNA, through internal development, collaborations and acquisitions. Our current development pipeline consists of product candidates targeting hepatitis B virus, or HBV, influenza A, human immunodeficiency virus, or HIV, and tuberculosis, or TB. VIR-2218, an HBV-targeting siRNA, is in an ongoing Phase 1/2 clinical trial and initial data have demonstrated substantial reduction of hepatitis B virus surface antigen, or HBsAg. Based on initial data, VIR-2218 has been generally well-tolerated. Additionally, we have initiated a Phase 1/2 clinical trial for VIR-2482, a monoclonal antibody, or mAb, designed for the prevention of influenza A. We have built an industry-leading team that has deep experience in immunology, infectious diseases and product development. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

Our Technology Platforms

Our four current technology platforms are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. We are using our platforms to advance product candidates for HBV, influenza A, HIV and TB, as well as to generate additional product candidates for viral, bacterial, fungal and parasitic infections.

Antibody Platform: We have established a robust method for capitalizing on unusually successful immune responses naturally occurring in people who are protected from, or have recovered from, infectious diseases. This method uses specialized mAbs which have the potential to treat and prevent rapidly evolving and/or previously untreatable pathogens via direct pathogen neutralization and immune system stimulation. We identify individuals who have recovered from an infection by the target pathogen, and then use a technology we refer to as High Throughput Isolation to screen hundreds of millions of B cells from those individuals for antibodies with specific properties. We engineer these fully-human antibodies that we discover to enhance their therapeutic potential. For example, we have engineered our mAbs to potentially act as T cell vaccines, which may enable continued protection from a pathogen even after the mAb is no longer present.

T Cell Platform: We are exploiting the unique immunology of human cytomegalovirus, or HCMV, a commonly occurring virus in humans, as a vaccine vector to potentially treat and prevent infection by pathogens refractory to current vaccine technologies. This approach is based on fundamental observations made in non-human primates, or NHPs, with rhesus cytomegalovirus, or RhCMV. HCMV is the most potent known inducer of T cell responses of any human virus and may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. In addition, we can make proprietary modifications in the HCMV genome that we expect will elicit different types of pathogen-appropriate T cell responses. We term this approach “immune programming.” We believe that this platform may also have applicability beyond infectious diseases, to areas such as cancer.

Innate Immunity Platform: Moving beyond more traditional approaches that are used to evoke adaptive immunity or that directly target pathogens, where the development of resistance can occur, we plan to target host proteins as

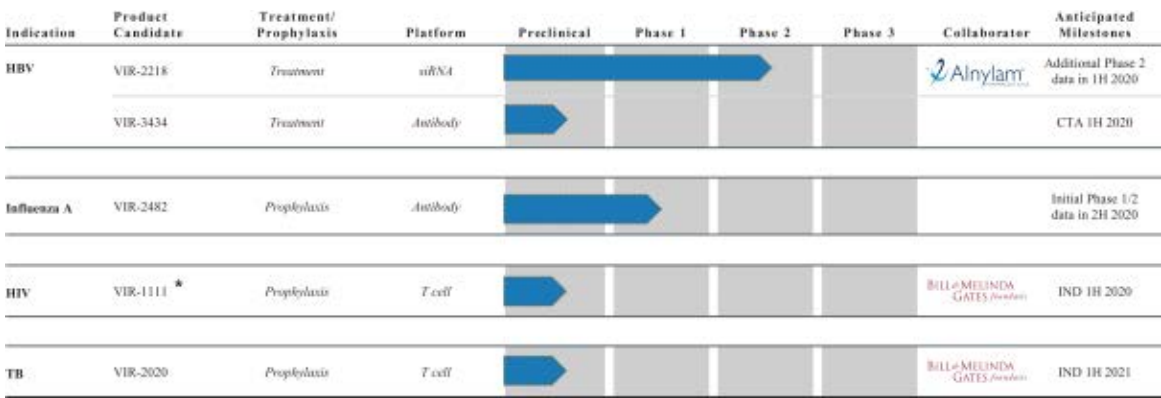
Table of Contents

a means of creating host-directed therapies with high barriers to resistance. We believe that by leveraging the power of innate immunity, we can create medicines that break the “one-drug-for-one-bug” paradigm by producing “one-drug-for-multiple-bugs.” For example, we believe this platform can create a single product for respiratory viruses, such as respiratory syncytial virus, or RSV, and influenza. This is enabled using CRISPR-based genomics, computational biology and machine learning to identify key host factors necessary for each pathogen’s survival and the protective effects of the innate immune system. We then identify product candidates that may be able to safely target host proteins to block pathogen replication or induce innate immunity to control infection.

siRNA Platform: We are harnessing the power of siRNA to inhibit pathogen replication, eliminate key host factors necessary for pathogen survival and remove microbial immune countermeasures. Our collaboration with Alnylam Pharmaceuticals, Inc., or Alnylam, includes VIR-2218 for HBV and up to four additional programs in infectious diseases. This platform can leverage Alnylam’s proprietary N-acetylgalactosamine, or GalNAc, delivery technology, for product candidates targeting the liver, allowing for subcutaneous administration and extended tissue half-life, as well as Enhanced Stabilization Chemistry Plus, or ESC+, technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index.

Our Development Pipeline

Our current product candidates are summarized in the chart below:



IND = Investigational New Drug Application; CTA = Clinical Trial Application.

* VIR-1111 is a vaccine designed to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans. Ultimately any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.

HBV: Approximately 290 million people globally are chronically infected with HBV and approximately 900,000 of them die from HBV-associated complications each year. There is a significant unmet medical need for more effective therapies that lead to life-long control of the virus after a finite duration of therapy, which is the definition of a functional cure. Currently, a year-long course of pegylated interferon-alpha, or PEG-IFN-a, is the best available curative therapy. It has a low functional cure rate of approximately three to seven percent. Alternatively, suppressive therapy with nucleotide/nucleoside reverse transcriptase inhibitors, or NRTIs, is commonly used, but patients often require a lifetime of therapy.

We are developing VIR-2218 and VIR-3434 for the functional cure of HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. While monotherapy with each of these agents may provide a functional cure in some patients, we believe combination therapy will be necessary for many patients. We are planning trials that combine VIR-2218 with VIR-3434, which we believe have the potential to act in concert by removing potentially tolerogenic HBV proteins and

[Table of Contents](#)

stimulating new HBV specific T cells. We are also planning additional trials that combine VIR-2218 with other immunotherapy agents and direct acting antiviral agents. We anticipate that the initial registration population for these product candidates will be patients chronically infected with HBV.

VIR-2218 is an HBV-targeting siRNA that is currently in a Phase 1/2 clinical trial. VIR-2218 is administered subcutaneously. By targeting a conserved region of the HBV genome, it is designed to inhibit the production of all HBV proteins, including HBsAg. Suppression of HBV proteins, particularly HBsAg, is hypothesized to remove the inhibition of T cell activity directed against HBV, allowing VIR-2218 to potentially result in a functional cure. VIR-2218 is the first siRNA in the clinic to include ESC+ technology, which has the potential to enhance the therapeutic index. As of September 18, 2019, 37 healthy volunteers have received VIR-2218 and 12 healthy volunteers have received placebo. 23 patients with chronic HBV have received VIR-2218 and eight patients with chronic HBV have received placebo. Initial data suggest that VIR-2218 is generally well-tolerated in healthy volunteers given as a single dose up to 600 mg and in patients given as two doses of 20 mg, 50 mg, 100 mg or 200 mg each dose. Initial data also demonstrate substantial reductions in HBsAg in patients at doses ranging from 20 mg to 200 mg. VIR-2218 is the first asset in our collaboration with Alnylam to enter clinical trials. We anticipate additional clinical data for this trial to be available in the first half of 2020.

VIR-3434 is an HBV-neutralizing mAb for which we plan to submit a CTA in the first half of 2020 and thereafter commence a Phase 1 clinical trial. VIR-3434 will be administered subcutaneously. By targeting a conserved region of HBsAg, it is designed to block entry of all 10 genotypes of HBV into liver cells called hepatocytes and reduce the level of virions and subviral particles in the blood. We have also engineered VIR-3434 to have an extended half-life and to potentially function as a T cell vaccine against HBV in infected patients. These modifications are intended to enhance its potential to result in an HBV functional cure. We anticipate clinical data from a Phase 1 clinical trial to be available in the first half of 2021.

Influenza: On average, each year the influenza virus infects 5% to 10% of the world's population and results in an estimated 500,000 deaths. In the 2017-2018 flu season, approximately 80,000 people died from influenza in the United States alone. The efficacy of the annual flu vaccine has ranged from 10% to 60% over the past 15 years, with an average of 40%. The limited success of influenza vaccines has been attributed to two primary factors. First, flu vaccines have incomplete strain coverage and therefore often do not provide protection against all strains of influenza that circulate in a given season, despite being updated every year. Second, flu vaccines are active immunizations that rely on a person's own immune system to create protective influenza virus antibodies, and many individuals do not generate an effective immune response. We are developing VIR-2482 as a universal prophylaxis for influenza A. Influenza A has been estimated in the United States to cause 85% of influenza hospitalizations from 2005 to 2013, and has been the source of all known influenza pandemics. VIR-2482 is designed to overcome the limitations of flu vaccines and lead to meaningfully higher levels of protection. We anticipate that the initial registration population for VIR-2482 will be individuals at high risk of influenza A complications, such as the elderly with chronic lung disease.

VIR-2482 is an influenza A-neutralizing mAb. In August 2019, we initiated dosing in a Phase 1/2 clinical trial for VIR-2482. VIR-2482 is administered intramuscularly. VIR-2482 targets a conserved region of the influenza A hemagglutinin protein and consequently has the potential to prevent illness by any strain of influenza A. In vitro, VIR-2482 has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. Since flu vaccines have incomplete strain coverage and limited efficacy, the broad coverage of VIR-2482 may allow it to achieve higher protection levels and for it to be used year after year. In addition, because VIR-2482 is an antibody that can directly confer protection, it does not rely on a person to create his or her own antibodies. Thus, we believe VIR-2482 has the potential to be effective even in a person with a compromised immune system. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long. We anticipate clinical data from the first flu season of a Phase 1/2 clinical trial to be available in the second half of 2020 and from the second flu season of this trial to be available in the first half of 2021.

[Table of Contents](#)

HIV: Each year there are approximately 1.8 million new cases of HIV and approximately 1.0 million HIV-related deaths globally. Current prevention approaches such as behavioral modification and pharmacological intervention have had only a modest effect on HIV transmission globally, leaving a high unmet medical need for a safe and effective vaccine for the billions of individuals who are or may become sexually active. Previous attempts at an HIV vaccine were designed to boost the natural immune response to HIV. We believe a different type of immune response is needed. VIR-1111 is a proof of concept HIV vaccine designed to elicit a type of immune response that is different from other vaccines. We anticipate the initial registration population for our eventual HIV vaccine will be individuals at high risk of contracting HIV.

VIR-1111 is an HIV T cell vaccine based on HCMV for which we plan to submit an IND in the first half of 2020 and thereafter commence a Phase 1 clinical trial. VIR-1111 will be administered by subcutaneous injection. VIR-1111 has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines, and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of NHPs from simian immunodeficiency virus, or SIV, the NHP equivalent of HIV. VIR-1111 is a vaccine designed to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans. Ultimately any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.

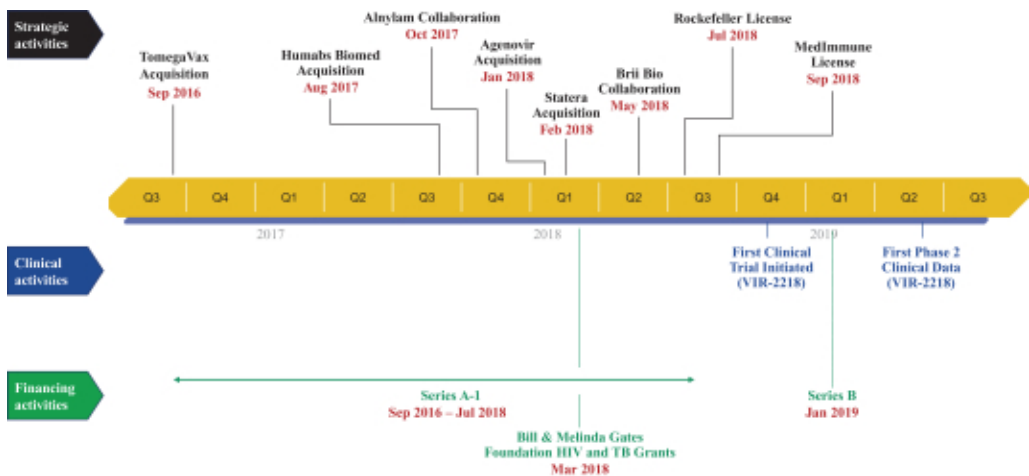
TB: Globally, nearly two billion people are latently infected with TB, and each year there are approximately 10 million new active cases of TB and approximately 1.6 million TB-related deaths. There is a high unmet medical need for a safe and effective vaccine that prevents active pulmonary TB in adolescents and adults, as they represent the key sources of TB transmission and are the primary contributors to overall disease burden. The bacterium that causes TB can evade the immune response, which often leads to persistent infection. We believe that a different type of immune response is needed. VIR-2020 is a vaccine designed to provide a type of immune response that is different from other vaccines and lead to meaningful levels of protection from active TB. We anticipate that the initial registration population for VIR-2020 will be people at high risk of developing active TB, such as those who have latent TB infection.

VIR-2020 is a TB T cell vaccine based on HCMV for which we plan to submit an IND in the first half of 2021 and thereafter commence a Phase 1 clinical trial. VIR-2020 will be administered by subcutaneous injection. VIR-2020 is designed to stimulate T cells that reside in the lung and to recognize TB epitopes that are different from those recognized by prior TB vaccines. In preclinical studies, a T cell vaccine based on rhesus cytomegalovirus, or RhCMV, has been shown to provide protection of NHPs from TB.

[Table of Contents](#)

Our Corporate History

We were founded in 2016 with the mission of creating a world without infectious disease. We are taking a multi-program, multi-technology platform approach, assembled through internal development, collaborations and acquisitions.



Our Team

We have an industry-leading management team, board of directors and scientific advisors with significant experience in immunology and infectious diseases, and progressing product candidates from early stage research to clinical trials, regulatory approval and ultimately commercialization.

Our Chief Executive Officer, George Scangos, Ph.D., has spent over 30 years developing treatments in infectious disease, neuroscience and oncology, among other fields, and was previously the Chief Executive Officer of Biogen Inc., or Biogen, the Chief Executive Officer of Exelixis, Inc. and the President of Bayer Biotechnology. Our Chief Scientific Officer, Herbert (Skip) Virgin, M.D., Ph.D., is a Member of the National Academy of Sciences, and was previously Chair of the Department of Pathology and Immunology at the Washington University School of Medicine, St. Louis, Missouri. Our Senior Vice President and Senior Research Fellow, Antonio Lanzavecchia, M.D., is a Member of the National Academy of Sciences, was a co-founder of Humabs Biomed SA, or Humabs, which we acquired in 2017, and is the Director of the Institute for Research in Biomedicine in Bellinzona, Switzerland. Our Chief Medical Officer, Phil Pang, M.D., Ph.D., was previously Chief Medical Officer of Riboscience LLC, and before that was the Harvoni® project lead at Gilead Sciences, Inc., or Gilead, where he led the team responsible for worldwide regulatory approval. Our Chief Technology Officer, Michael Kamarck, Ph.D., was previously Senior Vice President of Global Vaccines and Biologics Manufacturing at Merck & Co., Inc., President of Merck BioVentures and President of Technical Operations and Product Supply across all of the businesses of Wyeth Pharmaceuticals, Inc. Our Chief Business Officer and a co-founder, Jay Parrish, Ph.D., previously led infectious disease business development and was a medicinal chemist at Gilead. Our Senior Vice President of Regulatory Affairs and Program Leadership & Management, Lynne Krummen, Ph.D., previously served in many roles at Genentech, Inc. and F. Hoffmann-La Roche AG including, Head of U.S. Technical Development, Global Head of Technical Regulatory for Biologics, Head of Process Development and Clinical Development Project Team Lead for Avastin®. Our Chief Financial Officer, Howard Horn, was previously Vice President, Business Planning at Biogen, and before that was a senior consultant at McKinsey & Company and an equity analyst at UBS Group AG.

Our board of directors is composed of leaders from academia, Nobel laureate Phillip Sharp, Ph.D. and Klaus Frueh, Ph.D. (a co-founder); from the biopharmaceutical industry, Robert Perez, Saira Ramasastry and our

[Table of Contents](#)

Chairman Vicki Sato, Ph.D.; and from the life science investment community, Kristina Burow, Robert More, Robert Nelsen (a co-founder) and Dipchand (Deep) Nishar.

Our scientific advisors include members of the National Academies of Sciences, Engineering, and Medicine, Jeffrey Bluestone, Ph.D., Francis Chisari, Ph.D., Lawrence Corey, M.D. (a co-founder), Mark Davis, Ph.D., Jeffrey Ravetch, M.D., Ph.D. and Charles Rice, Ph.D., the director of the HIV program at the Bill & Melinda Gates Foundation, Emilio Emini, Ph.D., and professors of immunology, virology, infectious disease, oncology, and other fields, Suzanna Naggie, M.D., Louis Picker, M.D. (a co-founder) and George Poste, D.V.M., Ph.D.

Our team is further supported by a group of investors that share our commitment to the goal of creating a world without infectious disease, including a subsidiary of the Abu Dhabi Investment Authority, ARCH Venture Partners, the Alaska Permanent Fund, Baillie Gifford, the Bill & Melinda Gates Foundation, the SoftBank Vision Fund, Temasek and others.

Our Strategy

We are a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. The core elements of our business strategy include:

- **Rapidly advancing our pipeline.** We have commenced a Phase 1/2 clinical trial for each of VIR-2218 and VIR-2482. We anticipate moving multiple preclinical candidates into the clinic in the next 12-18 months and initiating combination trials where applicable.
- **Expanding our pipeline using our current technology platforms.** We are leveraging our four current technology platforms to discover and develop novel product candidates for HBV, influenza A, HIV and TB, as well as additional viral, bacterial, fungal and parasitic infections, and potentially cancers.
- **Acquiring new technology platforms and assets.** We continually evaluate external technology platforms and assets that may help us develop therapies to treat and prevent serious infectious diseases.
- **Scaling our capabilities.** We are investing in our people, processes and systems across all functions of our company to ensure that we are able to take full advantage of our multiple technology platforms and multiple product candidates.
- **Enabling global access to our future medicines.** We have established relationships with organizations seeking to make a global impact like the Bill & Melinda Gates Foundation and the NIH to further enable and facilitate access to our future medicines and to support our clinical development efforts. We will continue to pursue additional relationships like these moving forward.

Technology Platforms

Platforms for the Creation of Transformative Medicines for Infectious Diseases

We have purposefully assembled a portfolio of technology platforms that we believe will, individually or in combination, allow us to enhance immunity in innovative ways and to exploit the vulnerabilities of pathogens. Our current platforms are focused on antibodies, T cells, the innate immune response and siRNAs targeting pathogen and host gene expression. We have assembled these platforms through internal development, collaborations and acquisitions. We are using these platforms, and continue to evaluate others, to advance multiple new product candidates for HBV, influenza A, HIV and TB, as well as additional viral, bacterial, fungal and parasitic infections. Our platforms have generated five product candidates to date, one of which, an HBV-targeting siRNA, is currently in a Phase 1/2 clinical trial.

We follow the science to select the modality, or combination of modalities, that gives us the highest chance of success for a specific infection in a given patient population. The diversity of our different platforms allows us to select the best modality or modalities for a given clinical need.

[Table of Contents](#)

Antibody Platform

Overview

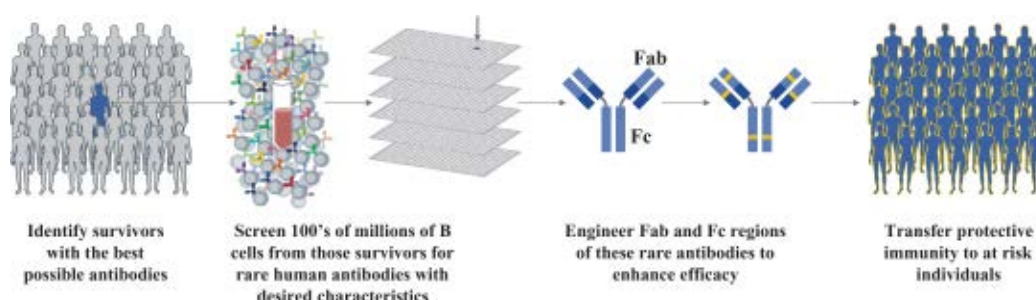
We are using specialized mAbs to treat or prevent rapidly evolving and/or previously untreatable pathogens. These mAbs act in a variety of ways, including direct pathogen neutralization and immune system stimulation. We combine high-throughput, rapid isolation of rare, highly potent, broad-spectrum and fully human antibodies with targeted engineering to enhance their therapeutic potential. We expect that these specialized mAbs can be administered to transfer protective immunity to all at-risk individuals.

We expect the following benefits from our antibody platform:

- Effective regardless of an individual's ability to generate his or her own immune response
- Diminished likelihood of self-reactivity because they are selected in humans
- Broad coverage of most or all strains of a pathogen, or even multiple pathogens
- High affinity binding to conserved pathogen antigens, resulting in a high barrier to resistance
- Longer half-life than naturally occurring antibodies
- Potential to induce a vaccinal effect, i.e., to elicit continued protection even after the mAb is no longer present

Two of our product candidates, VIR-3434 and VIR-2482, were identified and are being developed using our antibody platform.

Our Approach



We use a proprietary antibody screening technology that allows us to characterize the antibodies produced from hundreds of millions of B cells derived from survivors of an infection to identify those rare antibodies that have the rare characteristics needed to create an effective medicine. Rare characteristics include, for example, the ability to bind to a highly conserved antigen within a pathogen and the ability to neutralize multiple different pathogens. We refer to this technology as High Throughput Isolation since we are able to screen hundreds of millions of B cells to find rare antibodies in just weeks.

Following isolation, we clone the antibody genes and express the resulting fully human antibody for further studies, engineering and development. We have applied these methods to identify mAbs for a range of pathogens including Ebola, HBV, influenza A and influenza B virus, malaria and a range of bacterial pathogens, including *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Acinetobacter spp.* An example of the power of this platform is the anti-Ebola virus mAb114, which is now in a Phase 2/3 clinical trial in Africa as part of the efforts to quell the current virulent Ebola outbreak. This mAb was identified by our scientists using the technologies described above in collaboration with the NIH and others. mAb114 has been shown to cure severe Ebola virus-induced illness in infected NHPs and has successfully completed Phase 1 clinical trials in healthy volunteers. It is being developed by Ridgeback Biotherapeutics LP and the NIH.

[Table of Contents](#)

Precision Antibody Engineering to Create the Best Medicines

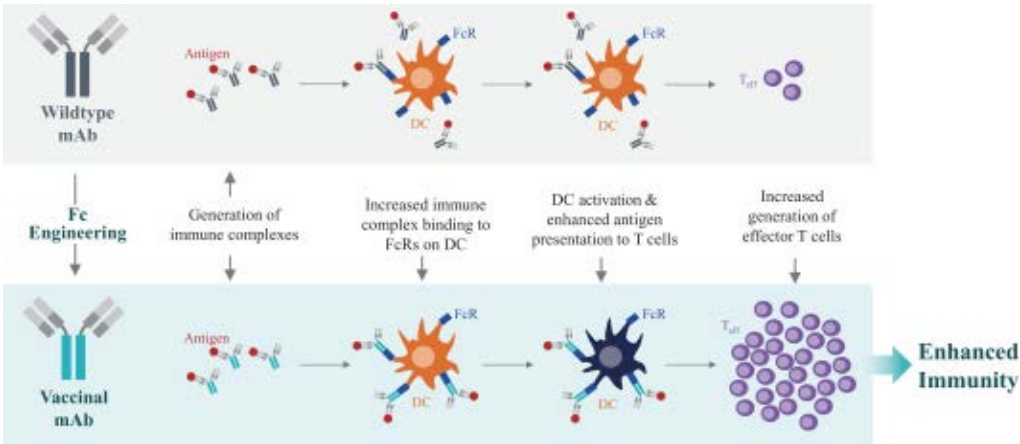
Our strategy is to optimize both the Fab and Fc domains of a mAb to generate the best medicine to treat or prevent infection. Having isolated a rare, fully human antibody via High Throughput Isolation, we then engineer as desired both parts of the mAb, the Fab and Fc domains, to enhance efficacy, potency and manufacturability. The Fab portion binds to the protective antigen on the pathogen. The Fc portion binds to effector proteins and cells in the body to engage the immune system in killing and clearing the infection.

Fab engineering is performed to further increase mAb potency and breadth of coverage. mAb potency and breadth are based on the epitope bound, affinity of binding and valency. In some cases, it may be valuable to create mAbs that bind to more than one epitope, so-called “multi-specific” mAbs, by engineering the Fab region. There are many approaches to creating multi-specific antibodies, and we are exploring a number of them, including some that naturally occur in people. We believe that naturally occurring multi-specific antibodies can be leveraged to create new and potent therapeutics and to enhance antibody prophylaxis of disease, and have the potential for higher manufacturing yields and better pharmacokinetics in patients, as compared to artificial multi-specific formats currently being developed.

Fc engineering selects and optimizes the specific ways in which mAbs engage Fc receptors, or FcRs, which in turn govern “effector functions” such as the half-life of the antibody and the way that the immune system is recruited by the mAb to fight infection. Effector functions can be enhanced or reduced via Fc mutations that alter the binding affinity of the Fc domain of an mAb to the various FcRs, based on a detailed understanding of the role of individual FcRs in half-life and immunity. Examples of immunity that can be altered in this way include the recruitment of serum proteins to infected areas, phagocytosis and destruction of viruses and viral particles, the killing of virus infected cells through a process known as antibody-dependent cell cytotoxicity, or ADCC, and the presentation of antigens to elicit B and T cell immunity.

Antibodies as T Cell Vaccines

We are using Fc engineering to create antibodies that are designed to not only directly treat infection but also to immunize an infected individual against future infections. We refer to this property as a vaccinal effect, i.e., eliciting continued protection even after the mAb is no longer present. This technology benefits from the fact that FcRs on specialized antigen-presenting cells, which are called dendritic cells, or DCs, internalize complexes of antibody and antigen. Our strategy leverages the observation that different FcRs on antigen presenting cells can bind different parts of the Fc portion of the mAb. By engineering the Fc region, we can select which FcRs interact with the antibody-antigen complex to generate activated DCs that we believe can effectively induce T cell immunity.



[Table of Contents](#)

Design and mechanism of vaccinal antibodies intended to induce enhanced immunity through induction of T cells. The Fc portion of mAbs interacts with FcRs on DCs to trigger uptake of antigen and induction of T cells. Engineering of the Fc portion of the mAb is predicted to increase the induction of T cells by these DCs.

Specific vaccinal mutations in the Fc domain can enhance immune responses to a pathogen in two ways. First, the mAb can deliver increased amounts of antigen to DCs. Second, FcRs deliver signals that activate DCs. In turn, activated DCs can stimulate T cells specific to the delivered antigen, resulting in T cell immunity. In this way, an antibody with vaccinal mutations can potentially actively immunize infected patients. The in vivo data supporting enhancement of the vaccinal effect through Fc mutants has been demonstrated by others in a CD20 positive tumor model, using mice with humanized Fc receptors. In this experiment, anti-CD20 mAbs and CD20 tumor cells were administered to mice months before being later rechallenged with a lethal dose of CD20 tumor cells. 80% of the mice who received a mAb with Fc mutants that enhanced binding to activating FcRs IIa and IIIa survived. Conversely, 70% or more mice who received a mAb without the enhancing Fc mutations died. This durable protection is believed to be the result of the induction of a T-cell response. We plan to do first-in-human testing of this concept in chronic HBV infection using VIR-3434. If this technology performs as expected, we believe that this platform may have applicability to multiple infections.

T Cell Platform

Overview

T cells can prevent or control infection and cancer. T cells are diverse in how they sense pathogens and cancer cells, the tissues that they protect and the effector functions that they use to control infection or cancer. Our approach is to use HCMV as a vaccine vector to potentially treat and prevent infection by pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. In addition, we can make proprietary modifications in the HCMV genome that we expect will elicit different types of pathogen-appropriate T cell responses. Experiments in NHPs demonstrate the ability of vaccine vectors based on the closely-related RhCMV to protect against SIV, a close relative of HIV, and TB, two of the most challenging infections for which to create effective vaccines.

HCMV infects a large proportion of the human population and causes a life-long asymptomatic infection that typically causes no harm. This is due to millions of years of co-evolution between the virus and host in which the virus evades sterilizing immunity using specialized viral genes, while at the same time allowing the generation of certain T cell responses that prevent HCMV infection from becoming lethal.

We expect the following benefits from our T cell platform:

- Highly-potent and long-lived T cell responses throughout the body
- Induction of high numbers of specialized T cells, known as effector memory cells, that allow control of disease in the first few days after infection
- Immune responses to three- to four-fold more antigenic epitopes in a target protein than other viral vectors
- Programmable T cell responses allowing selection of the type of T cells elicited
- Generation of universal T cells that may be active in most or all people despite high genetic variability between people in immune response genes
- Opportunity for repeated vaccination using the same backbone HCMV vector against different infections
- Opportunity to use the same vaccine to protect against multiple pathogens

[Table of Contents](#)

- Potential to induce responses even to proteins that the host is tolerant of, such as self-proteins expressed in a tumor

VIR-1111 and VIR-2020, were generated using our T cell platform.

Our Approach

We believe that the type of T cell response elicited by an HCMV-based vaccine vector can be selected by mutating certain genes in HCMV. We term this approach “immune programming.” We believe that immune programming is critical to combatting infections such as HIV and TB that have proven intractable, to date, for other vaccine technologies.

Immune programming is best understood in the context of the normal processes that elicit T cell immunity. T cells that fight infection and cancer are elicited by DCs, as well as other types of cells. The elicited T cells detect small peptide fragments from antigens on the surface of DCs and other antigen presenting cells, which have been captured in grooves found within specialized proteins encoded by major histocompatibility complex, or MHC, genes.

The unique immunology of HCMV depends on the virus’s ability to regulate the normal immune processes of antigen presentation by MHC genes. HCMV contains multiple genes that regulate many of the steps in antigen presenting cells that elicit T cell immunity by altering antigen presenting cell biology, the types of antigen presenting cells infected by the viral vaccine and the mechanisms responsible for the ability of a T cell to recognize antigens together with MHC molecules. Through manipulation of the HCMV genome, we believe we can program different types of pathogen-appropriate T cell responses.

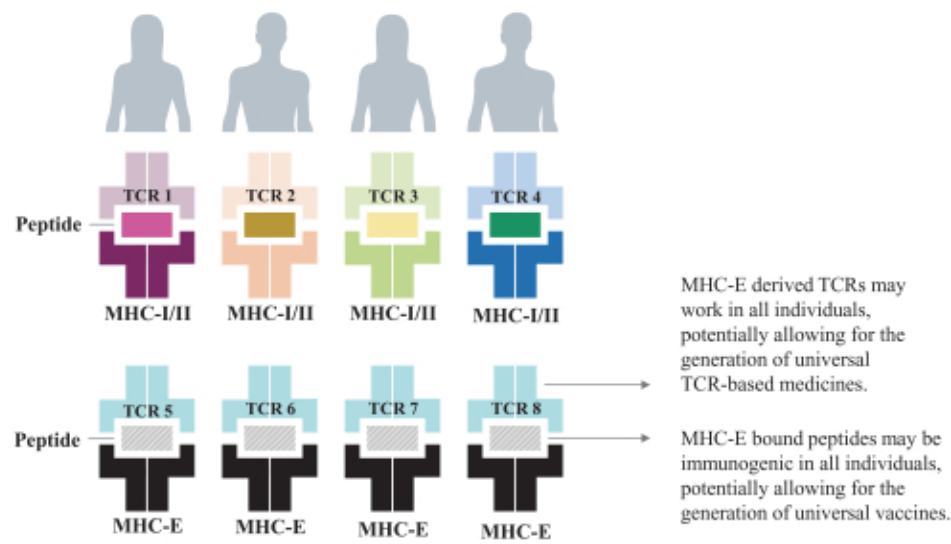
MHC-E as a Near-Universal Target for Medicines that Leverage T Cell Receptors

T cells need to be able to recognize a highly diverse set of pathogen proteins to be effective. This diversity comes from the use of multiple different host immune response MHC genes to present foreign antigens to T cells. Some immune response MHC genes are highly variable between individuals, while others are less variable between individuals as illustrated below. The immune response MHC genes that are highly variable between individuals are responsible for most T cell responses. These MHC molecules enable T cells to recognize foreign proteins through the use of a highly specialized T cell receptor, or TCR, on the T cell surface.

An important consequence of the inter-individual variation in some immune response MHC genes is that a TCR that recognizes an antigenic peptide associated with one person’s MHC molecules could attack even normal tissues of a person with different MHC genes. As a result, identifying universal TCRs and universal T cell antigens that work in all people has been very challenging.

Our T cell platform may enable us to create vaccines or other types of medicines that are near universal in their effects on human immunity. The programmed T cell responses elicited by engineered HCMV vectors are predicted to use immune response MHC genes that vary minimally between people, instead of the highly variable immune response MHC genes targeted by other types of vaccines. As demonstrated by the graphic below, TCRs recognizing antigenic peptides together with MHC-E may be functional in all individuals, potentially allowing for the generation of universal TCR-based medicines, such as off-the-shelf cancer cell therapy. The peptides presented by MHC-E may be immunogenic in all individuals, potentially allowing for the generation of universal infectious disease and cancer vaccines.

[Table of Contents](#)



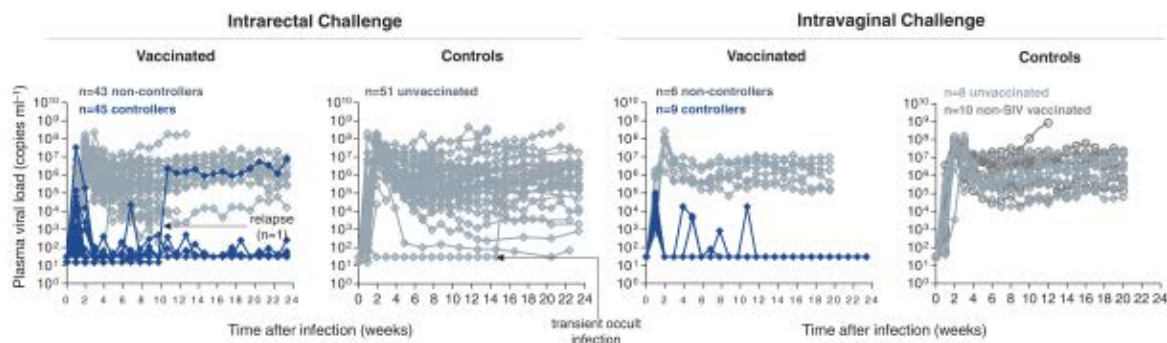
Comparison of standard T cell responses to MHC-E responses. Peptides that are bound to MHC-I, -II or -E proteins are expressed on cell surfaces where they are recognized by T cell receptors on T cells (TCRs). This interaction results in the expansion of T cells that can recognize diverse antigen peptides (top row) and that carry out functions that protect the host. Since MHC-I and MHC-II molecules are highly variable between people, peptide presentation to TCRs has a high degree of individual specificity, as illustrated by the different colors of each peptide in the top row. In contrast to MHC-I and MHC-II, MHC-E proteins (bottom row) are conserved in the human population.

Specifically programmed RhCMV vectors can elicit strong T cell responses that target MHC molecules which vary minimally between NHPs. One such protein is MHC-E. The fundamental discovery, by some of our founders, that enables this part of our T cell platform is that RhCMV responses can be programmed to generate abundant MHC-E-restricted T cells.

We believe that using our T cell programming approach will allow us to select vaccine antigens and to identify TCRs that work across the human population. An example of a use of such a TCR would be creating a biological product that specifically recognizes infected cells in all individuals.

Programming T Cell Responses to Create HIV and TB Vaccines

Two of the most challenging infections for vaccine development are HIV and TB. Preclinical studies have demonstrated that programmed RhCMV vectors can be used to vaccinate against either SIV or TB in NHPs. For example, as shown in the figure below, in an NHP study, an MHC-E programmed RhCMV vaccine effectively protected more than half of NHPs from infection when challenged with a highly virulent form of SIV, under conditions in which all animals in the control group became infected. SIV vaccines programmed in other ways were not protective, demonstrating the potential value of having a programmable T cell vaccine platform.



[Table of Contents](#)

Primary data for the protective effects of RhCMV-derived T cell vaccines on SIV infection. Rhesus monkeys were vaccinated with an RhCMV vaccine that elicits CD8 T cells recognizing SIV peptides presented by MHC-E and MHC-II or a control before challenge with SIV by rectal or vaginal routes. SIV genome copies were measured in peripheral blood (vertical axis) at intervals after challenge (horizontal axis). SIV infection was cleared in approximately 51% of intrarectal challenged animals and approximately 60% of intravaginal challenged animals while infection was progressive in all unvaccinated controls.

Protection has also been observed against TB in preclinical studies of NHPs after immunization with either of two different RhCMV vaccines. One of the protective vaccines was programmed to elicit MHC-II and MHC-E responses, while the other was programmed to elicit a response depending on MHC-I genes. This shows the potential significance of being able to specifically program a T cell vaccine to target a given infection, as the programming of a vaccine to protect against SIV can be different from the programming of a vaccine to protect against TB. These preclinical data support our plans to use our T cell platform to vaccinate against HIV and TB.

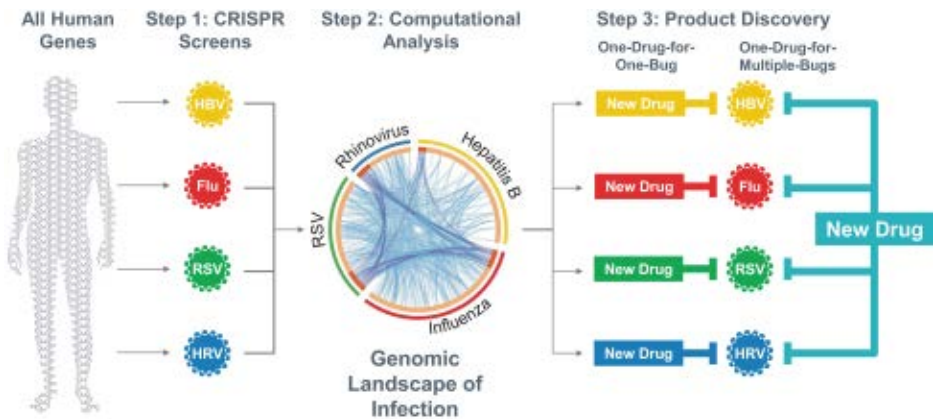
The Bill & Melinda Gates Foundation is providing funds for the manufacturing and early clinical development of our HIV and TB vaccine programs. If proof of concept for the potential efficacy of our T cell vaccine platform is obtained in currently planned clinical trials, we plan to apply this T cell platform for treating additional types of infections, as well as potentially even cancers.

Innate Immunity Platform

Overview

Innate immunity protects us during the early stages of infection until antibodies and T cells can be generated by the immune system. Importantly, innate immunity is not pathogen-specific. We believe that we can target innate immunity to create medicines that break the “one-drug-for-one-bug” paradigm by producing “one-drug-for-multiple-bugs.” We term this concept “host-directed therapy” because the medicine would target a host protein instead of pathogen proteins, which are the target of standard antibiotics and antivirals. We can also identify proteins that are critical for a high priority infection, such as HBV, for which host-directed therapy might be part of a functional cure or complete cure. This platform may also identify targets relevant to diseases outside of infection.

Our scientists have developed and applied cutting-edge CRISPR-based genetic technologies to identify host genes that regulate innate immunity and/or pathogen replication. We have built internal capacity to systematically extend such studies to multiple pathogens and multiple aspects of innate immunity. We have joined the Broad Institute’s Functional Genomics Consortium, which provides us access to cutting-edge CRISPR reagents and computational services for whole-genome and custom-designed genetic screens.



Design of steps in our innate immunity platform. We are systematically mapping the genes that regulate pathogen control across a diverse set of pathogens. To accomplish this, advanced gene editing technology (CRISPR) is used to create cell libraries in which

[Table of Contents](#)

individual genes are either knocked out or activated. By exposing these cell libraries to pathogens of interest, under different screening conditions, we can systematically create genomic maps that identify genes that could lead to pathogen control. By computationally comparing these genomic maps, genes or pathways that are common to multiple pathogens can be identified and could lead to the development of products that could treat more than a single pathogen. Human rhinovirus = HRV.

We expect the following benefits from our innate immunity platform:

- Enhancement of the potency of innate immunity, allowing for control of multiple unrelated pathogens
- High barrier to resistance since the targeted host protein is not likely to mutate
- Identification of key host targets in areas outside of infectious disease

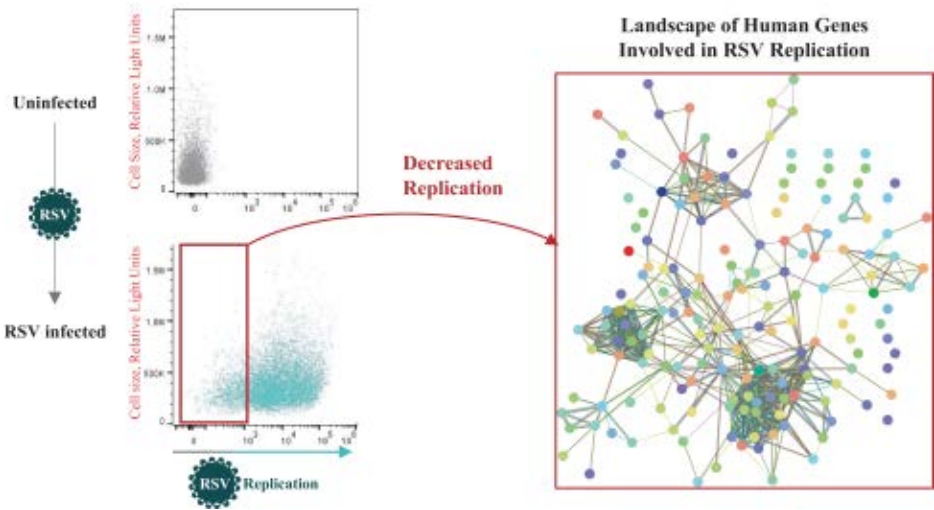
Our Approach

Our innate immunity platform envisions three steps leading to new medicines, as illustrated in the figure above.

Step 1: CRISPR Screens to Map the Genomic Landscape of Infection and Innate Immunity

Multiple types of proteins participate in innate immunity and infection, as they may be required for entry, replication, gene expression, pathogenicity and/or innate immune control of an infectious agent.

To identify such proteins, we screen CRISPR-derived cell libraries after infection, treatment with cytokines that trigger innate immunity, or both, and then select cells with desired properties. Using next-generation sequencing, we identify genes responsible for the desired property. By combining these data across screens and across pathogens, our team has created, and is continuously expanding, a proprietary database of the genomic landscape of infection and innate immunity.



CRISPR screen for genes involved in RSV replication. A CRISPR cell library was prepared in cells in which RSV can replicate. After a period of infection with an RSV strain expressing a fluorescent protein which serves as a surrogate for viral replication, cells were separated using flow cytometry into populations in which RSV replication was decreased or increased. Deep sequencing of the population exhibiting decreased replication compared to control revealed candidate genes required for efficient replication. Computational analysis represented on the right panel revealed that some of these genes fall into nodes that function in specific cellular processes. These nodes are represented as dots interconnected with a dense network of lines.

As an example, to identify genes required for RSV growth, we performed a screen in which a CRISPR-generated cell library was infected with RSV, as shown in the figure above. We then purified and sequenced

[Table of Contents](#)

populations exhibiting low or high RSV growth. Sequencing of the RSV low population revealed genes potentially required for RSV infection. When analyzed computationally, these genes fell into sets involved in specific cellular processes. These genes are potential targets for product candidates. We performed a similar screen with the influenza A virus and HRV and found that certain genes are shared between RSV, influenza A and HRV. Targeting such proteins might result in a pan-respiratory virus product candidate capable of treating RSV, influenza A and HRV.

The result from this step of the innate immune platform is a continuously updated database of the genomic landscape of pathogen replication and innate immunity. We have already performed multiple screens, and additional screens and target validation studies are in progress.

Step 2: Computational Analysis for Identification of Product Targets

Results from CRISPR screens provide the critical data that helps identify host targets necessary for a given pathogen. When creating a single drug for multiple pathogens, host targets in common among multiple pathogens are identified. After having identified the critical set of host targets necessary for a pathogen or pathogens, the specific target for a new medicine is selected by computationally integrating diverse data sets that account for tissue gene expression, human genetic variation, redundancies in cellular pathways and protein-protein interaction networks, among other factors.

Step 3: Product Discovery

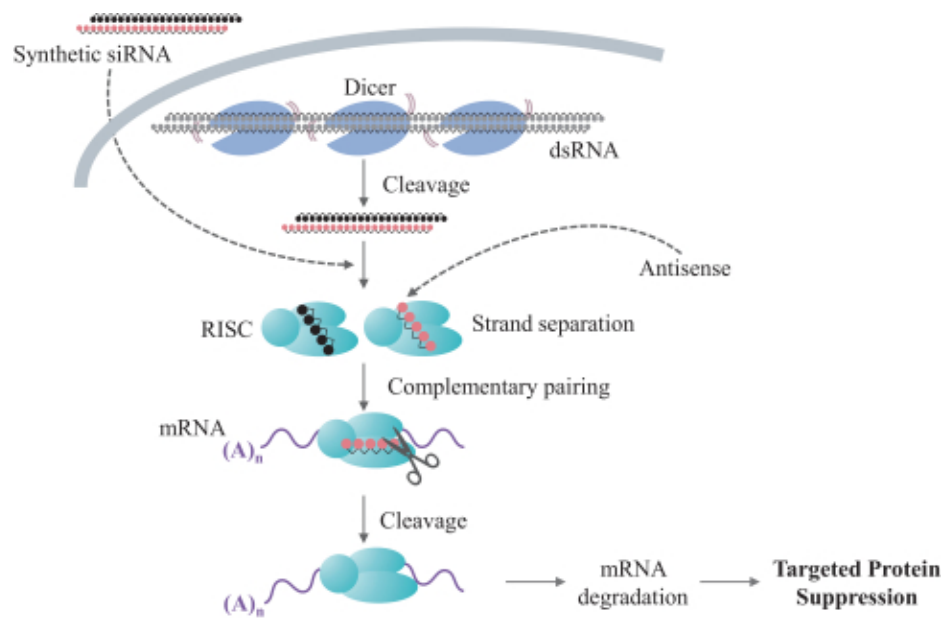
Once a specific target has been chosen, the modality used to disrupt the function of the target is then selected. Potential modalities may include small molecules, antibodies or siRNAs. Standard drug discovery efforts are then applied to identify a lead product candidate. Alternatively, machine learning and database mining can be used to identify pre-existing chemical matter that is already known to inhibit an identified host target. This chemical matter can then be verified as having anti-pathogen activity, and serve as a lead compound. There are two potential outcomes from Step 3: one-drug-for-one-bug and one-drug-for-multiple-bugs.

[Table of Contents](#)

siRNA Platform

Overview

Gene expression can be altered by two main types of ribonucleic acid, or RNA: (i) antisense oligonucleotides; and (ii) siRNAs. We believe that our current approach leveraging siRNAs may have safety and potency advantages over antisense oligonucleotides. The first FDA-approved siRNA in the United States was ONPATRO (patisiran), which was developed by our collaborator, Alnylam.



Mechanism of siRNA action to regulate gene expression. Intracellular double stranded RNA, or dsRNA, is processed by the “dicer” complex to produce siRNAs that become integrated into a multi-subunit protein complex, the RNA-induced silencing complex, or RISC, which guides the siRNAs to the target messenger RNA, or mRNA, sequence. The siRNA duplex unwinds, and the antisense strand remains bound to RISC and directs site-specific cleavage of the target complementary mRNA sequence, resulting in mRNA degradation and reduced expression of the target protein. (A)_n = polyadenylation.

siRNAs act via an RNA interference, or RNAi, mechanism involving cleaving of targeted RNAs. Our bodies create their own so-called endogenous siRNAs, which act via the RNAi mechanism. This RNAi mechanism can be exploited by chemically synthesizing synthetic siRNAs that are introduced as medicines to knock down target RNAs that express pathogen or host proteins of interest. Pursuant to our collaboration and license agreement with Alnylam, we have an option to license Alnylam’s siRNA technology for use in up to four other infectious disease targets in addition to the HBV target now in the clinic. See the section titled “Business—Our Collaboration, License and Grant Agreements” for a description of the collaboration and license agreement.

We expect the following benefits from our siRNA platform and siRNAs generally:

- Cutting-edge siRNA design, through collaboration with Alnylam
- Direct anti-pathogen activity and potential for immunomodulation
- Diminished off-target siRNA effects via use of next generation siRNA technology as a differentiator compared to other siRNA approaches, which has the potential to increase the therapeutic index
- Efficient targeting of siRNAs to the liver using GalNAc technology
- Extended effects of siRNA may last for weeks to months in humans

One of our product candidates, VIR-2218, was generated using our siRNA platform.

[Table of Contents](#)

Our Approach

We have elected to develop modified siRNAs initially for infectious diseases of the liver because these product candidates can be administered subcutaneously, are highly stable in the blood stream and are efficiently delivered into hepatocytes via GalNAc sugar modification. Once in a liver cell, the siRNA can act to reduce pathogen or host gene expression. Such siRNAs can be further modified to reduce off-target activity, and potentially increase the therapeutic index. Since October 2017, we have collaborated with Alnylam to leverage this validated technology, with the goal of eliminating key host factors necessary for pathogen survival and removing microbial immune countermeasures.

We believe that HBV persists in part due to the expression of viral proteins such as HBsAg, which potentially inhibit antibody, T cell and innate immune responses. This prevents the immune response from clearing HBV. By inhibiting the expression of these viral proteins, we envision enhancing immune function in persistently infected individuals. Furthermore, we believe that combining siRNA therapy with products derived from our other platforms, including antibodies, T cells and innate immune modulators, may allow us to rapidly advance a functional cure for HBV.

siRNA Delivery Mechanism

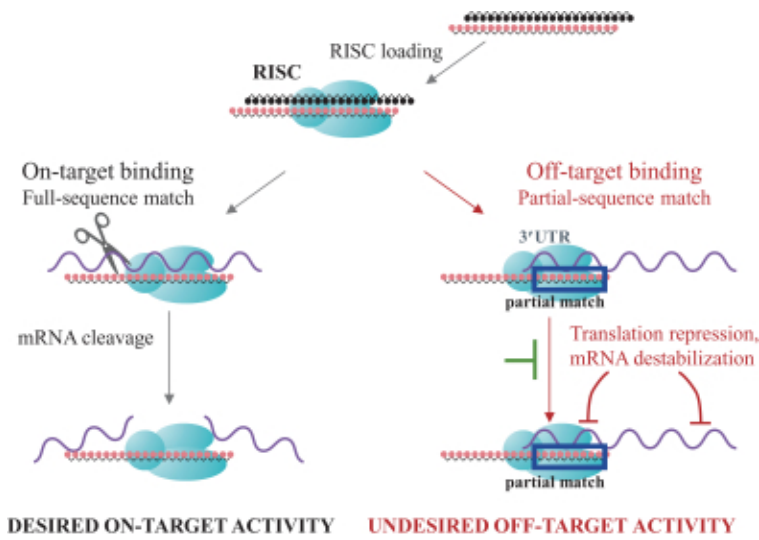
Since unmodified synthetic siRNAs can be unstable in the blood stream, methods to stabilize synthetic siRNAs have been pioneered by Alnylam using their ESC technology.

An approach that has been used successfully to deliver siRNA to liver cells is to conjugate siRNAs to a specific sugar known as a GalNAc, whose receptor is exclusively expressed at high levels on hepatocytes, allowing for uptake of large quantities of siRNA into hepatocytes. Importantly, a GalNAc-conjugated siRNA can be delivered to the liver by subcutaneous injection, making administration relatively simple.

Potentially Enhancing the Therapeutic Index by Diminishing Off-Target Activity of siRNAs

A distinguishing characteristic of VIR-2218 siRNA, and of future siRNAs that we may develop with Alnylam, is the application of a new approach to diminish off target effects of RNAi. siRNAs may cause unwanted alterations to non-target host RNAs, a process known as off-target activity, which can result in short- or long-term toxicity. To reduce off-target activity, which is thought to be due in part to microRNA, or miRNA, activity, it is necessary to preserve the RNAi activity of an siRNA while simultaneously decreasing its miRNA activity, as shown in the figure below. Alnylam scientists have pioneered placement of a modified nucleotide called a glycol nucleic acid, or GNA, into the part of the siRNA that generates miRNA-like activity. GNA modification has been shown to reduce miRNA activity, while preserving the RNAi activity of siRNA. The combination of GNA modification and other chemical modifications that enhance siRNA stability is called ESC+ technology. In animal models, reducing off-target miRNA activity can result in an increased therapeutic index of approximately five-fold. A higher therapeutic index has the potential to allow for higher siRNA doses and/or a longer duration of therapy, while maintaining a favorable safety profile. VIR-2218 is the first siRNA to enter the clinic with ESC+ technology.

[Table of Contents](#)



On-Target and Off-Target Activity of siRNA. siRNAs can have off-target activity when siRNA binds to mRNA with a partial sequence match, leading to translation repression or mRNA destabilization of unrelated messages (right side). This contrasts with the intended on-target activity of an siRNA, which binds to an mRNA through a match to the entire sequence, leading to mRNA cleavage (left side). mRNA = messenger ribonucleic acid; RISC = ribonucleic acid-induced silencing complex.

Development Programs

Our current development pipeline consists of product candidates that address unmet needs caused by HBV, influenza A, HIV and TB.

Indication	Product Candidate	Treatment/ Prophylaxis	Platform	Preclinical	Phase 1	Phase 2	Phase 3	Collaborator	Anticipated Milestones
HBV	VIR-2218	Treatment	siRNA					Alnylam	Additional Phase 2 data in 1H 2020
	VIR-3434	Treatment	Antibody						CTA 1H 2020
Influenza A	VIR-2482	Prophylaxis	Antibody						Initial Phase 1/2 data in 2H 2020
HIV	VIR-1111 *	Prophylaxis	T cell					BILL & MELINDA GATES Foundation	IND 1H 2020
TB	VIR-2020	Prophylaxis	T cell					BILL & MELINDA GATES Foundation	IND 1H 2021

* VIR-1111 is a vaccine designed to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans. Ultimately any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.

Functional Cure for HBV

Summary

We are developing VIR-2218 and VIR-3434 for the functional cure of HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. While monotherapy with each of these agents may provide a functional cure in some patients, we believe combination

[Table of Contents](#)

therapy will be necessary for many patients. We are therefore also planning trials that combine VIR-2218 with VIR-3434, which we believe have the potential to act in concert by removing potentially tolerogenic HBV proteins and stimulating new HBV specific T cells. We are also planning other trials that combine VIR-2218 with other immunotherapy agents and direct acting antiviral agents. VIR-2218, an HBV-targeting siRNA, is currently in a Phase 1/2 clinical trial. In this ongoing trial, which may enroll up to 104 subjects, initial data demonstrate substantial reductions in HBsAg in patients at doses ranging from 20 mg to 200 mg. Based on initial data, VIR-2218 has been generally well tolerated in healthy volunteers given as a single dose up to 600 mg and in patients given as two doses of 20 mg, 50 mg, 100 mg or 200 mg each dose. As of September 18, 2019, 37 healthy volunteers have received VIR-2218 and 12 healthy volunteers have received placebo. 23 patients with chronic HBV have received VIR-2218 and eight patients with chronic HBV have received placebo. We expect additional clinical data from our Phase 1/2 clinical trial of VIR-2218 in the first half of 2020. We plan to submit a CTA for VIR-3434, an HBV-neutralizing mAb, in the first half of 2020, and we anticipate clinical data from a Phase 1 clinical trial to be available in the first half of 2021.

Disease Overview and Limitations of Current Standard of Care

Approximately 290 million people globally are chronically infected with HBV. In the United States, up to two million people are chronically infected with HBV. Chronic HBV can lead to many serious complications, including liver scarring, liver failure and liver cancer. Globally, approximately 900,000 people die each year from HBV-associated complications.

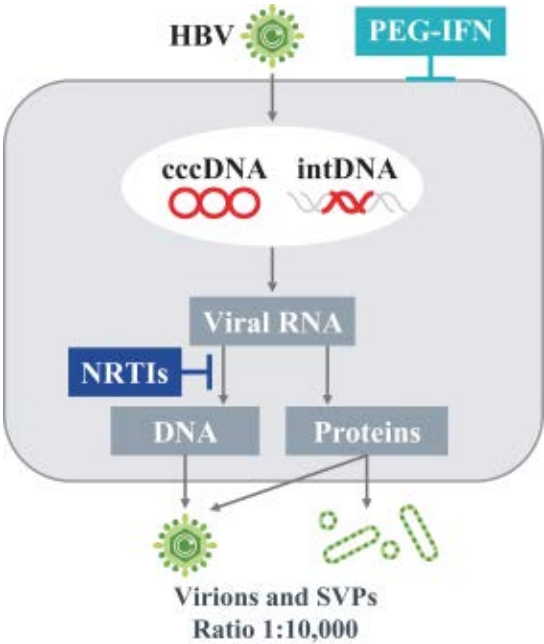
The most commonly used therapy for chronic HBV is life-long suppressive therapy with NRTIs, like tenofovir or entecavir. Of the hundreds of millions of people with chronic HBV worldwide, only an estimated two percent of patients are currently taking this suppressive therapy. NRTIs prevent HBV RNA from being transcribed into HBV deoxyribonucleic acid, or DNA, which is a process known as reverse transcription. NRTIs therefore have little to no direct impact on covalently closed circular DNA, or cccDNA, the reservoir for HBV. It has been reported that after a year of therapy with NRTIs, zero to three percent of patients experience a functional cure. Additionally, NRTIs reduce, but do not eliminate, the risk of HBV associated liver failure and liver cancer. Despite its low utilization rate, suppressive therapy with NRTIs for HBV represented a multi-billion dollar market in 2017.

An alternative treatment option for chronic HBV is a year-long course of PEG-IFN-a therapy, which results in a functional cure approximately three to seven percent of the time. The mechanisms by which PEG-IFN-a, an immune cytokine, achieves a functional cure are not known, but there is additional evidence supporting the need for immune stimulation to achieve a functional cure.

[Table of Contents](#)

HBV Life Cycle and Undetectable HBsAg as a Clinical Endpoint

The viral life cycle of HBV is shown in the figure below. After infecting a cell, the virus forms cccDNA. This form of HBV DNA is located in the nucleus of hepatocytes and acts like a mini-chromosome. HBV DNA can also integrate into the patient’s DNA. This form of HBV DNA is known as integrated DNA, or intDNA.



HBV lifecycle with inhibition of processes by currently available therapies. Arrows indicate viral life cycle process. Perpendicularly-ended lines indicate inhibition of viral process.

HBV releases infectious virions and subviral particles, or SVPs, from infected cells. Both virions and SVPs include forms of an HBV protein called HBsAg, a blood biomarker that indicates that the HBV cccDNA and/or intDNA in that patient’s hepatocytes are actively making HBV RNA and HBV proteins. For a registrational trial to demonstrate a functional cure, the formal endpoint accepted by the U.S. Food and Drug Administration, or the FDA, is undetectable HBsAg, defined as less than 0.05 international units per milliliter, or IU/ml, in the blood six months after the end of therapy. Achievement of this endpoint has been shown to predict improved clinical outcomes and the lack of need for further therapy.

VIR-2218 for HBV

Molecular Characteristics. VIR-2218 is a single siRNA targeting a conserved sequence of HBV that allows for predicted activity against 99.7% of the strains of HBV, including all 10 HBV genotypes. Because this conserved sequence falls within a specific region of the X gene of HBV that exists within all four HBV RNA transcripts, VIR-2218 is able to degrade each transcript, and consequently decrease the expression of all proteins produced by the virus. VIR-2218 is thus potentially a broad-spectrum, potent antiviral.

HBV DNA can become integrated into human DNA as intDNA. Because VIR-2218 targets a region of HBV that is conserved in the large majority of HBV intDNA, this single siRNA is predicted to be able to prevent the production of HBV proteins derived from intDNA, as well as the production of all other HBV proteins from cccDNA.

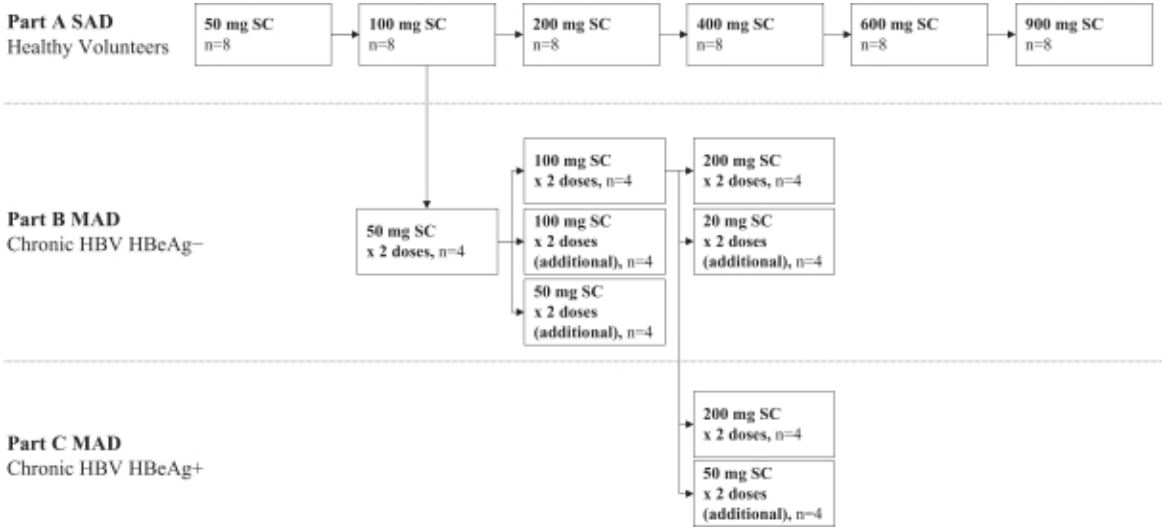
We believe that the large amount of HBV protein that is transcribed in liver cells can suppress the immune system. There are at least two potential mechanisms by which suppression occurs. The first mechanism is T cell

[Table of Contents](#)

tolerance and exhaustion by the presentation of intracellular HBV antigens on hepatocytes. The second is the large quantities of HBV proteins that are released into the blood, especially HBsAg, which may also be immunosuppressive. By directly reducing the amount of HBV proteins made, VIR-2218 has the potential to decrease the ability of HBV to suppress the immune system—in effect removing a brake on the immune system. In mice models, siRNAs that are able to reduce HBsAg expression can transform an otherwise ineffective therapeutic HBV vaccine into one that can functionally cure such mice of HBV, suggesting that HBsAg suppression has the ability to enhance the immune response against HBV.

We believe that VIR-2218 is the only HBV-targeting siRNA currently in development that includes ESC+ technology. We believe this technology may be able to enhance the potential safety and efficacy of VIR-2218. We submitted the first CTA for VIR-2218 in August 2018.

Phase 1/2 Trial of VIR-2218. VIR-2218-1001 is an adaptive clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of VIR-2218. The current trial design of VIR-2218-1001, as of September 2019, is shown below.



Status of VIR-2218-1001 trial in healthy volunteers and patients with chronic HBV infection. Arrows indicate trial progression. HBeAg- = hepatitis B virus e-antigen negative; HBeAg+ = hepatitis B virus e-antigen positive; MAD = multiple ascending dose; SAD = single ascending dose; SC = subcutaneous.

This trial currently has three parts and may enroll up to 104 subjects. Part A is a single ascending dose design in healthy volunteers. Parts B and C are multiple ascending dose designs in patients with chronic HBV on NRTIs. Patients in Part B are hepatitis B early antigen negative, or HBeAg negative, and patients in Part C are hepatitis B early antigen positive, or HBeAg positive. Patients in Parts B and C receive two doses of VIR-2218, four weeks apart. The trial has been designed with the potential for additional cohorts, which allow for more patients to be evaluated at a dose that has been previously evaluated or for patients to receive lower or higher doses, according to pre-specified rules.

HBeAg positive patients are generally younger, and thought to have more preserved immune function, as compared to HBeAg negative patients who are generally older and have experienced greater immune exhaustion. HBeAg negative patients are also thought to have larger amounts of intDNA compared to HBeAg positive patients. As a result, we anticipate that the magnitude of HBsAg decline observed for patients in this trial will be the same or greater in HBeAg positive patients compared to HBeAg negative patients.

The primary endpoints across Parts A-C of the trial are safety and tolerability. Key secondary endpoints in Parts B and C include the maximum reduction of serum HBsAg from baseline until Week 16 and the number of

[Table of Contents](#)

patients with HBsAg loss or anti-hepatitis B surface antibody seroconversion. Patients with chronic HBV who experience a greater than 10% decline from baseline at Week 16 in HBsAg will be followed for up to 32 additional weeks.

Clinical Trial Status. VIR-2218-1001 is an ongoing clinical trial. As of September 18, 2019, 49 healthy volunteers have enrolled in Part A of the trial. Each Part A completed cohort includes six subjects receiving VIR-2218 and two subjects receiving placebo. The cohorts receiving 50 mg, 100 mg, 200 mg and 400 mg have completed dosing and follow-up, and the 600 mg and 900 mg cohorts have completed dosing and remain in follow-up. In the 400 mg cohort, a replacement subject was enrolled due to a subject who voluntarily withdrew from the trial. The 900 mg cohort is designed to assess the maximum tolerated dose of VIR-2218.

In Part B of the trial, 24 patients with chronic HBV who are HBeAg negative have been enrolled. Each Part B completed cohort includes three patients receiving VIR-2218 and one patient receiving placebo. The planned cohorts receiving 50 mg, 100 mg and 200 mg, as well as additional cohorts receiving either 20 mg or 100 mg, have completed dosing and are in follow-up. The 50 mg additional cohort has initiated dosing.

In Part C of the trial, seven patients with chronic HBV who are HBeAg positive have been enrolled. Each completed cohort will include three patients receiving VIR-2218 and one patient receiving placebo. Patients in the 200 mg cohort have all received at least one dose of VIR-2218 or placebo. The 50 mg additional cohort has initiated dosing.

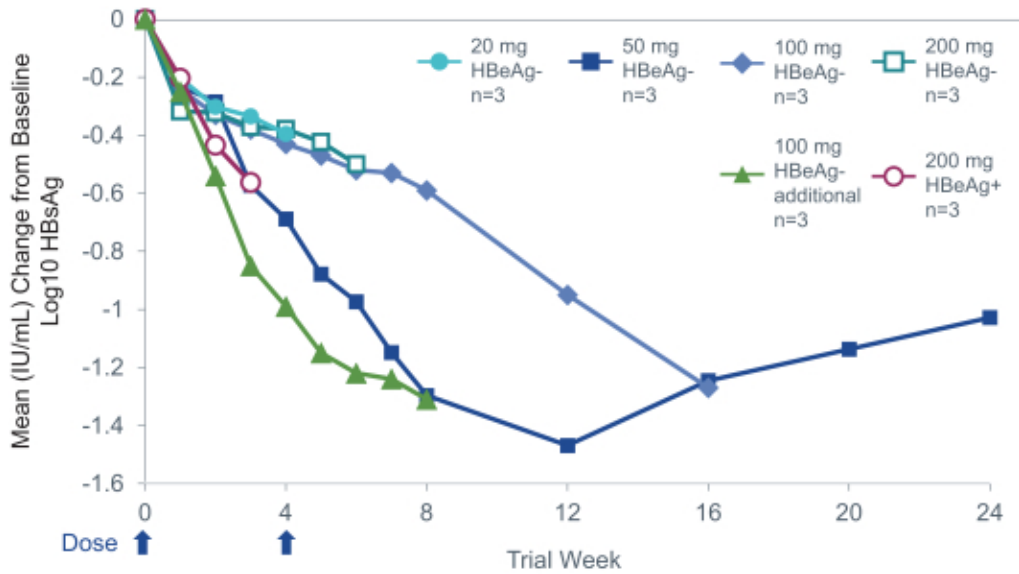
Clinical Data. Across healthy volunteers and chronic HBV patients, VIR-2218 has been generally well-tolerated. No clinically significant alanine transaminase, or ALT, abnormalities, which are a marker of liver inflammation, have been observed. In the Part A 900 mg cohort, asymptomatic Grade 1 ALT abnormalities less than two-fold the upper limit of normal, with no associated changes in bilirubin, have been observed in a subset of subjects. Two serious adverse events, or SAEs, have been reported, both in Part B. The first, a Grade 2 headache, resolved with intravenous fluids and non-opioid pain medications. This patient had additional symptoms of fever, nausea, vomiting and dehydration, assessed by us as consistent with a viral syndrome. The second SAE, a Grade 4 depression, occurred over 50 days after the last drug dose was administered, and was assessed by us as not related to VIR-2218. Three Grade 3 adverse events of upper-respiratory tract infection, chest pain and low phosphate levels in the blood have also been reported. We did not consider any of these Grade 3 events as related to VIR-2218.

The biologic activity of VIR-2218 was assessed by declines in HBsAg. The activity of VIR-2218 in the cohorts that have completed enrollment is shown in the graph below. The data provided are for time points that have been reached by all patients in a given cohort. For Part B, the average baseline HBsAg levels were similar across all cohorts, ranging from 3.3 log₁₀IU/mL to 3.4 log₁₀IU/mL. For Part C, the average baseline HBsAg level in the 200 mg cohort was 3.9 log₁₀IU/mL. Only in the planned 50 mg cohort from Part B have all patients reached their apparent maximal decline in HBsAg, or nadir, with an average decline in HBsAg at Week 12 of 1.5 log₁₀, or approximately a 30-fold reduction. The declines observed in this cohort in HBsAg at Week 12 ranged from 0.6 log₁₀ to 2.3 log₁₀, or approximately four to a 200-fold reduction, with two doses. Nadir data is not yet available for other cohorts.

Data from two different 100 mg cohorts are shown in the graph below: the planned 100 mg cohort and a 100 mg additional cohort. The data from these two cohorts show distinct patterns of HBsAg decline. In the planned cohort, denoted by blue diamonds in the graph below, HBsAg declined at a slower rate through Week 8, then more rapidly afterwards. This pattern of decline in the planned cohort was driven in part by one patient who exhibited a minimal decline through Week 8 of only 0.05 log₁₀, or a 1.1-fold reduction, followed by a 1.5 log₁₀ decline, or a 30-fold reduction, between Weeks 8 and 16. In the 100 mg additional cohort, denoted by green triangles in the graph below, a steeper initial decline was observed. We believe that these different patterns could potentially be the result of underlying patient variability combined with limited patient numbers per cohort. Based on the data available, the ultimate pattern of decline in other cohorts cannot be determined.

[Table of Contents](#)

The ability of VIR-2218 to result in substantial declines in HBsAg after only two doses suggests that VIR-2218 has the potential to play an important role in the functional cure of chronic HBV. We plan to conduct clinical trials evaluating additional dosing regimens of VIR-2218 alone, as well as given in combination with the potential vaccinal mAb VIR-3434 and other immunomodulatory agents.

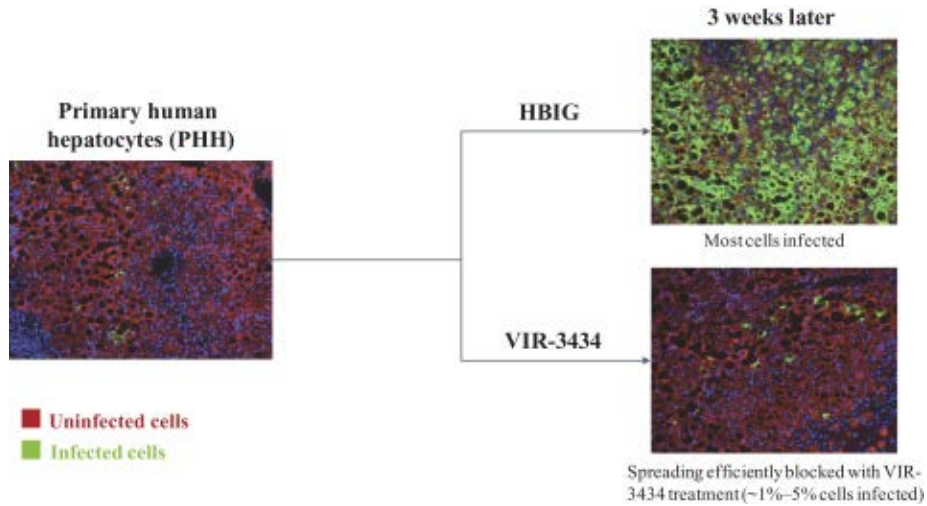


Mean change from Baseline in HBsAg following administration of VIR-2218. Each line represents the average activity of VIR-2218 in either HBeAg negative or positive patients at the specified dose level, excluding placebo patients.

[Table of Contents](#)

VIR-3434 for HBV

Molecular Characteristics and Preclinical Data. VIR-3434 is a mAb targeting a conserved region on HBsAg that allows it to neutralize strains from all 10 HBV genotypes. VIR-3434 specifically targets the antigenic loop, or AGL, on HBsAg. The AGL helps the virus bind to hepatocytes and subsequently infect these liver cells. By binding to the AGL, VIR-3434 prevents viral entry, which prevents spread of HBV to uninfected hepatocytes. VIR-3434, through a process called opsonization, also helps remove HBV virions and SVPs from the blood. Hepatitis B immunoglobulin, or HBIG, an approved therapy for preventing reinfection after transplantation and which consists of polyclonal antibodies against HBV, acts by similar mechanisms. In vitro, VIR-3434 demonstrates approximately 5000-fold greater potency than HBIG in neutralization assays. As shown in the figure below, in vivo compared to HBIG, VIR-3434 is better able to prevent the spread of HBV to uninfected cells. VIR-3434 is thus a potential broad spectrum, potent antiviral.

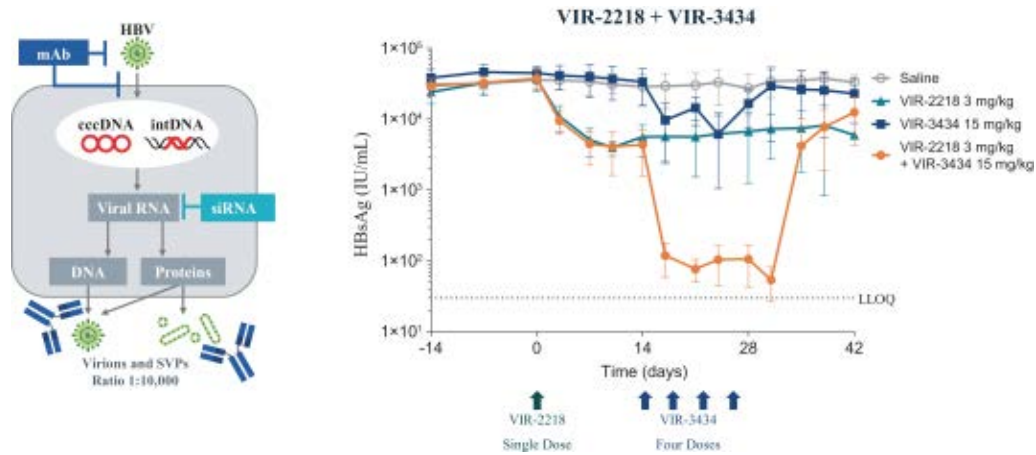


Progression of infection in primary human hepatocytes with hepatitis B immune globulin or VIR-3434 in vivo. PHH = primary human hepatocytes.

VIR-3434 also has the potential to activate the immune system, via three different processes. First, due to specialized mutations in the Fc domain of VIR-3434, it has the potential to act as a T cell vaccine. VIR-3434 has been engineered with mutations that enhance binding to the FcR IIa activating receptor, and diminish binding to the FcR IIb inhibitory receptor. As such, VIR-3434 is designed to capture virions and SVPs, deliver such virions and SVPs to DCs, and instruct these DCs to mature and stimulate T cells to mature and stimulate T cells that can eliminate HBV infected hepatocytes. Second, VIR-3434 has the potential to act via ADCC. In this process, by binding to HBsAg at the cell surface, VIR-3434 recruits natural killer cells to eliminate infected hepatocytes. The Fc domain of VIR-3434 has been engineered to promote ADCC. Third, by reducing the amount of HBsAg in the blood, VIR-3434 has the potential to remove a brake on the immune system by decreasing the ability of HBV to suppress it.

Table of Contents

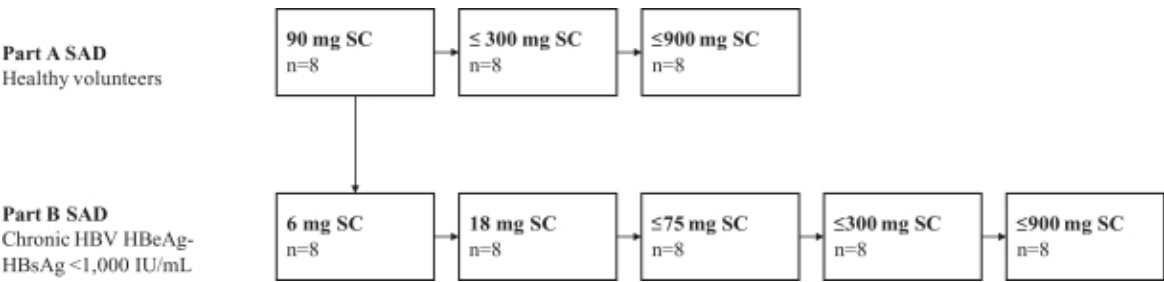
We have also evaluated the antiviral activity of the combination of VIR-2218 and VIR-3434 in an adeno-associated virus-HBV mouse model. As shown in the figure below, VIR-2218 and VIR-3434 work together to reduce the level of HBsAg.



VIR-2218 and VIR-3434, which was modified to have a mouse mAb backbone for this experiment, administered alone or together result in reduced HBsAg in a mouse model.

Planned Phase 1 Trial of VIR-3434. VIR-3434-1002 is an adaptive clinical trial designed evaluate the safety, tolerability, pharmacokinetics and antiviral activity of VIR-3434. The current trial design of VIR-3434-1002 is shown below. We plan to submit a CTA for VIR-3434 in the first half of 2020. We anticipate clinical data from a Phase 1 clinical trial to be available in the first half of 2021.

We anticipate that this trial will have three parts. Part A is a single ascending dose design in healthy volunteers. Parts B and C are single ascending dose designs in patients with chronic HBV on NRTIs. Patients in Part B will have HBsAg levels less than 1,000 IU/ml. It is possible that patients with such lower HBsAg levels will have a more profound response to VIR-3434. Patients with HBsAg levels greater than or equal to 1,000 IU/ml may be evaluated in an optional Part C.



VIR-3434-1002 is an adaptive clinical trial design in healthy volunteers and patients with chronic hepatitis B virus infection. Arrows indicate trial progression. SC = subcutaneous. Optional Part C not shown.

The primary endpoints across all parts of the trial are safety and tolerability. The key secondary endpoint in Parts B and C is the maximum reduction of serum HBsAg from baseline.

Other HBV Combinations and New Product Candidates

In addition to planned combination trial of VIR-2218 and VIR-3434, we are planning clinical trials that will combine our product candidates with other immunomodulatory agents. We plan to commence a Phase 2

[Table of Contents](#)

combination clinical trial in 2020. Furthermore, in parallel with the above development programs, research efforts are underway to use our innate immunity platform to identify and disrupt the host proteins necessary for HBV cccDNA formation and stability, which we believe could result in a complete cure. We also have an HBV therapeutic vaccine that leverages our T cell platform in preclinical development. This exemplifies the potential value of combining outputs from our four technology platforms to complex infectious diseases.

Universal Prophylaxis for Influenza A

Summary

We are developing VIR-2482 as universal prophylaxis for influenza A. VIR-2482 is a mAb that targets a conserved region of the influenza A hemagglutinin protein and consequently has the potential to prevent illness by any strain of influenza A. In vitro, VIR-2482 has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. Since flu vaccines have incomplete strain coverage and limited efficacy, the broad coverage of VIR-2482 may allow it to achieve higher protection levels and for it to be used year after year. In addition, because VIR-2482 is an antibody that can directly confer protection, it does not rely on a person to create his or her own antibodies. Thus, we believe VIR-2482 has the potential to be effective even in a person with a compromised immune system. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long. In August 2019, we initiated dosing in the Phase 1/2 clinical trial for VIR-2482. We anticipate clinical data from the first flu season of this trial to be available in the second half of 2020 and from the second flu season of this trial to be available in the first half of 2021.

Disease Overview and Limitations of Current Standard of Care

On average, each year the influenza virus infects 5% to 10% of the world's population and results in an estimated 500,000 deaths. The efficacy of the flu vaccine has ranged from 10% to 60% over the past 15 years, with an average of 40%. In the 2017-2018 flu season, despite the availability of the flu vaccine, approximately 48 million people were diagnosed with influenza, one million people were hospitalized and 80,000 people died from influenza in the United States alone. Thus, more Americans died of influenza in the 2017-2018 flu season than from breast or prostate cancer in all of 2018. The large majority of these influenza-related deaths occurred in the elderly and/or those who had either pre-existing lung and/or heart disease. These patients comprise a population with a high unmet economic and medical need for better preventive measures. For example, there are 16 million Americans with a known diagnosis of chronic obstructive pulmonary disease, the care of whom is estimated to directly cost up to \$49 billion annually. Approximately 11% of acute chronic obstructive pulmonary disease exacerbations are thought to be attributable to influenza. Overall, it is estimated that the annual influenza-related economic burden is approximately \$87 billion.

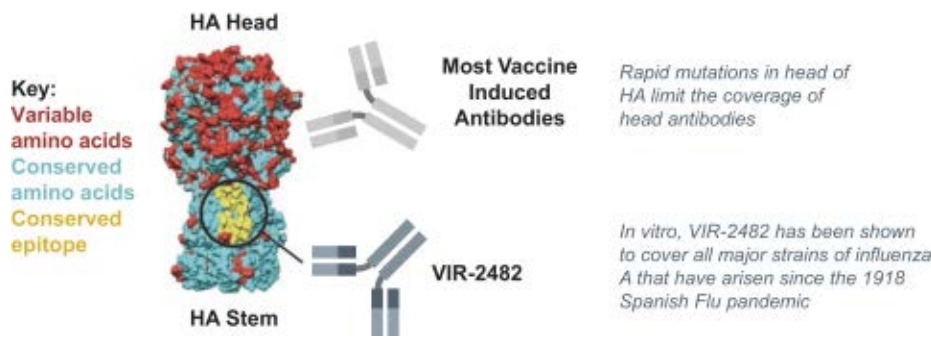
There are two major types of influenza virus, type A and type B. Influenza A has been estimated in the United States to cause over 85% of influenza hospitalizations from 2005 to 2013, and has been the source of all known influenza pandemics. During the 1918 Spanish flu pandemic, up to 3% of the world's population is estimated to have died.

While vaccines to prevent illness from seasonal influenza exist, their efficacy is limited. In the United States, over the last 15 years, on average only approximately 40% of those who received the influenza vaccine were protected. In some seasons, such as the 2004-2005 flu season, the vaccine's efficacy was as low as 10%. The limited success rate of influenza vaccines has been attributed to two primary factors. First, flu vaccines have incomplete strain coverage and therefore often do not, provide protection against all strains of influenza that circulate in a given season, despite being updated every year. Second, flu vaccines are active immunizations that rely on a person's own immune system to create protective influenza virus antibodies, and many individuals do not generate an effective immune response. Clinical and technology advances in flu vaccines, such as cell-based manufacturing and higher dose administration, do not address these two fundamental limitations.

[Table of Contents](#)

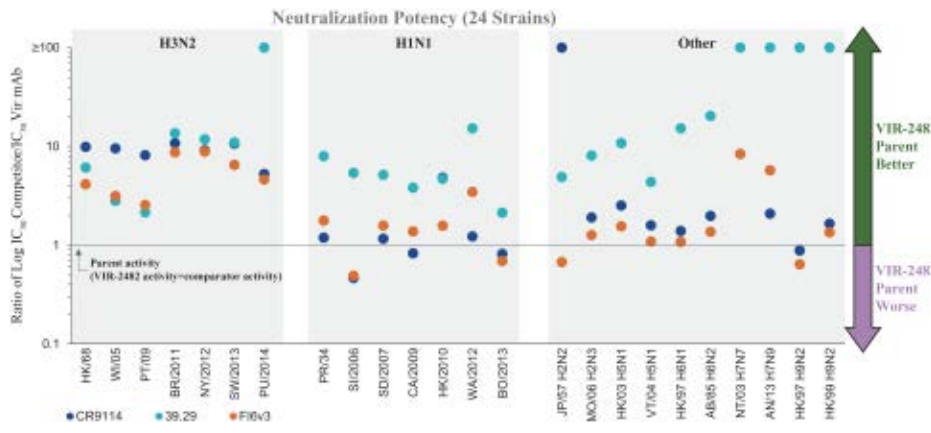
VIR-2482 for Influenza A

Molecular Characteristics and Preclinical Data. VIR-2482 is a mAb targeting a functionally conserved epitope on the influenza A hemagglutinin protein located within the stem region. We believe that all strains of influenza, past and future, have and likely will contain this conserved epitope within the stem region. In preclinical studies, we have demonstrated that, in vitro, VIR-2482 covers all the major strains of influenza A that have arisen since 1918. Thus, unlike flu vaccines, whose incomplete strain coverage results in limited efficacy despite being updated every year, the broad coverage of VIR-2482 may allow it to achieve higher protection levels and to be used year after year. In addition, because VIR-2482 is an antibody that can directly confer protection, it does not rely on a person to create his or her own antibodies. Thus, we believe VIR-2482 has the potential to be effective irrespective of the status of a person’s immune system.



VIR-2482 targets a highly conserved region of the influenza virus and exhibits potency against the last century of influenza viruses. Following vaccination, most anti-influenza antibodies target the variable head region. VIR-2482 binds to the stem region which is highly conserved over time. HA = hemagglutinin.

While other stem-binding influenza A antibodies have been identified, we have demonstrated that VIR-2482 has the broadest coverage when compared to a large representative panel of stem-binding mAbs. In prophylactic lethal challenge studies of influenza A in mice, at exposures we believe to be clinically relevant, VIR-2482 was able to protect mice from death. We have also demonstrated that the parent form of VIR-2482, an antibody that has the same antibody binding domain (Fab) as VIR-2482, has, in general, greater potency, when compared to three other stem-binding mAbs, as shown in the figure below.



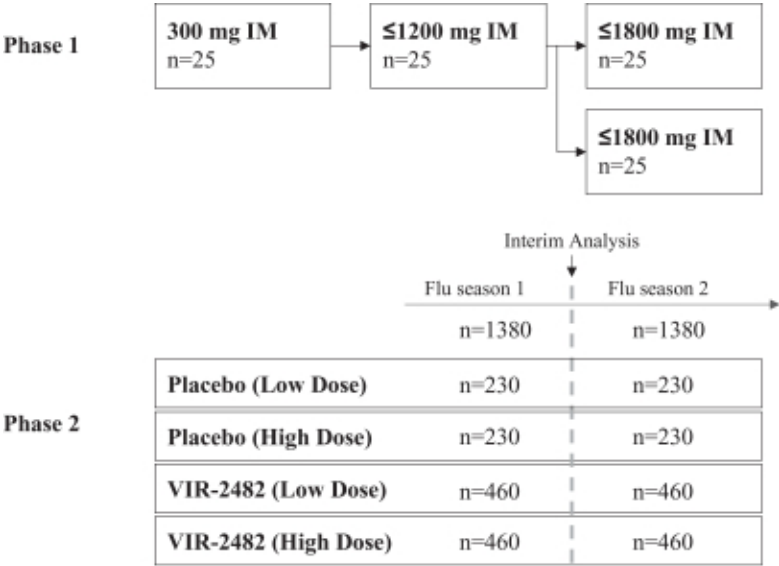
Neutralization potency of four stem-binding antibodies. VIR-2482, and three other third-party antibodies, CR9114, 39.29, and F16v3, were tested for their neutralization potency against 24 representative strains. These strains were selected to cover the antigenic variation of the seasonal H1N1 and H3N2 strains back to 1938 and 1968, respectively, and strains from other subtypes that infected humans in past pandemics or that caused sporadic animal-derived outbreaks.

[Table of Contents](#)

We engineered the parent form of VIR-2482 to extend its half-life to create VIR-2482. This half-life extension potentially allows for a single injection of VIR-2482 given at the start of the influenza season to maintain a protective concentration in the respiratory tract for the duration of the influenza season.

Notably, in a recent clinical epidemiology study, it was observed that the presence of rare, stem-binding influenza antibodies correlated with protection from influenza infection.

Phase 1/2 Trial of VIR-2482. VIR-2482-3001 is a clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and efficacy of VIR-2482. The current design of VIR-2482-3001 is shown below. In August 2019, we initiated dosing in the Phase 1/2 clinical trial for VIR-2482. This trial is designed to include up to 2,860 healthy volunteers across the Phase 1 and Phase 2 portions. We anticipate clinical data from the first flu season of a Phase 1/2 clinical trial to be available in the second half of 2020 and from the second flu season of this trial to be available in the first half of 2021.



VIR-2482-3001 clinical trial design in healthy adult volunteers. Flu = influenza.

We anticipate that the Phase 1 portion of this trial will be a single ascending dose trial in healthy adult volunteers and that the Phase 2 portion of this trial will be a dose-ranging, double-blind, placebo-controlled trial in healthy adult volunteers. Healthy volunteers in the Phase 1 portion may receive a second dose, one year later, to evaluate for the possibility of anti-drug antibodies.

The primary endpoints of the Phase 1 and Phase 2 portions of this trial are safety and tolerability. The primary efficacy endpoint of the Phase 2 portion is laboratory confirmed influenza A illness with key secondary endpoints of severity and duration of illness due to influenza A, as well as quantification of influenza A viral load at the time of presentation with influenza illness.

Vaccine for HIV Prophylaxis

Summary

We are developing a vaccine to prevent HIV. We have designed VIR-1111 to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines, and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. An HLA-E

[Table of Contents](#)

restricted immune response has been shown to be associated with protection of NHPs from SIV. We plan to submit an IND for VIR-1111 in the first half of 2020 and thereafter commence a Phase 1 clinical trial. VIR-1111 is a proof of concept vaccine, because, at minimum, changes to the vaccine antigen from HIV will be required before subsequent phases of clinical development. The need to alter the antigen within VIR-1111 to allow for further clinical development will require an abbreviated Phase 1 clinical trial with the altered product candidate that contains this new antigen. That Phase 1 clinical trial is currently estimated to begin two years after the commencement of the VIR-1111 Phase 1 clinical trial, and as a result any potential regulatory approval will be delayed by approximately two years.

Disease Overview and Limitations of the Current Standard of Care

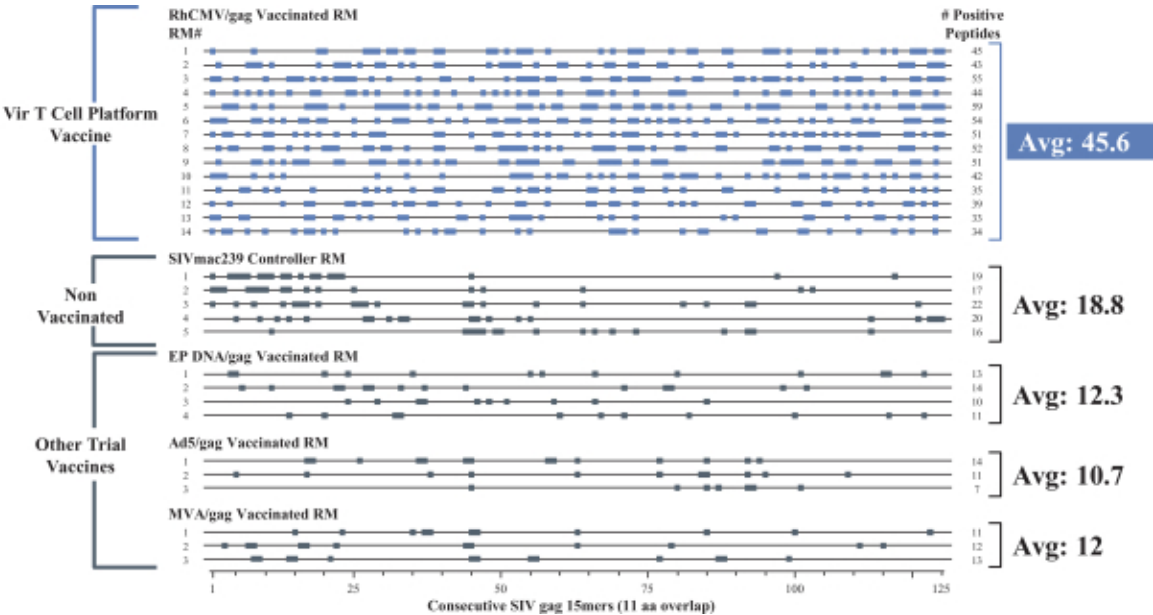
Each year there are approximately 1.8 million new cases of HIV and approximately 1.0 million HIV-related deaths globally. Unless treated, infection with HIV results in an almost universally fatal disease, acquired immune deficiency syndrome, or AIDS. According to the World Health Organization, over 35 million people have died from HIV-related illnesses globally.

Highly effective HIV treatments are now available, but these medicines only suppress HIV and are not curative. They require life-long administration and carry the risk for viral breakthrough and resistance. Furthermore, while HIV prevention programs based on behavioral modification, pharmacological intervention, use of barrier devices and other methods continue to be developed, such approaches have had at most a modest effect on HIV transmission globally in high-risk populations. Therefore, we believe the most effective means of curbing the worldwide HIV epidemic would be a safe and effective vaccine for individuals who are or may become sexually active. We believe that the target population for an HIV vaccine is comprised of billions of individuals and is potentially larger than the target population for Gardasil®, a vaccine to prevent human papillomavirus and the cancers human papillomavirus causes, due to the higher lethality associated with HIV. In 2018, Gardasil® revenue approached \$3.2 billion. Despite nearly 30 years of intensive efforts, no vaccine for HIV has been successfully developed.

VIR-1111 for HIV

Molecular Characteristics and Preclinical Data. VIR-1111 is a proof of concept T cell vaccine based on HCMV that is designed to elicit T cells that recognize parts of HIV epitopes that are different from those recognized by prior HIV vaccines, and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. In NHP models, T cell vaccines based on an RhCMV elicited T cells that recognized 3-4 times the number of epitopes compared to other vaccine platforms; the specific epitopes recognized were also different, as shown in the figure below. SIV is the NHP equivalent of HIV.

Table of Contents



Number of epitopes recognized by T cells using RhCMV compared to other vaccine vector technologies or NHPs naturally achieving SIV control. Each line represents a different NHP. Each box denotes the relative location of the epitope within the antigen that is recognized by the T cells elicited by that vaccine vector or SIV. The total number of epitopes recognized is shown on the right. RM = rhesus macaque; SIVmac239-controller = infected with a virulent strain of SIV; EP DNA/gag = electroporation of DNA expressing the SIV gag protein; Ad5/gag = Adenovirus type 5 expressing the SIV gag protein; MVA/gag = Modified vaccinia virus Ankara expressing the SIV gag protein.

Further, in such NHP models, introducing different mutations to RhCMV allows the vector to be programmed to elicit an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of NHPs from SIV. In these series of experiments, large groups of NHPs were given an RhCMV-based vaccine, which protected more than 50% of the NHPs from repeated exposure to SIV.

Preliminary data suggest the ability to predict which NHPs will be protected from SIV after administration of the RhCMV-based vaccine. This is made possible using transcriptomic signatures, a blood test that evaluates how cells in the body respond to the vaccine. Transcriptomic signatures will be analyzed in human clinical trials. If protection effectiveness is found to be less than 100%, such data may allow us to predict who will be protected as well as to generate next generation vaccines.

Planned Phase 1 Trial of VIR-1111. VIR-1111-2001 is a clinical trial designed to evaluate the safety, tolerability and immunogenicity of VIR-1111 in CMV-positive healthy volunteers. The immunogenicity evaluation includes assessment of the breadth and nature of the T cell response to the vaccine. The design of this trial is under development. We plan to submit an IND in the first half of 2020 and thereafter commence the Phase 1 clinical trial. The manufacture and early clinical development of VIR-1111 is funded by the Bill & Melinda Gates Foundation. Modifications to VIR-1111 will be required before subsequent phases of clinical development, as VIR-1111 is a proof of concept vaccine and will not in its current format result in a commercial product.

Vaccine for TB Prophylaxis

Summary

We are developing VIR-2020 as a vaccine to prevent active TB, including preventing latent infection from progressing to active pulmonary disease, which is a key source of ongoing transmission of TB. VIR-2020, a T

[Table of Contents](#)

cell vaccine based on HCMV, is designed to stimulate T cells that reside in the lung and recognize TB epitopes different from those recognized by prior TB vaccines. A vaccine based on an NHP version of cytomegalovirus, or CMV, was shown to provide protection against TB. We plan to submit an IND for VIR-2020 in the first half of 2021 and thereafter commence a Phase 1 clinical trial.

Disease Overview and Limitations of the Current Standard of Care

TB is the leading cause of death from a single infectious agent globally. Each year there are approximately 10 million new cases of TB and approximately 1.6 million deaths. Approximately 1.7 billion people are estimated to have an asymptomatic form of TB known as latent TB. These approximately 1.7 billion people with latent TB worldwide are at risk of progressing to active disease.

Treatment for active TB requires multiple medications, taken for a minimum of six months. Treatment is unsuccessful approximately 20% of the time for drug susceptible cases and 45% of the time for multidrug-resistant cases. The World Health Organization estimates that the current global economic burden of TB amounts to approximately \$12 billion annually. We believe the most effective means of curbing this worldwide TB epidemic would be a safe and effective vaccine that prevents active pulmonary TB.

Currently, the only vaccine recommended for preventing TB is the Bacillus Calmette–Guérin, or BCG, vaccine, which was introduced over 80 years ago. Although BCG is partially efficacious at protecting infants and young children from disseminated disease, it is poorly protective against pulmonary disease in adolescents and adults, who represent the key sources of TB transmission and are the primary contributors to the overall disease burden. We believe that a key reason why an effective TB vaccine does not exist is because TB is not easily cleared by boosting our immune system's natural response to infection.

VIR-2020 for TB

Molecular Characteristics and Preclinical Data. VIR-2020, a T cell vaccine based on HCMV, is designed to stimulate T cells that reside in the lung and recognize TB epitopes which are different from those recognized by prior TB vaccines.

In NHPs, a vaccine based on a NHP version of CMV was shown to protect against TB. To our knowledge, this was the first demonstration of complete prevention of active TB in a substantial portion of NHPs by a peripherally administered vaccine after challenge with a highly pathogenic strain of *Mycobacterium tuberculosis*, the causative agent of TB. As shown previously in the NHP-SIV model, the TB vaccine was observed to elicit T cells that recognize three to four times the number of epitopes compared to other vaccine platforms. Similarly, preliminary data suggest that determining which NHPs will be protected from TB after vaccination can be predicted using transcriptomic signatures.

Planned Phase 1 Trial of VIR-2020. VIR-2020-4001 is a clinical trial designed to evaluate the safety, tolerability and immunogenicity of VIR-2020 in CMV-negative and CMV-positive healthy volunteers. The immunogenicity evaluation will include assessment of the breadth and nature of the T cell response to the vaccine. The design of this trial is under development. We plan to submit an IND for VIR-2020 in the first half of 2021. The manufacture and early clinical development of VIR-2020 is funded by the Bill & Melinda Gates Foundation.

Our Collaboration, License and Grant Agreements

Collaboration and License Agreement with Alnylam

In October 2017, we entered into a collaboration and license agreement with Alnylam, or the Alnylam Agreement, for the development of siRNA products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA products directed to up to four other infectious disease targets selected by us. The technology licensed under the Alnylam Agreement forms the basis of our siRNA technology platform.

[Table of Contents](#)

Pursuant to the Alnylam Agreement, we obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such as excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to our selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. Our options are each exercisable during a specified period following selection of candidates for each program, or two years following the initiation of certain activities under an agreed upon development plan, if earlier. On a product-by-product basis for each product arising from the HBV and, following our option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

We and Alnylam are jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept studies. Prior to the exercise of our option for each siRNA program directed to one of our selected infectious disease targets, Alnylam is responsible for conducting all development activities, at our expense, in accordance with an agreed upon development plan. Following our exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, we are solely responsible, at our expense, for conducting all development, manufacture and commercialization activities for products arising from each such program unless Alnylam exercises its profit-sharing option. We are required to use commercially reasonable efforts to develop and commercialize one siRNA product directed to HBV and one siRNA product directed to the target of each other infectious disease program for which we exercise our option, in each of the major markets. If Alnylam exercises a profit-sharing option for a product, we will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

We retain final decision-making authority with respect to which infectious disease product candidates we advance and the development programs for the HBV and infectious disease product candidates, subject to certain limitations. During the term of the Alnylam Agreement, neither we nor Alnylam may develop or commercialize any gene-silencing, oligonucleotide-based product directed to the same target as any product candidate under the Alnylam Agreement, other than pursuant to the Alnylam Agreement, subject to certain exceptions.

Pursuant to the Alnylam Agreement, we paid Alnylam an upfront fee of \$10.0 million and issued to Alnylam 1,111,111 shares of our common stock. Upon the achievement of a certain development milestone, we will also issue shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone is achieved. We will be required to pay Alnylam up to \$190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to \$115.0 million for the achievement of specified development and regulatory milestones for the first product directed to the target of each infectious disease siRNA program for which we exercised our option. Following commercialization, we will be required to pay to Alnylam up to \$250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to \$100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which we exercised our option. We will also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. Alnylam is also entitled to receive a portion of any consideration we receive as a result of granting a sublicense under the licenses granted to us by Alnylam under

[Table of Contents](#)

the Alnylam Agreement or an option to acquire such a sublicense, determined based on the timing of the grant of such sublicense. In November 2018, in connection with the inclusion of the HBV siRNA program as the subject of a potential grant of a sublicense to Bii Bio under the Bii Agreement, each as defined under the section titled “—Collaboration and License Agreement with Bii Bio,” which triggered certain payment obligations under the Alnylam Agreement, we entered into a letter agreement with Alnylam, or the Alnylam Letter, making certain modifications to the payments due to Alnylam as a result of the grant of the option and potential payments that would result from Bii Bio’s exercise of rights under such sublicense. As a result of the rights granted under the Bii Agreement and pursuant to the Alnylam Letter, we will transfer to Alnylam a specified percentage of the equity consideration allocable to the HBV siRNA program that we received from Bii Bio and its affiliated companies in connection with the entry into the Bii Agreement.

The term of the Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Alnylam Agreement. If we do not exercise our option for an infectious disease program directed to one of our selected targets, the Alnylam Agreement will expire upon the expiration of the applicable option period with respect to such program. However, if Alnylam exercises its profit-sharing option for any product, the term of the Alnylam Agreement will continue until the expiration of the profit-sharing arrangement for such product. We may terminate the Alnylam Agreement on a program-by-program basis or in its entirety for any reason on 90 days’ written notice. Either party may terminate the agreement for cause for the other party’s uncured material breach on 60 days’ written notice (or 30 days’ notice for payment breach), or if the other party challenges the validity or enforceability of any patent licensed to it under the Alnylam Agreement on 30 days’ notice.

License Agreements with MedImmune

2012 Sub-License and Collaboration Agreement with MedImmune

In March 2012, our subsidiary Humabs entered into a sub-license and collaboration agreement with MedImmune, LLC, or MedImmune, as amended, or the 2012 MedImmune Agreement, pursuant to which Humabs conducted certain activities under a mutually agreed research plan for the development of therapeutic antibodies directed to influenza viruses (including influenza A and influenza B) and to Klebsiella bacteria. The 2012 MedImmune Agreement was amended in April 2013, April 2015, December 2015, August 2016, July 2017, and September 2018, to designate Klebsiella as an extra target, to extend the term of the research program and provide for related payments, and to incorporate certain research activities funded by MedImmune under a specified government grant. Under the 2012 MedImmune Agreement, as amended, MedImmune obtained a worldwide exclusive license from Humabs to develop and commercialize products directed to such targets for all uses in humans and animals except for active vaccination. MedImmune is obligated to use commercially reasonable efforts to develop at least one product directed to influenza viruses.

In consideration for the grant of the license, MedImmune made certain upfront payments to Humabs. MedImmune is obligated to pay Humabs development, regulatory and commercial milestone payments of up to \$96.5 million in the aggregate for the first product directed to influenza viruses to achieve the applicable milestones, and up to \$12.0 million for the first product directed to Klebsiella to achieve the applicable milestones. MedImmune will also be obligated to pay royalties based on net sales of products directed to influenza viruses or Klebsiella at certain fixed percentages in the low to mid-single-digits, with the rate determined based on the specific target to which the product is directed, in each case subject to specified reductions and a royalty floor. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the last to expire valid claim that would, but for the licenses granted under the 2012 MedImmune Agreement, be infringed by the sale of such product in such country, and 10 years from the first commercial sale of the first product in such country. MedImmune also made certain payments to Humabs in consideration for Humabs’ conduct of the research program. We will be obligated to pass through the milestone payments and royalty payments that we receive under the 2012 MedImmune Agreement, following deduction of certain expenses incurred by us or Humabs thereunder, to Humabs’ securities holders pursuant to the Humabs SPA, as defined under the section titled “—Securities Purchase Agreement with Humabs.”

[Table of Contents](#)

The 2012 MedImmune Agreement will remain in force until MedImmune has fulfilled all of its obligations to make milestone and royalty payments. MedImmune may terminate the 2012 MedImmune Agreement in its entirety, or on a product-by-product, license-by-license or country-by-country basis, for convenience, upon 90 days' notice. Either MedImmune or Humabs may terminate the 2012 MedImmune Agreement for the other party's uncured material breach or in the event of bankruptcy of the other party.

2018 License Agreement with MedImmune

In September 2018, we entered into a license agreement with MedImmune, or the 2018 MedImmune Agreement, pursuant to which we obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The license from MedImmune includes the grant of a sublicense under MedImmune's license to certain intellectual property controlled by Humabs that was granted to MedImmune pursuant to the 2012 MedImmune Agreement. Under certain circumstances and during certain periods of time we have the right to nominate up to two variants of each of these antibodies for inclusion under the license. MedImmune retained the rights to continue to develop and to commercialize the two specified antibodies that target influenza A and influenza B, in each case that are not the half-life extended versions that are licensed to the Company. Additionally, we obtained a worldwide, exclusive license under MedImmune's antibody half-life extension technology to develop and commercialize half-life extended antibodies directed to up to two additional targets selected by us for all uses in humans or animals for the prevention, treatment or diagnosis of infectious diseases. We have the right to nominate such additional targets during a specified period following the effective date of the 2018 MedImmune Agreement. MedImmune may only refuse our nomination if such targets are already the subject of internal development by MedImmune, are subject to third party rights at the time of our selection, or are the subject of good faith discussions between MedImmune and a third party for a license for products directed to such targets. We are solely responsible, at our sole cost, for the development of products containing half-life extended versions of antibodies directed to the influenza targets and any additional selected targets, and are obligated to use commercially reasonable efforts to develop and obtain regulatory approval for at least one product containing half-life extended versions of antibodies directed to each of influenza A, influenza B and any additional targets, if applicable, in the United States and specified markets in Europe and Asia. We are also obligated to use commercially reasonable efforts to commercialize products containing half-life extended versions of antibodies directed to such targets in such markets. We are developing VIR-2482 using technology licensed under the 2018 MedImmune Agreement.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, we made an upfront payment to MedImmune of \$10.0 million. We will be obligated to make development and regulatory milestone payments to MedImmune of up to \$92.0 million in the aggregate for products containing half-life extended versions of antibodies directed to influenza A that we licensed, up to \$51.0 million in the aggregate for such products directed to influenza B that we licensed, and up to \$250,000 in the aggregate for certain specified products directed to the additional selected targets, if applicable. We will also be required to make sales related milestone payments to MedImmune following commercialization up to an aggregate of \$200.0 million for the achievement of specified levels of aggregate annual net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits and a royalty based on net sales of products containing half-life extended versions of antibodies directed to any additional selected targets, if applicable, at a percentage in the low single-digits, in each case subject to specified reductions. These royalties are payable, on a product-by-product and country-by-country basis, until the latest to occur of expiration of the last to expire valid claim covering such product in such country, expiration of regulatory exclusivity for such product in such country, and 12 years after the first commercial sale of such product in such country. Additionally, we are responsible for paying any royalties due under the 2012 MedImmune Agreement as a result of our commercialization of products under the 2018 MedImmune Agreement.

[Table of Contents](#)

The 2018 MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of our obligations to pay royalties to MedImmune. We may terminate the 2018 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 2018 MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party. Additionally, MedImmune may terminate the 2018 MedImmune Agreement for cause on 30 days' written notice if we challenge the validity or enforceability of the patents to which we have obtained a license under the 2018 MedImmune Agreement.

Master Exclusive License Agreement with OHSU

In June 2012, our subsidiary TomegaVax, Inc., or TomegaVax, entered into a master exclusive license agreement, or the OHSU Agreement, with Oregon Health & Science University, or OHSU. The OHSU Agreement was revised and restated in August 2014 and again in August 2019, at which time we assumed TomegaVax's rights and obligations as licensee under the OHSU Agreement. Under the OHSU Agreement, we obtained a worldwide exclusive license under certain patent rights and a non-exclusive license under certain know-how to make, have made, use, offer to sell, sell, have sold, export and import certain products relating to CMV vectors in all fields of use. The OHSU Agreement provides for us to include within the license grant additional patent or know-how rights covering certain inventions arising at OHSU and relating to the use of CMV vaccine vectors through the execution of technology addenda, each such addendum, a Technology Addendum. Each Technology Addendum relates to a single invention disclosure and family of patent or know-how rights. During the term of the OHSU Agreement to date, we have entered into 15 such Technology Addenda. We must use reasonably diligent efforts to develop and commercialize the CMV vector products consistent with its reasonable business practices and judgment, including by achieving certain specified development and regulatory milestones within certain periods. We use technology licensed under the OHSU Agreement in our T cell platform and in our product candidates VIR-1111 and VIR-2020.

Pursuant to the initial entry into the OHSU Agreement and certain of the Technology Addenda, TomegaVax issued a specified percentage of its then outstanding common stock to OHSU, which was subsequently exchanged for shares of our common stock as a result of our acquisition of TomegaVax in September 2016. In connection with the second revision and restatement of the OHSU Agreement in August 2019, we issued an additional specified number of shares of our common stock to OHSU. We are obligated to pay OHSU up to \$1.3 million upon the achievement of certain development and regulatory milestones for each CMV vector product, and up to \$2.0 million upon the achievement of certain aggregate annual net sales milestones for all CMV vector products. We will also be required to pay OHSU a royalty in the low single-digits on net sales of licensed products on a product-by-product basis, subject to specified reductions and offsets, and specified minimum annual royalty payments. The royalties are payable, on a product-by-product and country-by-country basis, until the later of (a) the expiration of all valid claims in the licensed patents covering such product in the country of sale or country of manufacture, as applicable, and (b) 10 years after the first commercial sale of such product in the country of sale. OHSU is also entitled to receive a specified percentage of any consideration received by us as a result of the grant of a sublicense under the rights granted under the OHSU Agreement, with the applicable percentage based on the development stage of the applicable program at the time of the grant of the sublicense.

The OHSU Agreement will remain in force until the expiration of all licensed patent rights or 10 years after the effective date of the last Technology Addendum, whichever is the later. Each individual Technology Addendum remains in force until the expiration of the patent rights to which it applies, or 10 years after the effective date of such Technology Addendum, whichever is later. Either party may terminate the OHSU Agreement, or any individual Technology Addendum, for the other party's uncured material breach on 60 days' written notice, which may be extended by an additional 120 days under certain conditions. The OHSU Agreement and each Technology Addendum also terminate in the event of bankruptcy of either party. We may also terminate the OHSU Agreement in its entirety, or any Technology Addendum individually, upon 60 days'

[Table of Contents](#)

notice. OHSU may immediately terminate the OHSU Agreement if we or our sublicensees bring any action or proceeding against OHSU, subject to certain exceptions.

Exclusive License Agreement with the Institute for Research in Biomedicine

In December 2011, Humabs Holdings GmbH, or Humabs Holdings, the parent company of our subsidiary Humabs, entered into an exclusive license agreement, or the IRB Agreement, with the Institute for Research in Biomedicine, or IRB. The IRB Agreement amended and restated an original 2004 exclusive license agreement between the parties in connection with IRB's proprietary technologies relating to human monoclonal antibodies and the discovery of unique epitopes recognized by such antibodies. In May 2008, Humabs entered into an exclusive license agreement with IRB, or the Humabs IRB Agreement, and together with the IRB Agreement, the Current IRB License Agreements. Pursuant to the Humabs IRB Agreement, IRB granted to Humabs an exclusive license under certain intellectual property rights for the development of certain monoclonal antibodies. Following the entry into the Humabs IRB Agreement, in February 2012, Humabs and IRB entered into a research agreement, or the IRB Research Agreement, concurrently with the termination of an original research agreement dated July 2004 between Humabs Holdings and IRB, to provide for a continuing research collaboration between Humabs and IRB, and to coordinate the exploitation of intellectual property rights arising from the IRB Research Agreement with the rights granted under the Current IRB License Agreements. Under the terms of the IRB Research Agreement, IRB performs certain research activities for Humabs, and all intellectual property rights arising under the IRB Research Agreement are either owned by Humabs, or included in and licensed to Humabs pursuant to the terms of the Current IRB License Agreements. In August 2017, we acquired all of the share capital of Humabs as described further below. Prior to the closing of such acquisition, Humabs Holdings was consolidated into Humabs, such that Humabs Holdings ceased to exist as a separate legal entity, and Humabs became the successor-in-interest to Humabs Holdings' rights under the IRB Agreement. As a result, Humabs is the licensee under each of the Current IRB License Agreements.

We use technology licensed under the Current IRB License Agreements in our antibody platform and in our product candidates VIR-2482 and VIR-3434.

Pursuant to the Current IRB License Agreements, IRB granted to Humabs an exclusive, worldwide, royalty-bearing, sublicensable license under patent and know-how rights covering or associated with IRB's proprietary technology platform relating to antibody discovery, as well as rights in certain antibodies, including as a result of activities under the IRB Research Agreement, in each case for all purposes, including to practice the licensed technology platform, and to develop, manufacture and commercialize any drug, vaccine or diagnostic product containing such licensed antibodies. Humabs is required to use commercially reasonable efforts to develop and commercialize licensed products, and must maintain an active program to commercialize licensed products. Humabs is required to pay to IRB a flat royalty on net sales of licensed products approved for non-diagnostic use in the low single-digits, and a flat royalty on licensed products for diagnostic use at 50% of the non-diagnostic product rate, in each case subject to standard reductions and offsets. A single royalty stream is payable on products that include the licensed antibodies (including antibodies that are owned by Humabs, but developed using the licensed technology), irrespective of whether a given product is covered by patents under both of the Current IRB License Agreements. Humabs' obligation to pay royalties to IRB, on a country-by-country basis, is reduced upon the expiration of the relevant patents in such country, and expires 10 years after the date of first commercialization of a licensed product in such country. Humabs is also required to pay to IRB a specified percentage in the sub-teen double-digits of consideration received in connection with the grant of a sublicense to a non-affiliate third party, subject to a specified maximum dollar amount for the first up front or milestone payment received under such sublicense for each licensed product, and a lower specified maximum dollar amount for subsequent up front or milestone payments for such licensed product.

Each of the Current IRB License Agreements remains in force until the expiration of all valid claims of the licensed patent rights and trade secrets included in the licensed IRB know-how. Humabs may terminate the IRB Agreement at will on 90 days' written notice to IRB, and either party may terminate either of the Current IRB License Agreements on 60 days' written notice for the uncured material breach of the other party.

[Table of Contents](#)

Exclusive License Agreement with The Rockefeller University

In July 2018, we entered into an exclusive license agreement with The Rockefeller University, or Rockefeller, and such agreement, as amended in May 2019, the Rockefeller Agreement. Pursuant to the Rockefeller Agreement, Rockefeller granted us a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The licenses granted to us are freely sublicensable to third parties. Rockefeller retains the right to use the licensed patents outside the field of use, and within the field of use solely in connection with educational, research and non-commercial purposes, as well as for certain research being conducted in collaboration with us. We are obligated to grant sublicenses to third parties with respect to products that are not being pursued and are not of interest to us following a specified anniversary of the May 2019 amendment date. Pursuant to the Rockefeller Agreement, we are required to use commercially reasonable efforts to develop and commercialize infectious disease products as soon as reasonably practicable, including by achieving certain specified development milestone events within specified time periods for products arising from our HBV and influenza programs.

We use technology licensed under the Rockefeller Agreement in our antibody platform and in our product candidate VIR-3434.

We paid Rockefeller an upfront fee of \$300,000 for entry into the Rockefeller Agreement, and are required to pay annual license maintenance fees of \$1.0 million, which will be creditable against royalties following commercialization. In addition, for achievement of specified development and regulatory milestone events, we will be required to pay up to \$8.5 million with respect to the first infectious disease product for the HIV indication, up to \$7.0 million with respect to each of the first four other infectious disease products with specified projected peak worldwide annual net sales, and up to \$3.6 million with respect to any other infectious disease product. Following regulatory approval, we will be required to pay commercial success milestones of up to \$40.0 million in the aggregate for the achievement of specified aggregate worldwide annual net sales of the first infectious disease product for the HIV indication and the first four infectious disease products with specified projected peak worldwide annual net sales. We will also be required to pay to Rockefeller a tiered royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. Our obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction. If we grant a sublicense to a non-affiliate third party under the Rockefeller technology, we will be required to pay to Rockefeller a specified percentage of consideration received from such sublicensee for the grant of the sublicense, depending on the date of receipt of the applicable sublicense income from such sublicensee.

The Rockefeller Agreement will remain in force, absent earlier termination, until the expiration of all of our obligations to pay royalties to Rockefeller in all jurisdictions. We have the right to terminate the Rockefeller Agreement in its entirety, or in part, for any reason on 60 days' written notice to Rockefeller. Rockefeller may terminate the Rockefeller Agreement on 90 days' written notice for our uncured material breach, or if we challenge the validity or enforceability of any of the licensed patents, or immediately in the event of our insolvency. Rockefeller may also terminate the Rockefeller Agreement if we cease to carry on business with respect to the rights granted to us under the agreement.

Collaboration and License Agreement with Bria Bio

In May 2018, we entered into an option and license agreement with Bria Biosciences Limited (previously named BiiG Therapeutics Limited), or Bria Bio Parent, and Bria Biosciences Offshore Limited, or Bria Bio, and

[Table of Contents](#)

such agreement, the Brie Agreement, pursuant to which we granted to Brie Bio, with respect to up to four of our programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau, or collectively the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. Our HBV siRNA program being developed under the Alnylam Agreement (described above) is included within the Brie Agreement as a program for which Brie Bio may exercise one of its options. Brie Bio may exercise each of its options following the achievement by us of proof of concept for the first product in such program. In partial consideration for the options granted by us to Brie Bio, Brie Bio Parent and Brie Bio granted us, with respect to up to four of Brie Bio Parent's or Brie Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brie Bio programs in the United States for the Field of Use. The number of options that we may exercise for a Brie Bio program is limited to the corresponding number of options that Brie Bio exercises for a Vir program. All options granted to Brie Bio under the Brie Agreement that are not exercised will expire no later than seven years following the effective date, or two years earlier than such date if Brie Bio has not undergone an initial public offering within such shorter period. All options granted to us under the Brie Agreement that are not exercised will expire no later than two years following the expiration of all options granted to Brie Bio. Neither we nor Brie Bio has exercised an option under the Brie Agreement.

We are responsible, at our expense and discretion, for the conduct of all development activities under our programs prior to the exercise of Brie Bio's options, and Brie Bio is responsible, at its expense and discretion, for all activities under its programs prior to the exercise of our options. Following exercise of an option for a specified program by either us or Brie Bio, the exercising party is granted an exclusive, royalty-bearing license to develop, manufacture and commercialize products arising from the applicable program in the United States (where we are exercising the option) or the China Territory (where Brie Bio is exercising the option), and such party is thereafter responsible for all development and commercialization activities, at its expense, in the optioned territory. If Brie Bio exercises its option with respect to our development program being conducted under the Alnylam Agreement, Brie Bio's rights will be subject to the terms of the Alnylam Agreement, as amended by the Alnylam Letter.

Under the terms of the Brie Agreement, following our option exercise, we are obligated to use commercially reasonable efforts to develop at least one licensed product arising from each optioned Brie Bio program, and to commercialize each such product in the United States following regulatory approval, and following Brie Bio's option exercise, Brie Bio is obligated to use commercially reasonable efforts to develop at least one licensed product arising from each optioned Vir program and to commercialize each such product in the China Territory following regulatory approval.

With respect to programs for which Brie Bio exercises its options, Brie Bio will be required to pay us an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to \$20.0 million, determined based on the commercial potential of the licensed program. Brie Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to \$30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brie Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of \$175.0 million per licensed program. Brie Bio also will pay us royalties that range from the mid-teens to the high-twenties, as described below.

As partial consideration for our entry into the Brie Agreement, upon closing of Brie Bio Parent's Series A preferred stock financing, we received ordinary shares equal to 9.9% of the outstanding shares in Brie Bio Parent. As a result of Brie Bio's right to exercise one of its options for our HBV siRNA program, under the terms of the Alnylam Agreement, as amended by the Alnylam Letter, we will transfer to Alnylam a specified percentage of such equity consideration allocable to such program. Upon exercise of each option for a Brie Bio program, we will be required to pay to Brie Bio an option exercise fee ranging from the low tens of millions to up to

[Table of Contents](#)

\$50.0 million, determined based on the commercial potential of the licensed program. We will be required to make regulatory milestone payments to Bii Bio on a licensed product-by-licensed product basis ranging from the low tens of millions up to \$100.0 million, also determined based on the commercial potential of such program. We will also be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products in the United States arising from each licensed program, up to an aggregate of \$175.0 million per licensed program.

In addition, we are obligated under the Bii Agreement to pay Bii Bio tiered royalties based on net sales of products arising from the licensed programs in the United States, and Bii Bio is obligated to pay us tiered royalties based on net sales of products arising from the licensed programs in the China Territory. The rates of royalties payable by us to Bii Bio, and by Bii Bio to us on net sales range from mid-teens to high-twenties. Each party's obligations to pay royalties expires, on a product-by-product and territory-by-territory basis, on the latest of 10 years after the first commercial sale of such licensed product in the United States or China Territory, as applicable; the expiration or abandonment of licensed patent rights that cover such product in the United States or China Territory, as applicable; and the expiration of regulatory exclusivity in the United States or the China Territory, as applicable. Royalty rates are subject to specified reductions and offsets.

The Bii Agreement will remain in force until expiration of all options or, if any option is exercised, expiration of all royalty payment obligations for all licensed products within such licensed program, unless terminated in its entirety or on a program-by-program basis by either party. Each party may terminate for convenience all rights and obligations with respect to any program for which it has an option, with 30 days' written notice (if the terminating party has not exercised an option for such program) or 180 days' notice (following the exercise of an option for such program). The Bii Agreement may also be terminated by either party for insolvency of the other party, and either party may terminate the Bii Agreement in its entirety or on a program-by-program basis for the other party's uncured material breach on 60 days' written notice (or 30 days' notice following failure to make payment).

Patent License Agreement with Xencor

In August 2019, we entered into a patent license agreement with Xencor, Inc., or Xencor, and such agreement, the Xencor Agreement. Pursuant to the Xencor Agreement, we obtained a non-exclusive, sublicensable (only to our affiliates and subcontractors) license to incorporate Xencor's half-life extension Fc region-related technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. We are obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's half-life extension Fc-related technologies, for each of the influenza A and HBV research programs. These technologies are used in our VIR-2482 and VIR-3434 product candidates.

In consideration for the grant of the license, we paid Xencor an upfront fee. For each of the influenza A and HBV research programs, we will be required to pay Xencor development and regulatory milestone payments of up to \$17.8 million in the aggregate, and commercial sales milestone payments of up to \$60 million in the aggregate, for a total of up to \$77.8 million in aggregate milestones for each program and \$155.5 million in aggregate milestones for both programs. On a product-by-product basis, we will also be obligated to pay tiered royalties based on net sales of licensed products in the low single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the expiration of the last to expire valid claim in the licensed patents covering such product in such country.

The Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Xencor Agreement. We may terminate the Xencor Agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either

[Table of Contents](#)

party may terminate the Xencor Agreement for the other party's uncured material breach upon 60 days' written notice (or 30 days in the case of non-payment) or in the event of bankruptcy of the other party immediately upon written notice. Xencor may terminate the Xencor Agreement immediately upon written notice if we challenge, or upon 30 days' written notice if any of our sublicensees challenge, the validity or enforceability of any patent licensed to us under the Xencor Agreement.

Letter Agreement with the Bill & Melinda Gates Foundation

In December 2016, we entered into a letter agreement with the Bill & Melinda Gates Foundation, or the Gates Agreement, in connection with the Bill & Melinda Gates Foundation's investment in us through the purchase of \$10.0 million of shares of our Series A-1 convertible preferred stock in December 2016 and \$10.0 million of shares of our Series B convertible preferred stock in January 2019. We are obligated to use the proceeds of the Bill & Melinda Gates Foundation's investment in furtherance of its charitable purposes to (i) conduct our programs to develop products to treat or prevent infectious disease caused by HIV and TB, respectively, with at least 50% of the funds to be used for such programs, and (ii) develop our HCMV-based vaccine technology platform in a manner reasonably expected to result in the generation of products for the treatment or prevention of other specified infectious diseases, in each case for use in specified developing countries. We agreed to use reasonable efforts to achieve specified research and development milestones with respect to our HIV program and TB program and, if requested by the Bill & Melinda Gates Foundation, to work with the Bill & Melinda Gates Foundation on an additional mutually agreeable infectious disease program. Additionally, we are bound by specified global access commitments including a commitment to provide any products developed using the proceeds of the Bill & Melinda Gates Foundation's investment at an affordable price to the people most in need within the specified developing countries, not to exceed a specified percentage over our fully burdened manufacturing and sales costs.

If we fail to comply with (i) our obligations to use the proceeds of the Bill & Melinda Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a Specified Default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Bill & Melinda Gates Foundation under the Gates Agreement, at the Bill & Melinda Gates Foundation's request, at a price equal to the greater of (a) the original purchase price plus 5% compounding interest or (b) the fair market value as determined by an independent third-party, such redemption or sale, a Gates Foundation Redemption. Following a Gates Foundation Redemption, if either (i) a sale of the company or all of our material assets relating to the Gates Agreement, or (ii) a firmly underwritten public offering of our common stock at a per share valuation in excess of 200% of the valuation used for the Gates Foundation Redemption occurs, in each case closing prior to the first anniversary of the Gates Foundation Redemption, then solely if a preliminary prospectus for such offering, or a binding agreement with respect to any such sale transaction, was filed or signed, as applicable, prior to the six month anniversary of the first redemption or sale of any stock in such Gates Foundation Redemption, then the Bill & Melinda Gates Foundation will receive compensation equal to the excess of what it would have received in such transaction if it still held the stock redeemed or sold at the time of such public offering or sale transaction over what it actually received in the Gates Foundation Redemption. Additionally, if a Specified Default occurs, if we are unable or unwilling to continue the HIV program, TB program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the Bill & Melinda Gates Foundation will have the right to exercise a non-exclusive, fully-paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the Bill & Melinda Gates Foundation's charitable purpose.

In the event that we sell, exclusively license or transfer to a third party all or substantially all of our assets, the technology platform, or products arising from programs that are funded using the proceeds of the Bill & Melinda Gates Foundation's investment, such third party is required to assume our specified global access

[Table of Contents](#)

commitments on terms that are reasonably acceptable to the Bill & Melinda Gates Foundation. Additionally, we will not grant to any third party any rights or enter into any agreement with any third party that would restrict the Bill & Melinda Gates Foundation's rights with respect to our specified global access commitments unless such third party expressly assumes such commitments to the reasonable satisfaction of the Bill & Melinda Gates Foundation. Consistent with the foregoing restriction, we also specifically will not enter into any such agreement negotiated in connection with a decision by us not to pursue the technology platform controlled by us as a result of our acquisition of TomegaVax. The global access commitments will continue for as long as the Bill & Melinda Gates Foundation continues to be a charitable entity.

Separately, in January 2018 and March 2018, we entered into two grant agreements with the Bill & Melinda Gates Foundation, pursuant to which the Bill & Melinda Gates Foundation agreed to grant additional funding to us for our HIV and TB programs, respectively, through the award of two research grants totaling in the aggregate up to \$12.2 million with respect to the HIV program, and up to \$14.9 million with respect to the TB program if we achieve all the specified research and development milestones or reporting deliverables under the grants. As of June 30, 2019, we had received \$11.7 million with respect to the HIV program and \$10.8 million with respect to the TB program. These grant agreements will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for our breach, failure to progress the applicable funded projects, in the event of our change of control, change in our tax status, or significant changes in our leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the applicable project.

Our Acquisition Agreements

Agreement and Plan of Merger with TomegaVax

In September 2016, we entered into an agreement and plan of merger with TomegaVax, or the TomegaVax Merger Agreement, pursuant to which we purchased all equity interests of TomegaVax, a preclinical private biotechnology company. The primary asset purchased in the acquisition was a CMV vector-based vaccine platform for the development of products directed to HBV, HIV and TB.

In connection with the entry into the TomegaVax Merger Agreement, we also entered into a letter agreement with TomegaVax, or the TomegaVax Letter Agreement, which provides for certain payments to TomegaVax's former stockholders prior to September 2024, in each case so long as we are continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, we will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of \$30.0 million if the per share price of our publicly traded common stock, or implied price per share of our Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least \$45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and the stage of our clinical development at the time of the relevant event triggering the payment. The share price of our publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of our common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of our common stock, at the discretion of our board of directors.

Securities Purchase Agreement with Humabs

In August 2017, we entered into a securities purchase agreement with Humabs and its securities holders, or the Humabs SPA, pursuant to which we purchased all equity interests of Humabs. Pursuant to the Humabs SPA,

[Table of Contents](#)

we are required to pay up to \$135.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for an HBV product, or the HBV Milestones, and up to \$105.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for another product. Pursuant to the Humabs SPA, we are required to use commercially reasonable efforts to achieve such milestones during a specified period following the closing of the Humabs acquisition. In addition, Humabs' securities holders are also entitled to receive certain pass-through payments that Humabs receives under certain license agreements, including the 2012 MedImmune Agreement, following deduction of certain expenses incurred by us or Humabs thereunder.

Agreement and Plan of Merger with Agenovir

In January 2018, we entered into an agreement and plan of merger, or the Agenovir Merger Agreement, with Agenovir Corporation, or Agenovir, pursuant to which we purchased all equity interests of Agenovir. The primary assets purchased in the acquisition were in-process research and development programs in human papillomavirus, or HPV, and hepatitis B virus, or HBV, generally intended to utilize CRISPR/Cas9.

Pursuant to the Agenovir Merger Agreement, we are required to use commercially reasonable efforts following the closing date to develop and seek regulatory approval in the United States for at least one product arising from the HBV program acquired under the Agenovir Merger Agreement. With respect to the HPV program, other than an obligation of Agenovir during a specified period (which has now expired) to use reasonable efforts to divest or grant a license to a third party, we do not have any ongoing diligence obligations to progress activities under the HPV program. During a specified period following the closing of the Agenovir acquisition, we will be required to pay Agenovir's former stockholders up to \$45.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first HBV product, and if we elect to progress the HPV program, we will owe up to \$45.0 million in the aggregate for the achievement of development and regulatory milestones for the first HPV product. In addition, during a specified period following the closing of the Agenovir acquisition, if we successfully commercialize one or more products arising from the HBV program or the HPV program, we will owe milestone payments for the achievement of specified levels of worldwide annual net sales of up to \$90.0 million for products arising from each program, or up to \$180.0 million in the aggregate, if we were to commercialize products from both the HBV program and the HPV program.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We are currently manufacturing product candidates of three different platforms: antibodies, T cells and siRNAs. We have established our own internal chemistry, manufacturing and control, or CMC, capabilities and are working with contract development and manufacturing organizations, or CDMOs, to supply our early stage product candidates in the near-term. We have completed our internal capacity build in process development, analytical development, quality, manufacturing, and supply chain. Specifically, our San Francisco, California and Portland, Oregon facilities include laboratories that support process development, production of HCMV research viral seed stock and selected quality control testing for our products.

We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1 and Phase 2 clinical trials. Material for any Phase 3 clinical trials and commercial supply will

[Table of Contents](#)

require large-volume, low-cost-of-goods production, and we are in discussions with additional large-scale CDMOs to plan for future scale-up and capacity.

Production Modalities

Antibody Platform

The technology and industrial processes for producing mAbs represent mature technical disciplines. Process optimization and standardization over the last 20 years has enabled process portability and facilitates production at a network of CDMOs, as well as the partnered use of excess capacity with other biopharmaceutical companies. We have already produced batches of Phase 1/2 mAb clinical trial material for two of our programs through a CDMO. For Phase 3 clinical trials and commercial supply, we are in discussions with additional large-scale CDMOs.

T Cell Platform

Our T cell platform is based on genetically engineered HCMV. We have attenuated the HCMV for the purpose of patient safety, but this attenuation also reduces its yield in production. To address this inefficiency, we have made significant internal investments in process development and scale-up, largely funded by the Bill & Melinda Gates Foundation. We have established a reproducible Good Manufacturing Practices, or GMP, process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred and executed at two CDMOs specializing in live vaccine manufacturing.

siRNA Platform

Alnylam is currently supplying clinical material from their CDMO sites for the current VIR-2218 Phase 1/2 clinical trial. We will assume responsibility for technology transfer and manufacturing in advance of any Phase 3 clinical trial. In addition to the current manufacturing locations, other CDMOs are capable of producing kilogram-scale batches of siRNA and we may contract for Phase 3 manufacturing at one of these qualified facilities.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less

[Table of Contents](#)

expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

HBV

Current FDA-approved treatments for chronic HBV infection include PEG-IFN-a, marketed by Roche Holding AG, or Roche, and oral antiviral agents such as nucleoside analogs, marketed by Gilead Sciences, Inc., or Gilead, and Bristol-Myers Squibb Company. These treatments do not lead to either a functional or a complete cure in the vast majority of patients, and in the case of nucleoside analogs, require life-long therapy. Several large and small pharmaceutical companies are developing programs with various mechanisms of action, to be used alone or in combination, with the goal of achieving an HBV functional or complete cure. Companies with RNAi agents in clinical development include Arbutus Biopharma Corporation, Dicerna Pharmaceuticals, Inc., Ionis Pharmaceuticals, Inc. (together with GlaxoSmithKline plc, or GSK), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals, Inc., or Janssen), and Roche. In addition, GC Pharma is developing an antibody against surface antigen. Several companies, including Altimmune, Inc., GSK, Janssen and Transgene SA, have therapeutic vaccines in late-preclinical or early-clinical development.

Flu

There are numerous approved seasonal influenza vaccines, including trivalent, quadrivalent, high-dose, and adjuvanted products, marketed by GSK, Sanofi Pasteur, and Seqirus (owned by CSL Limited). In addition, there are approved antiviral agents to treat influenza, such as Xofluza and Tamiflu, marketed by Roche, as well as other neuraminidase inhibitors.

While several companies, including Janssen, Roche, AstraZeneca plc have conducted clinical trials of antibodies for the treatment of influenza, to our knowledge, there are currently no other prophylactic mAbs in development. Several vaccines are in clinical development from large companies such as GSK, and smaller ones such as Medicago Inc., Novavax, Inc., and Vaccitech Limited, among others. Some intend to improve efficacy or convenience over existing seasonal vaccines, and others are pursuing a universal flu vaccine approach with broad strain coverage and at least one year of protection.

HIV

No FDA-approved vaccine is currently available for the prevention of HIV. Several large and small pharmaceutical companies, including Sanofi, GSK, Janssen, GeoVax Labs, Inc., and Profectus Biosciences, Inc. are actively engaged in vaccine research and development in this area. These and other companies are developing vaccines using viral vectors, nanoparticles, DNA, or formulations, with the goal of stimulating T cell-mediated and/or neutralizing antibody responses against HIV. To our knowledge, none are using a CMV-based vector. Numerous clinical trials of these vaccines are ongoing with support from the National Institutes of Health Vaccine Research Center, the Bill & Melinda Gates Foundation, the U.S. military, the International AIDS Vaccine Initiative, the European Vaccine Initiative, the South African AIDS Initiative, and their academic and industry partners. In addition, many of these institutions are also studying the passive transfer of broadly neutralizing antibodies against HIV for prophylactic and therapeutic applications.

We may also compete with oral or long-acting antiretroviral therapies for pre-exposure prophylaxis of HIV. Truvada, marketed by Gilead, is a once-daily therapy approved for this indication. Janssen and Merck & Co., Inc. have long-acting formulations in development.

[Table of Contents](#)

TB

BCG is the only approved prophylactic vaccine for TB, and widely used in routine newborn immunization in endemic regions. However, BCG does not prevent pulmonary TB, the most common form of disease at any age. In addition, it is not recommended for immune-compromised persons, such as HIV-infected. Because of these limitations, several booster and primary vaccines are in clinical development, led by consortiums including the Tuberculosis Vaccine Initiative, International AIDS Vaccine Initiative, academic institutions, and industry partners such as GSK, among others. To prevent latent TB infection from progressing to active disease, rifapentine-based therapies are the current standard of care. Sanofi-Aventis is the main supplier of rifapentine. There are several ongoing clinical trials aimed at reducing dosing frequency or duration.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new therapeutic approaches and potential indications, and other inventions that are important to our business. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important for the development and implementation of our business. We also rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on confidentiality agreements to protect our interests. We require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our patent portfolio includes patents and patent applications that are licensed from a number of collaborators and other third parties, including Alnylam, OHSU, MedImmune, IRB, Rockefeller and Xencor, and patents and patent applications that are owned by us. Our patent portfolio includes patents and patent applications that cover our product candidates VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-2020, and the use of these candidates for therapeutic purposes. Our proprietary technology has been developed primarily through acquisitions, relationships with academic research centers and contract research organizations.

For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, process of making, formulation and dosing regimen-related claims.

In total, our patent portfolio, including patents licensed from our collaborators and other third parties, comprises over 75 different patent families as of August 31, 2019, filed in various jurisdictions worldwide. Our patent portfolio includes issued patents and patent applications in the United States and in many international countries. Our patent portfolio for our product candidates and technology platforms is outlined below:

Patent Portfolio by Product Candidate

VIR-2218

Licensed Patents

Our VIR-2218 intellectual property portfolio includes three different patent families that we have exclusively licensed from Alnylam.

One of these families includes, as of August 31, 2019, one issued patent in Lebanon directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of this patent is presently estimated to expire in 2035, absent any available patent term adjustments or extensions.

[Table of Contents](#)

The three licensed families also collectively include, as of August 31, 2019, one patent application in the United States, two pending international Patent Cooperation Treaty, or PCT, applications and 28 patent applications in Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Gulf Cooperation Council (GCC), Hong Kong, India, Jordan, Japan, Mexico, Pakistan, Paraguay, Singapore, South Korea, Thailand, Taiwan, Venezuela and Vietnam directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire between 2035 and 2039, absent any available patent term adjustments or extensions.

Patents Owned by Us

In addition, we own three different patent families that are directed to VIR-2218 in combination with one or more other therapeutics. These families collectively include, as of August 31, 2019, four patent applications in the United States. The applications in these families include method of treatment claims and composition for use in treatment claims for VIR-2218 in combination as a second therapeutic. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire between 2039 and 2040, absent any available patent term adjustments or extensions.

VIR-3434

Licensed Patents

Our VIR-3434 intellectual property portfolio includes a patent family that we have exclusively licensed from Rockefeller, which includes, as of August 31, 2019, one pending patent application in the United States, one pending PCT patent application and one pending patent application in Europe. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from the application in this family is presently estimated to expire in 2038, absent any available patent term adjustments or extensions.

Our VIR-3434 intellectual property portfolio also includes patents and patent applications that we have non-exclusively licensed from Xencor. As of August 31, 2019, these patents and applications include seven issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2025, absent any available patent term adjustments or extensions. Additionally, as of August 31, 2019, these patents and applications include 69 issued patents in Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Estonia, Finland, France, Germany, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of August 31, 2019, a pending patent application in the United States and six patent applications pending in Brazil, Canada, China, Europe and Russia directed to composition of matter claims, pharmaceutical composition claims, composition for use in treatment claims, and process (methods of producing) claims. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

Patents Owned by Us

We also own one patent family that includes, as of August 31, 2019, one pending patent application in the United States. The application includes composition of matter claims, pharmaceutical composition claims,

[Table of Contents](#)

method of treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2040, absent any available patent term adjustments or extensions.

In addition, through our subsidiary Humabs, we own two different patent families that collectively include, as of August 31, 2019, three pending patent applications in the United States and 24 pending patent applications in the African Regional Intellectual Property Organization, or ARIPO, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, Nigeria, New Zealand, Organisation Africaine de la Propriété Intellectuelle, or OAPI, the Philippines, Singapore, South Africa, South Korea, Sri Lanka, Thailand and Vietnam. The applications in these families include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2036 and 2039, absent any available patent term adjustments or extensions.

VIR-2482

Licensed Patents

Our VIR-2482 intellectual property patent portfolio includes two different patent families that we have exclusively licensed from MedImmune, which collectively include, as of August 31, 2019, two issued patents in Japan and Taiwan that include composition of matter claims, pharmaceutical composition claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2034, absent any available patent term adjustments or extensions.

The two families licensed from MedImmune also collectively include, as of August 31, 2019, two patent applications in the United States and 24 patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, Mexico, Russia, Singapore and Taiwan. The applications in these families include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2034 and 2037, absent any available patent term adjustments or extensions.

Our VIR-2482 intellectual property portfolio also includes patents and patent applications that we have non-exclusively licensed from Xencor. As of August 31, 2019, these patents and applications include seven issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2025, absent any available patent term adjustments or extensions. Additionally, as of August 31, 2019, these patents and applications include 69 issued patents in Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Estonia, Finland, France, Germany, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of August 31, 2019, a pending patent application in the United States and six patent applications pending in Brazil, Canada, China, Europe and Russia directed to composition of matter claims, pharmaceutical composition claims, composition for use in treatment claims, and process (methods of producing) claims. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

[Table of Contents](#)

Patents Owned by Us

We also own one patent family that includes, as of August 31, 2019, one pending patent application in the United States. The application includes composition of matter claims, pharmaceutical composition claims, method of treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2040, absent any available patent term adjustments or extensions.

Through our subsidiary Humabs, we co-own a patent family (with MedImmune) that includes, as of August 31, 2019, two issued patents in Japan and Taiwan that include composition of matter claims, pharmaceutical composition claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2034, absent any available patent term adjustments or extensions.

This co-owned family also includes, as of August 31, 2019, one patent application in the United States and 14 patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, South Korea, Mexico, Russia, Singapore and Taiwan. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2034, absent any available patent term adjustments or extensions.

In addition, through our subsidiary Humabs, we own a patent family that includes, as of August 31, 2019, one pending PCT patent application. The application in this family includes composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of any patents issuing from the patent application in this family is presently estimated to expire in 2039, absent any available patent term adjustments or extensions.

VIR-1111

Licensed Patents

Our VIR-1111 intellectual property patent portfolio includes seven different patent families that we have exclusively licensed from OHSU.

Two of these families collectively include, as of August 31, 2019, three issued patents in the United States directed to composition of matter claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2031 and 2032, absent any available patent term adjustments or extensions. Additionally, four of the seven patent families collectively include, as of August 31, 2019, 133 issued patents in Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Monaco, Macedonia, Malta, New Zealand, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

The seven licensed families also collectively include, as of August 31, 2019, eight patent applications in the United States and 96 patent applications in Algeria, ARIPO (Africa), Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Mexico, New Zealand, Nigeria, OAPI (Africa), Panama, Peru, Singapore, South Africa, South Korea, Thailand, Tunisia and the Ukraine directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods

[Table of Contents](#)

of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2025 and 2037, absent any available patent term adjustments or extensions.

Patents Owned by Us

We co-own a patent family that includes, as of August 31, 2019, one patent application in the United States and 20 patent applications in ARIPO (Africa), Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore, South Africa, Thailand and the Ukraine directed to composition of matter claims, method of treatment claims and composition for use in treatment claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2035, absent any available patent term adjustments or extensions.

VIR-2020

Licensed Patents

Our VIR-2020 intellectual property patent portfolio includes five different patent families that we have exclusively licensed from OHSU.

Two of these families collectively include, as of August 31, 2019, three issued patents in the United States directed to composition of matter claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2031 and 2032, absent any available patent term adjustments or extensions. Additionally, the five patent families collectively include, as of August 31, 2019, 133 issued patents in Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Monaco, Macedonia, Malta, New Zealand, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

The five licensed families also collectively include, as of August 31, 2019, six patent applications in the United States and 30 patent applications in ARIPO (Africa), Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, Mexico, New Zealand, Singapore, South Africa, Thailand and the Ukraine directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2025 and 2037, absent any available patent term adjustments or extensions.

Patent Portfolio by Technology Platform

siRNA Platform

Licensed Patents

Our siRNA intellectual property portfolio includes three additional different patent families that we have exclusively licensed from Alnylam.

Two of the three families collectively include, as of August 31, 2019, seven issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims.

[Table of Contents](#)

The 20-year term of these patents is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions. Additionally, the three patent families collectively include, as of August 31, 2019, 58 issued patents in Albania, Australia, Belgium, Canada, China, Croatia, Denmark, Finland, France, Germany, Hungary, Iceland, Indonesia, Ireland, Japan, Latvia, Lithuania, Luxembourg, Monaco, Macedonia, Macao, Netherlands, Norway, Russia, Singapore, Slovenia, Sweden, Switzerland and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions.

The three licensed families also collectively include, as of August 31, 2019, three patent applications in the United States and 14 patent applications in Australia, Canada, China, Europe, Hong Kong, India, Japan, South Korea, Russia and Thailand directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of the issued patent and any patents issuing from pending patent applications in these families is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions.

We have also exclusively licensed from Alnylam, as of August 31, 2019, two issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2022 and 2028, absent any available patent term adjustments or extensions.

We have also exclusively licensed from Alnylam, as of August 31, 2019, two patent applications in the United States directed to composition of matter claims and pharmaceutical composition claims. The 20-year term of any patents issuing from these pending applications is presently estimated to expire in 2023, absent any available patent term adjustments or extensions.

We also have an exclusive license to additional Alnylam platform technology for HBV licensed products.

Antibody Platform

Licensed Patents

We have exclusively licensed from Rockefeller a patent family that includes, as of August 31, 2019, one patent application in the United States, one pending international PCT patent application and one pending application in Europe directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from the applications in this family is presently estimated to expire in 2038, absent any available patent term adjustments or extensions.

We have exclusively licensed from IRB two patent families that relate to our antibody platform technology. One of these families includes, as of August 31, 2019, two issued patents in the United States directed to process (methods of producing) claims, and 23 issued patents in Austria, Australia, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Netherlands, Portugal, Romania, Singapore, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to process (methods of producing) claims. The two families also collectively include one pending patent application in the United States directed to process (methods of producing) claims, and one pending international PCT patent application directed to composition of matter claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of the issued patents and any patent issuing from the pending patent applications in these families is presently estimated to expire between 2024 and 2037, absent any available patent term adjustments or extensions.

In addition, we have non-exclusively licensed a group of patents and applications from Xencor. As of August 31, 2019, these patents and applications include seven issued patents in the United States directed to

[Table of Contents](#)

composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2025, absent any available patent term adjustments or extensions. Additionally, as of August 31, 2019, these patents and applications include 69 issued patents in Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Estonia, Finland, France, Germany, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Poland, Russia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of August 31, 2019, a pending patent application in the United States and six patent applications pending in Brazil, Canada, China, Europe and Russia directed to composition of matter claims, pharmaceutical composition claims, composition for use in treatment claims, and process (methods of producing) claims. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2021 and 2028, absent any available patent term adjustments or extensions.

T Cell Platform

Licensed Patents

We have exclusively licensed from OHSU 10 different patent families related to our T cell portfolio.

Four of the 10 families collectively include, as of August 31, 2019, seven issued patents in the United States, directed to composition of matter claims and method of treatment claims. The 20-year term of the issued patents in these families is presently estimated to expire between 2031 and 2034, absent any available patent term adjustments or extensions. In addition, six of the 10 families collectively include, as of August 31, 2019, 165 issued patents in Albania, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Germany, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, New Zealand, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey and the United Kingdom directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treating claims and process (methods of producing) claims. The 20-year term of the issued patents in these families is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

The 10 patent families also collectively include, as of August 31, 2019, 10 patent applications in the United States and 90 patent applications in Algeria, ARIPO (Africa), Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Mexico, New Zealand, Nigeria, OAPI (Africa), Panama, Peru, Singapore, South Africa, South Korea, Thailand, Tunisia and the Ukraine directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treating claims and process (methods of producing) claims. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire between 2025 and 2040, absent any available patent term adjustments or extensions.

Patents Owned by Us

In addition, we own a patent family that includes, as of August 31, 2019, one patent application in the United States directed to process (method of producing) claims. The 20-year term of any patent issuing from the pending patent application in this family is presently estimated to expire in 2040, absent any available patent term adjustments or extensions.

[Table of Contents](#)***Innate Immunity Platform***

We have know-how relating to our innate immunity platform and are continually developing our intellectual property in this area, as well as evaluating external technologies and assets that may also help grow this platform.

We do not currently license or own any patents related to our innate immunity platform.

Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. In addition, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trademarks and Know-How

In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patent and trademark protection, we rely upon know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by our employees and through relationships with third parties. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

[Table of Contents](#)

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing.

Small molecule drugs are subject to regulation under the Food, Drug, and Cosmetic Act, or FDCA, and biological products are additionally subject to regulation under the Public Health Service Act, or PHSA, and both are subject to additional federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

U.S. Biopharmaceuticals Regulation

The process required by the FDA before drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of a drug candidate and safety, purity and potency of a proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a new drug application, or NDA, or biologics license application, or BLA, as applicable, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA, or licensure of a BLA, to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the

[Table of Contents](#)

investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent institutional review board for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

For purposes of biopharmaceutical development, human clinical trials are typically conducted in three sequential phases that may overlap or be combined;

- *Phase 1.* The investigational product is initially introduced into patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the application. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

[Table of Contents](#)

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an institutional review board can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the institutional review board's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

NDA/BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA, as applicable, requesting approval to market the product for one or more indications. The application must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an application requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. The FDA has sixty days from the applicant's submission to either issue a refusal to file letter or accept the application for filing, indicating that it is sufficiently complete to permit substantive review.

Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine whether a drug is safe and effective for its intended use and a BLA to determine whether a biologic is safe, pure and potent. FDA also reviews whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an application and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

[Table of Contents](#)

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the application with a risk evaluation and mitigation strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. Priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies

[Table of Contents](#)

to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

[Table of Contents](#)

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, only a handful of biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as

[Table of Contents](#)

the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Hatch-Waxman Amendments and Exclusivity

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredient(s) in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the

[Table of Contents](#)

ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents, or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

The FDA also cannot approve an ANDA or 505(b)(2) application until all applicable non-patent exclusivities listed in the Orange Book for the branded reference drug have expired. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug containing an active moiety that has not been approved by FDA in any other NDA. An “active moiety” is defined as the molecule responsible for the drug substance’s physiological or pharmacologic action. During that five-year exclusivity period, the FDA cannot accept for filing (and therefore cannot approve) any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA that relies on the FDA’s approval of the drug, provided that the FDA may accept an ANDA four years into the NCE exclusivity period if the ANDA applicant also files a paragraph IV certification.

Drugs and biologics can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

Federal and State Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties laws.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which can be enforced by individuals through civil whistleblower and qui tam actions, prohibit

[Table of Contents](#)

any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities, which include certain healthcare providers, healthcare clearinghouses and health plans, that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished

[Table of Contents](#)

profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Coverage and Reimbursement

The future commercial success of our product candidates, if approved, will depend in part on the extent to which third-party payors, such as governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage of and establish adequate reimbursement levels for our product candidates. Third-party payors generally decide which products they will pay for and establish reimbursement levels for those products. In particular, in the United States, no uniform policy for coverage and reimbursement exists. Private health insurers and other third-party payors often provide coverage and reimbursement for products based on the level at which the government, through the Medicare program, provides coverage and reimbursement for such products, but also on their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

In the United States, the European Union, or EU, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of products, particularly for new and innovative products, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for products. For example, federal and state governments reimburse products at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Similarly, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party payor reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates, if approved, or exclusion of our product candidates from coverage and reimbursement. The cost containment measures that third-party payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates.

[Table of Contents](#)

Healthcare Reform

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by third-party payors, and significantly impacts the U.S. pharmaceutical industry. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expands eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the Public Health Service Act. At this time, we are unsure of the full impact that the ACA will have on our business.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA, and we expect such challenges and amendments to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain ACA provisions or otherwise circumvent requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on nonexempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In December 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

[Table of Contents](#)

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the BBA, will continue through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and is implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019. On January 31, 2019, the HHS Office of Inspector General proposed modifications to U.S. federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. In addition, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These measures could reduce future demand for our products or put pressure on our pricing.

Additionally, in May 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

[Table of Contents](#)

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidates. For example, in the EU, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Further, some countries outside of the United States, including the EU member states, Switzerland and the United Kingdom, have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, the collection and use of personal health data is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical companies in relation to the processing of personal data of EU subjects. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to process personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern potentially burdensome documentation requirements, granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them, the information provided to the individuals, the transfer of personal data out of the EU, security breach notifications, and security and confidentiality of the personal data. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU. Guidance on implementation and compliance practices are often updated or otherwise revised.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Facilities

Our corporate headquarters are located in San Francisco, California, where we lease approximately 43,500 square feet of office, research and development, engineering, and laboratory space pursuant to a lease agreement which commenced on April 1, 2017 and expires on August 31, 2024, with an option to extend for five years. We also have several other locations, including a location in Portland, Oregon, where we lease approximately 3,862 square feet of office, research and development, engineering, and laboratory space pursuant to a lease agreement which commenced on June 15, 2015 and expires on January 31, 2021, with no option to extend, a location in Bellinzona, Switzerland, where we lease approximately 12,500 square feet of office, research and development, engineering, and laboratory space pursuant to a lease agreement which commenced on January 1, 2019 and expires on December 31, 2028, with an option to extend, and a location in South San Francisco, California, where we lease approximately 5,525 square feet of office, research and development and engineering space

[Table of Contents](#)

pursuant to a lease agreement which commenced on June 1, 2019 and expires on May 1, 2020, with an option to extend. We also have offices located in Boston, Massachusetts, San Diego, California and St. Louis, Missouri. We believe that our existing facilities are adequate for our near-term needs, but expect to need additional space as we grow, and we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Employees

As of August 31, 2019, we had 206 full-time employees, 162 of whom were primarily engaged in research and development activities. A total of 82 employees have an M.D., Ph.D. or Pharm.D. degree. Substantially all of our employees are located in San Francisco, California, South San Francisco, California, Portland, Oregon and Bellinzona, Switzerland. None of our employees is represented by a labor union and we consider our employee relations to be good.

[Table of Contents](#)

MANAGEMENT

The following table sets forth information regarding our executive officers and directors, including their ages as of September 30, 2019:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Executive Officers		
George Scangos, Ph.D.	71	President, Chief Executive Officer and Director
Howard Horn	42	Chief Financial Officer and Secretary
Michael Kamarck, Ph.D.	68	Chief Technology Officer
Phil Pang, M.D., Ph.D.	44	Chief Medical Officer
Jay Parrish, Ph.D.	44	Chief Business Officer
Herbert (Skip) Virgin, M.D., Ph.D.	63	Executive Vice President, Research and Chief Scientific Officer
Non-Employee Directors		
Vicki Sato, Ph.D.(3)	71	Chairman of the Board of Directors
Kristina Burow(2)	45	Director
Klaus Frueh, Ph.D.(4)	59	Director
Robert More(1)(2)	52	Director
Robert Nelsen(3)	56	Director
Dipchand (Deep) Nishar(3)	50	Director
Robert Perez(1)(2)	55	Director
Saira Ramasastry(1)	43	Director
Phillip Sharp, Ph.D.(2)	75	Director

- (1) Member of our audit committee.
- (2) Member of our compensation committee.
- (3) Member of our nominating and corporate governance committee.
- (4) Dr. Frueh will resign from our board of directors effective immediately upon the closing of this offering.

Executive Officers

George Scangos, Ph.D., has served as our President and Chief Executive Officer and as a member of our board of directors since January 2017. From July 2010 to December 2016, Dr. Scangos served as Chief Executive Officer and as a member of the board of directors of Biogen Inc., or Biogen, a publicly traded biopharmaceutical company focused on the treatment of serious diseases. From October 1996 to July 2010, Dr. Scangos served as President and Chief Executive Officer at Exelixis, Inc., a drug discovery and development company. From 1993 to 1996, Dr. Scangos served as President of Bayer Biotechnology, where he was responsible for research, business development, process development, manufacturing, engineering and quality assurance of Bayer Biotechnology's biological products. Before joining Bayer Biotechnology in 1987, Dr. Scangos was a Professor of Biology at Johns Hopkins University. Dr. Scangos has served as a member of the board of directors of various publicly traded companies, including: Exelixis, Inc., since 1996; Agilent Technologies, Inc., a life sciences, diagnostics and applied chemical analysis company, since 2014; and Anadys Pharmaceuticals, Inc., a biopharmaceutical company, from 2003 to 2010. Dr. Scangos served as Chair of PhRMA in 2016, and as the Chair of the California Healthcare Institute in 2010. He was a member of the board of directors of the Global Alliance for TB Drug Development from 2006 until 2010. Dr. Scangos currently serves on the Board of Trustees of Cornell University and the Board of Overseers of the University of California, San Francisco. Dr. Scangos received his B.A. in Biology from Cornell University and a Ph.D. in Microbiology from the University of Massachusetts. We believe that Dr. Scangos is qualified to serve on our board of directors due to his extensive training as a scientist, significant knowledge and experience with respect to the biotechnology, healthcare and pharmaceutical industries, and his perspective and experience he brings as our President and Chief Executive Officer.

[Table of Contents](#)

Howard Horn has served as our Chief Financial Officer since March 2017. Prior to joining us, Mr. Horn served Biogen as its Vice President, Business Planning from June 2015 to October 2016, where he led Biogen's resource allocation processes across all functions and regions. From October 2013 to June 2015, Mr. Horn served Biogen's Vice President, Strategic Corporate Financing, where he led Biogen's corporate capital allocation processes. Mr. Horn previously held positions of increasing responsibility as a consultant in the Pharmaceutical and Medical Products Practice at McKinsey & Company, from 2004 to 2013, and as an equity research analyst in the Life Sciences group at UBS Group AG, from 1999 to 2002. Mr. Horn received his B.A. in Economics from Princeton University and his M.B.A. from the Wharton School of the University of Pennsylvania.

Michael Kamarck, Ph.D., has served as our Chief Technology Officer since June 2017. From September 2013 to May 2017, Dr. Kamarck served as a principal for Willow Creek Biotech Consulting, where he provided consultation in the field of biotechnology technical operations for numerous large and small companies. From March 2014 to December 2014, Dr. Kamarck served as interim head of the Therapeutic Monoclonal Antibodies organization at Sanofi, where he led the integration and reorganization of the biotechnology assets of Sanofi and Genzyme. From December 2009 until March 2012, Dr. Kamarck served as President of Merck BioVentures and as Senior Vice President of Vaccines and Biologics Manufacturing at Merck & Co., Inc., or Merck. From May 2001 to October 2009, he held various senior executive positions at Wyeth Pharmaceuticals, Inc., or Wyeth, including President, Technical Operations and Product Supply and was responsible for global technical operations for all of the Wyeth businesses. Dr. Kamarck also served as a member of the Wyeth Management Committee. Prior to Wyeth, he was employed by Bayer AG for 17 years in a variety of technical and leadership capacities. Dr. Kamarck previously served on the board of directors of public companies Omni Bio Pharmaceutical, Inc. and Unilife Corporation, from January 2013 to June 2015 and July 2016 to October 2017, respectively. Dr. Kamarck received his B.A. from Oberlin College, his Ph.D. from Massachusetts Institute of Technology, or MIT, and was a Leukemia Society Fellow at Yale University.

Phil Pang, M.D., Ph.D., has served as our Chief Medical Officer since December 2018. Prior to that, Dr. Pang served as our Senior Vice President, Development, from September 2017 to December 2018. From December 2016 to September 2017, Dr. Pang served as our Vice President, Clinical. From January 2016 to December 2016, Dr. Pang served as Chief Medical Officer of Riboscience LLC, a biotech startup focused on developing small molecule antivirals, where he oversaw both pre-clinical and clinical development. From May 2011 to November 2015, he worked as Program Lead at Gilead Sciences, Inc., or Gilead, where his responsibilities included, among other things, leading a large matrix team responsible for worldwide approval of a hepatitis C treatment. Dr. Pang received his B.S. in Biological Sciences from Stanford University and his Ph.D. in Biochemistry and Biophysics from Columbia University and his M.D. from Columbia University Vagelos College of Physicians and Surgeons.

Jay Parrish, Ph.D., has served as our Chief Business Officer since July 2017 and is one of our co-founders. Prior to that, Dr. Parrish served as our Senior Vice President, Strategy and Corporate Development, from April 2017 to July 2017. Dr. Parrish is a Venture Partner at ARCH Venture Partners, L.P., or ARCH Venture Partners, where he has served since May 2016. From September 2011 to May 2016, Dr. Parrish served in Gilead's Corporate Development group, where he was involved in building Gilead's oncology and infectious disease portfolio, ultimately leading infectious disease business development for the company. Dr. Parrish also served as a scientist in Gilead's medicinal chemistry group, from March 2004 to September 2011. Since 2012, Dr. Parrish has served as a part-time instructor at UC Berkeley Extension, where he teaches chemistry to undergraduates and post-baccalaureates. He also previously completed a postdoctoral fellowship at the Scripps Research Institute. Dr. Parrish received his B.S. in Chemistry from Emory University, a Ph.D. in Synthetic Organic Chemistry from the University of South Florida and an M.B.A. from the University of California, Berkeley Haas School of Business.

Herbert (Skip) Virgin, M.D., Ph.D., has served as our Executive Vice President of Research and Chief Scientific Officer since January 2018. From July 1990 to February 2019, Dr. Virgin was a full-time member of the faculty of Washington University School of Medicine, St. Louis, Missouri. At Washington University School

[Table of Contents](#)

of Medicine he served as the Edward Mallinckrodt Professor and Chair of the Department of Pathology & Immunology from 2006 until 2017. He maintains an association with Washington University as a non-tenured faculty member. Earlier in his career, Dr. Virgin trained in internal medicine at Brigham and Women's Hospital in Boston and in infectious diseases at Barnes Hospital in St. Louis. He is a member of the American Society for Clinical Investigation, the Association of American Physicians, the American Academy of Microbiology and the National Academy of Sciences. Dr. Virgin previously served on the Board of Reviewing Editors of *Science*, and is currently on the Editorial Boards of *Cell* and *Cell Host and Microbe*. Dr. Virgin received his A.B. in Biology, his M.D. and his Ph.D. in Immunology from Harvard University and Harvard Medical School.

Non-Employee Directors

Vicki Sato, Ph.D., has served as Chairman of our board of directors since December 2016. She was a professor of management practice at Harvard Business School from September 2006 to July 2017 and was a professor in the Department of Molecular and Cell Biology at Harvard University from July 2005 until October 2015. Previously, she served as President of Vertex Pharmaceuticals, Inc., or Vertex, a publicly-traded biotechnology company, which she joined in 1992. Prior to becoming President of Vertex, she was the Chief Scientific Officer and Senior Vice President of Research and Development. Prior to joining Vertex, Dr. Sato served as Vice President of Research at Biogen. Dr. Sato is a member of the board of directors of the following public companies: Bristol Myers Squibb Company, BorgWarner, Inc., Denali Therapeutics, Inc., and Syros Pharmaceuticals, Inc. Dr. Sato received her A.B. in Biology from Radcliffe College and her A.M. and Ph.D. in Biology from Harvard University. She conducted her postdoctoral work at both the University of California, Berkeley and Stanford Medical Center. We believe Dr. Sato is qualified to serve on our board of directors due to her experience as a senior executive and as a director of several life sciences companies, and because of her knowledge of our industry.

Kristina Burow has served as a member of our board of directors since December 2016. Ms. Burow has served as Managing Director with ARCH Venture Partners since November 2011 and previously held positions of increasing responsibility at ARCH from August 2002 to November 2011. Ms. Burow also currently serves on the board of directors of the following companies: Gossamer Bio, Inc., a public biopharmaceutical company, Vividion Therapeutics, Inc., or Vividion, a biotechnology company, Lycera Corp., a biopharmaceutical company, BlackThorn Therapeutics, Inc., a biopharmaceutical company, Metacrine, Inc., a biotechnology company, Scholar Rock Holding Corporation, a public biotechnology company, Unity Biotechnology, a public biotechnology company, Beam Therapeutics Inc., a biotechnology company, Pretzel Therapeutics, Inc., a biotechnology company, Rome Therapeutics, Inc., a biotechnology company, Boragen, Inc., an agtechnology company, AgBiome Inc., a biotechnology company, and Sienna Biopharmaceuticals, Inc., a public pharmaceutical company. She previously was a co-founder and member of the board of directors of Receptos, Inc., a public pharmaceutical company, prior to its acquisition by Celgene Corporation, and of Sapphire Energy, Inc., an energy company. Ms. Burow has participated in a number of other ARCH portfolio companies including Kythera Biopharmaceuticals, Inc., a biotechnology company acquired by Allergan plc, and Ikaria Inc., a biotechnology company acquired by Madison Dearborn Partners LLC. Prior to joining ARCH, Ms. Burow was an associate with the Novartis BioVenture Fund in San Diego and an early employee at the Genomics Institute of the Novartis Research Foundation. Ms. Burow received her B.S. in Chemistry from the University of California, Berkeley, an M.A. in Chemistry from Columbia University and an M.B.A. from the University of Chicago. We believe that Ms. Burow is qualified to serve on our board of directors due to her extensive experience serving on the board of directors of clinical-stage biotechnology companies and her investment experience in the life sciences industry.

Klaus Frueh, Ph.D., has served as a member of our board of directors since September 2016. As our co-founder, Dr. Frueh also serves as a consultant to us since June 2016. Dr. Frueh is professor for molecular microbiology and immunology at the Vaccine and Gene Therapy Institute of Oregon Health & Science University since 2000. From March 2011 to September 2016, Dr. Frueh also served as President and Chief Scientific Officer of Tomegavax, Inc., a biotechnology company which we acquired in September 2016. From

[Table of Contents](#)

1994 to 2000 he was a Senior and then Principal Scientist for Johnson & Johnson, and from 1991 to 1994, a Postdoctoral Scientist at The Scripps Research Institute. Dr. Frueh received his B.S. in Biology from the University of Konstanz in Baden-Württemberg, Germany, and his Ph.D. in Molecular Biology from the University of Heidelberg in Baden-Württemberg, Germany. We believe Dr. Frueh is qualified to serve on our board of directors due to his extensive experience in molecular immunology and virology, his intimate knowledge of key technology platforms, and his perspective and vision as one of our co-founders. Dr. Frueh has informed us of his intention to resign from our board of directors effective immediately upon the closing of this offering.

Robert More has served as a member of our board of directors since September 2016. Since October 2016, Mr. More has served as Managing Director of Alta Partners, a venture capital firm. From July 2013 to May 2015, Mr. More served as Senior Advisor for the Bill & Melinda Gates Foundation and led its Global Health Venture Initiative. He served as a General Partner of venture capital firms Frazier Healthcare Ventures and Domain Associates from September 2008 to June 2013 and from June 1996 to July 2008, respectively. Mr. More currently serves on the board of directors of Sienna Biopharmaceuticals, Inc., a public pharmaceutical company. He also currently serves on the board of directors of the following private companies: Affinivax, Inc., a biotechnology company, eGenesis, a biotechnology company, Qihan Biotech, a biotechnology company, Sirenas, LLC, a biotechnology company, Tyra Biosciences, Inc., a biotechnology company, and as an advisor on Liquiglide, Inc. a biotechnology company. Mr. More previously served on the board of directors of the following public companies: Achaogen, Inc., a biopharmaceutical company, Carticcept Medical, Inc., a medical device company, Cartiva, a medical device company, Neothetics Inc., a pharmaceutical company, Glaukos Corporation, a medical technology company, and IntraLase Corp., a medical device company acquired by Advanced Medical Optics in 2007. He also previously served on the board of directors of the following life sciences companies: ESP Pharma, Inc., Proxima Therapeutics, Inc., NovaCardia, Inc., Esprit Pharma, Inc. and Oceana Therapeutics, Inc. Mr. More was a founding member of the board of directors of the Kauffman Fellows Program and previously served on the board of directors of One Revolution and The Foundation for Innovative New Diagnostics (FIND). Mr. More currently serves on one of the governing boards of the Biotechnology Innovation Organization (BIO). He received his B.S. in Biology from Middlebury College and an M.B.A. from the Darden School of Business Administration at the University of Virginia. We believe that Mr. More is qualified to serve on our board of directors due to his experience serving on the board of directors of clinical-stage biotechnology companies, his extensive experience as a director of public companies and his investment experience in the life sciences industry.

Robert Nelsen has served as a member of our board of directors since April 2016. Mr. Nelsen co-founded ARCH Venture Partners in 1986 and has served as a Managing Director since 1994. Mr. Nelsen has served on the board of directors of Denali Therapeutics, Inc. since May 2015, Unity Biotechnology, Inc. since November 2011 and Karuna Therapeutics, Inc. since August 2018, each a public biotechnology company, and currently serves on the board of directors of a number of private companies. Mr. Nelsen previously served on the board of directors of a number of public biotechnology companies, including Agios Pharmaceuticals, Inc. from 2007 to June 2017, Fate Therapeutics, Inc. from 2007 to June 2014, Syros Pharmaceuticals, Inc. from 2012 to June 2018, Sage Therapeutics, Inc. from 2013 to March 2016, Juno Therapeutics, Inc. from 2013 to March 2018 (until it was acquired by Celgene Corporation), Bellerophon Therapeutics, Inc. from February 2014 to November 2015, Sienna Biopharmaceuticals, Inc. from October 2015 to September 2018 and Gossamer Bio, Inc. from January 2018 to December 2018 (prior to its initial public offering). He previously served as a trustee of the Fred Hutchinson Cancer Research Institute and the Institute for Systems Biology, and was a member of the board of directors of the National Venture Capital Association. Mr. Nelsen received an M.B.A. from the University of Chicago and a B.S. from the University of Puget Sound with majors in Economics and Biology. We believe that Mr. Nelsen is qualified to serve on our board of directors due to his venture capital experience in the biotechnology industry.

Dipchand (Deep) Nishar has served as a member of our board of directors since August 2017. Since June 2015, Mr. Nishar has worked for SoftBank Investment Advisors and currently serves as Senior Managing Partner. From January 2009 to October 2014, Mr. Nishar served in various roles with LinkedIn Corporation,

[Table of Contents](#)

most recently as Senior Vice President, Products and User Experience. From August 2003 to January 2009, Mr. Nishar served in various roles with Google Inc., most recently as the Senior Director of Products for the Asia-Pacific region. Mr. Nishar has served on the board of directors of Guardant Health, Inc. since October 2018, and previously served on the board of directors of Tripadvisor, Inc. from September 2013 to June 2019 and the board of directors of OPower, Inc. from August 2013 to June 2016. Mr. Nishar received his M.B.A. with highest honors (Baker Scholar) from Harvard Business School, his M.SEE from the University of Illinois, Urbana-Champaign, and his B.Tech with honors from the Indian Institute of Technology. We believe Mr. Nishar is qualified to serve on our board of directors due to his extensive background in the technology industry and his investment activities in the life science sector.

Robert Perez has served as a member of our board of directors since January 2017. Mr. Perez has been an Operating Partner at General Atlantic, a global growth equity firm, since January 2019, the Executive Chairman and member of the board of directors of Akili Interactive Labs, Inc. since 2017, the founder and Chairman of Life Science Cares, a non-profit organization, since 2016, and was the founder and Managing Partner at Vineyard Sound Advisors, LLC, a biopharmaceutical consulting firm, from March 2015 to December 2018. He previously served as Chief Executive Officer of Cubist Pharmaceuticals, Inc., or Cubist, a public pharmaceutical company, from January 1, 2015 until Cubist was acquired by Merck later that month. Mr. Perez joined Cubist in 2003 as Senior Vice President, Sales and Marketing, and served as Executive Vice President and Chief Operating Officer from 2007 to 2012 and President and Chief Operating Officer from 2012 to December 2014. Prior to joining Cubist, Mr. Perez held positions of increasing responsibility at Biogen from 1995 to 2003, most recently as Vice President of Biogen's CNS business unit. Mr. Perez previously held various sales and marketing positions at Zeneca Pharmaceuticals. Mr. Perez has been a director of AMAG Pharmaceuticals, Inc., a public pharmaceutical company, since January 2009, Zafgen, Inc. a public biopharmaceutical company, since September 2015, and Spark Therapeutics, Inc., a public gene therapy company, since January 2018. In addition, Mr. Perez has served as a director of ImmusanT, Inc., a biotechnology company, since April 2018. Mr. Perez also currently serves as a member of the Board of Trustees at the Dana-Farber Cancer Institute, Inc. Mr. Perez was a member of the board of directors of Cidara Therapeutics, Inc., a public biotechnology company, from March 2015 to June 2018, Flex Pharma, a public biotechnology company, from September 2015 to January 2018, Cubist from April 2014 to January 2015 and Unum Therapeutics Inc., a public biopharmaceutical company, from March 2018 to June 2019. Mr. Perez received his B.S. from California State University, Los Angeles and an M.B.A. from the Anderson Graduate School of Management at the University of California, Los Angeles. We believe that Mr. Perez is qualified to serve on our board of directors due to his expertise and experience as an executive in the pharmaceutical industry and his board experience provide him with the qualifications and skills to serve on our Board.

Saira Ramasastry has served as a member of our board of directors since September 2019. Ms. Ramasastry has served as Managing Partner of Life Sciences Advisory, LLC since April 2009, a company that she founded to provide strategic advice, business development solutions and innovative financing strategies for the life science industry. Ms. Ramasastry also serves on the Industry Advisory Board of the Michael J. Fox Foundation for Parkinson's Research, and as business and sustainability lead for the European Prevention of Alzheimer's Dementia consortium. From August 1999 to March 2009, Ms. Ramasastry was an investment banker with Merrill Lynch & Co., Inc. where she helped establish the biotechnology practice and was responsible for origination of mergers and acquisitions, strategic and capital markets transactions. Prior to joining Merrill Lynch she served as a financial analyst in the mergers and acquisitions group at Wasserstein Perella & Co., an investment banking firm, from July 1997 to September 1998. Ms. Ramasastry currently serves on the board of directors of the following public companies: Sangamo Therapeutics Inc., Cassava Sciences, Inc., Innovate Biopharmaceuticals, Inc., Glenmark Pharmaceuticals, Ltd. Ms. Ramasastry previously served on the board of directors of Repros Therapeutics Inc. from March 2013 until it was acquired by Allergan plc in January 2018. Ms. Ramasastry received her B.A. in economics with honors and distinction and an M.S. in management science and engineering from Stanford University, as well as an M. Phil. in management studies from the University of Cambridge where she is a guest lecturer for the Bioscience Enterprise Programme and serves on the Cambridge Judge Business School Advisory Council. Ms. Ramasastry is also a Health Innovator Fellow of the Aspen Institute and a member of the Aspen Global Leadership Network. We believe that Ms. Ramasastry is qualified to serve on our board of

[Table of Contents](#)

directors due to her extensive experience in global healthcare investment banking and strategic advisory consulting in the life sciences industry.

Phillip Sharp, Ph.D., has served on our board of directors since January 2017. Dr. Sharp has been an institute professor at MIT since 1999. Prior to that, he led MIT's Department of Biology from 1991 to 1999 before assuming the directorship of the McGovern Institute from 2000 to 2004. Much of Dr. Sharp's scientific work has been conducted at MIT's Center for Cancer Research (now the Koch Institute), which he joined in 1974 and directed from 1985 to 1991. Dr. Sharp is the winner of the 1993 Nobel Prize in Physiology or Medicine. Dr. Sharp is a member of the board of directors of Alnylam Pharmaceuticals, Inc. and Syros Pharmaceuticals, Inc., each a publicly traded biopharmaceutical company. From 1982 to 2009, Dr. Sharp served as a director of Biogen, which he co-founded in 1978. Dr. Sharp earned his B.A. from Union College (Kentucky) and his Ph.D. in Chemistry from the University of Illinois, Champaign-Urbana. He completed his postdoctoral training at the California Institute of Technology. We believe Dr. Sharp is qualified to serve on our board of directors due to his scientific expertise and his experience as a director of a publicly traded company.

Family Relationships and Other Arrangements

There are no family relationships among our directors and executive officers. Pursuant to our amended and restated voting agreement, which will terminate upon the closing of this offering, the following directors were designated as directors to our board of directors:

- Mr. Nelsen and Ms. Burow were designated by ARCH Venture Fund IX, L.P. and elected by the holders of a majority of the shares of our Series A-1 convertible preferred stock.
- Mr. Nishar was designated by Softbank Vision Fund (AIV M1) L.P. and elected by the holders of a majority of the shares of our Series A-1 convertible preferred stock.
- Dr. Frueh was designated by the holders of a majority of the shares of our Series A-2 convertible preferred stock.
- Dr. Scangos was designated by the holders of a majority of shares of our common stock and convertible preferred stock, voting together as a single class.
- Drs. Sato and Sharp, Ms. Ramasastry and Messrs. More and Perez were designated by the other members of our board of directors or elected by the holders of a majority of shares of our common stock and convertible preferred stock, voting together as a single class.

Board Composition

Our board of directors currently consists of 10 members with no vacancies but will be reduced to nine members in connection with Dr. Frueh's resignation effective immediately upon the closing of this offering. In accordance with our amended and restated certificate of incorporation, which will be effective immediately after the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Ms. Burow, Mr. More and Dr. Sato, and their terms will expire at the annual meeting of stockholders to be held in 2020;
- The Class II directors will be Mr. Nelsen, Mr. Perez and Dr. Sharp, and their terms will expire at the annual meeting of stockholders to be held in 2021; and
- The Class III directors will be Mr. Nishar, Ms. Ramasastry and Dr. Scangos, and their terms will expire at the annual meeting of stockholders to be held in 2022.

[Table of Contents](#)

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under The Nasdaq Stock Market LLC, or Nasdaq, Marketplace Rules, or the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors as a public company within one year of listing.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors except Dr. Scangos and Dr. Frueh, representing two of our 10 directors, do not have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the applicable rules and regulations of the U.S. Securities and Exchange Commission, or the SEC, and the listing requirements of the Nasdaq Listing Rules. Our board of directors has determined that Dr. Scangos, by virtue of his position as our President and Chief Executive Officer, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which we will post on our website at www.vir.bio upon the completion of this offering.

Audit Committee

The audit committee is responsible for assisting our board of directors in its oversight of the integrity of our consolidated financial statements, the qualifications and independence of our independent auditors and our internal financial and accounting controls. The audit committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the audit committee. The audit committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

Our audit committee consists of Ms. Ramasastry, Mr. More and Mr. Perez. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The chair of our audit committee is Ms. Ramasastry. Our board of directors has determined that Ms. Ramasastry and Mr. More are each an “audit committee financial expert” as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental consolidated financial statements, in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector.

[Table of Contents](#)

Compensation Committee

The compensation committee approves the compensation objectives for the company, the compensation of the chief executive officer and approves, or recommends to our board of directors for approval, the compensation for other executives. The compensation committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

Our compensation committee consists of Mr. More, Ms. Burow, Mr. Perez and Dr. Sharp. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and are “non-employee directors” as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is Mr. More.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee makes recommendations regarding corporate governance, the composition of our board of directors, identification, evaluation and nomination of director candidates and the structure and composition of committees of our board of directors. In addition, the nominating and corporate governance committee is responsible for developing and recommending corporate governance guidelines to our board of directors, as applicable to the company.

Our nominating and corporate governance committee consists of Dr. Sato, Mr. Nishar and Mr. Nelsen. The chair of our nominating and corporate governance committee is Dr. Sato. Each member of the nominating and corporate governance committee is an independent director as defined by the Nasdaq Listing Rules.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a written code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions, and agents and representatives. The full text of our code of business conduct and ethics will be posted on our website at www.vir.bio upon the completion of this offering. The nominating and corporate governance committee of our board of directors will be responsible for overseeing our code of business conduct and ethics and any waivers applicable to any director, executive officer or employee. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and agents and representatives, on our website identified above.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective immediately after the completion of this offering, and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, limits our directors’ liability, and may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL

[Table of Contents](#)

provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with some of our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

[Table of Contents](#)

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2018, which consist of our principal executive officer and our two most highly compensated executive officers, are:

- George Scangos, Ph.D., our President and Chief Executive Officer;
- Herbert (Skip) Virgin, M.D., Ph.D., our Executive Vice President, Research and Chief Scientific Officer; and
- Phil Pang, M.D., Ph.D., our Chief Medical Officer.

Summary Compensation Table

The following table provides information regarding the compensation earned by our named executive officers for the year ended December 31, 2018.

Name and Principal Position	Year	Salary \$(1)	Bonus \$(2)	Option Awards \$(3)	Non-Equity Incentive Plan Compensation \$(4)	All Other Compensation \$(5)	Total (\$)
George Scangos, Ph.D. <i>President and Chief Executive Officer</i>	2018	512,019	—	—	260,000	11,000	783,019
Herbert (Skip) Virgin, M.D., Ph.D. <i>Executive Vice President, Research and Chief Scientific Officer</i>	2018	592,308	600,000	627,750	259,000	84,000	2,163,058
Phil Pang, M.D., Ph.D. <i>Chief Medical Officer</i>	2018	388,594	—	290,900	186,000	11,000	876,494

- (1) Salary amounts represent (i) actual amounts paid during 2018 (see “—Narrative to the Summary Compensation Table—Annual Base Salary” below), plus (ii) payments made during 2018 to cash out accrued paid time off in the following amounts: (1) for Dr. Scangos, \$12,019; (2) for Dr. Virgin, \$3,671; and (3) for Dr. Pang, \$13,594. The salary amount paid to Dr. Virgin was prorated for his start date in January 2018.
- (2) Reflects sign-on bonus awarded to Dr. Virgin. See “—Narrative to the Summary Compensation Table—Bonuses and Non-Equity Incentive Plan Compensation” below for a description of the material terms pursuant to which this compensation was awarded.
- (3) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during fiscal year 2018 computed in accordance with ASC 718 for stock-based compensation transactions. See Note 12 to our audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumptions used in the calculation of these amounts. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.
- (4) Reflects performance-based cash bonuses awarded to our named executive officers. See “—Narrative to the Summary Compensation Table—Bonuses and Non-Equity Incentive Plan Compensation” below for a description of the material terms pursuant to which this compensation was awarded.
- (5) Represents: (i) for Dr. Scangos, \$11,000 for matching contributions made by us under our 401(k) plan; (ii) for Dr. Virgin, \$84,000 for a housing allowance; and (iii) for Dr. Pang, \$11,000 for matching contributions made by us under our 401(k) plan.

Narrative to the Summary Compensation Table

Our board of directors reviews compensation annually for all employees, including our named executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has historically determined our executive officers’ compensation and has typically reviewed and discussed management’s proposed compensation with our chief executive officer for all executives

[Table of Contents](#)

other than our chief executive officer. Based on those discussions and its discretion, our board of directors then approved the compensation of each executive officer. Upon the completion of this offering, the compensation committee will determine our executive officers' compensation and follow this process, but generally the compensation committee itself, rather than our board of directors, will approve the compensation of each executive officer.

Annual Base Salary

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with executives at other companies. The 2018 base salaries for our named executive officers were as follows: (i) \$500,000 for Dr. Scangos; (ii) \$600,000 for Dr. Virgin; and (iii) \$325,000 for Dr. Pang from January 1, 2018 through June 30, 2018 and \$425,000 from July 1, 2018 through December 31, 2018. Dr. Virgin's 2018 salary was prorated for his start date in January 2018.

Bonuses and Non-Equity Incentive Plan Compensation

Our named executive officers are each eligible to receive an annual bonus based on individual and company performance. In 2018, Dr. Scangos was eligible to earn an annual target performance bonus equal to 50% of his 2018 base salary based on the achievement of corporate objectives, and Dr. Virgin and Dr. Pang were eligible to earn an annual target performance bonus equal to 40% of each executive's 2018 base salary based on the achievement of individual and corporate objectives. Payment of 2018 annual bonuses was based in part on us achieving certain research and product development, capital raising and other target goals. The compensation committee recommended and our board of directors determined that Dr. Scangos, Dr. Virgin and Dr. Pang were entitled to approximately 104.0%, 108.0% and 109.25%, respectively, of their target bonuses. In addition, Dr. Virgin received a one-time sign-on bonus of \$600,000 in January 2018 pursuant to his offer letter agreement.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees and consultants, including our named executive officers. As of December 31, 2018, stock option awards and restricted stock awards were the only forms of equity awards we granted to our named executive officers.

We have historically used stock options, as well as a restricted stock grant and restricted stock purchase for Dr. Scangos, as incentives for long-term compensation to our named executive officers because the return on the awards is tied to an increase in the stock price. We may grant equity awards at such times as our board of directors determines appropriate. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to this offering, all of the equity incentive awards we granted were made pursuant to our 2016 Equity Incentive Plan, as amended, or the 2016 Plan. Following this offering, we will grant equity incentive awards under the terms of our 2019 Equity Incentive Plan, or the 2019 Plan. The terms of our equity plans are described below under "—Equity Incentive Plans."

All options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award. Our stock option grants generally vest over a four-year period,

[Table of Contents](#)

and may be subject to acceleration of vesting and exercisability under certain termination and change in control events. The restricted stock held by Dr. Scangos vested and continues to vest over consecutive two-year periods, for an aggregate vesting period of 4 years. See “—Outstanding Equity Awards at Fiscal Year-End” below for additional information.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding the outstanding equity awards held by our named executive officers as of December 31, 2018. All awards were granted pursuant to the 2016 Plan. See “—Equity Incentive Plans—2016 Equity Incentive Plan” below for additional information.

Name and Principal Position	Grant Date	Vesting Commencement Date	Option Awards				Stock Awards	
			Number of Securities Underlying Unexercised Options (Exercisable) (#)	Number of Securities Underlying Unexercised Options (Unexercisable) (#)	Option Exercise Price (\$)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(1)
George Scangos, Ph.D. <i>President and Chief Executive Officer</i>	1/7/2017 ⁽²⁾	11/1/2018	—	—	—	—	3,060,037	15,835,692
Herbert (Skip) Virgin, M.D., Ph.D. <i>EVP, Research and Chief Scientific Officer</i>	1/26/2018 ⁽³⁾	1/8/2018	—	555,555	\$ 1.53	1/26/2028	—	—
Phil Pang, M.D., Ph.D. <i>Chief Medical Officer</i>	3/9/2017 ⁽³⁾	12/14/2016	55,556	55,555	\$ 0.86	3/9/2027	—	—
	4/27/2018 ⁽³⁾	4/27/2018	—	111,111	\$ 1.53	4/27/2028	—	—
	7/19/2018 ⁽³⁾	7/19/2018	—	111,111	\$ 1.58	7/19/2028	—	—

- (1) Based on the fair market value of our common stock of \$5.18 as of December 31, 2018 as determined by our board of directors in reliance of a third party valuation.
- (2) The restricted shares vest in 24 equal monthly installments ending on October 1, 2020 and are eligible for accelerated vesting as described below under the section titled “Potential Payments and Benefits upon Termination or Change in Control.”
- (3) 25% of the shares underlying this option vest on the one-year anniversary of the vesting commencement date and the remainder vest in 36 equal monthly installments thereafter and are eligible for accelerated vesting as described below under the section titled “Potential Payments and Benefits upon Termination or Change in Control.”

Employment Arrangements

Below are descriptions of our employment letter agreements with Drs. Scangos, Virgin and Pang. The letter agreements generally provide for at-will employment without any specific term and set forth the named executive officer’s initial base salary and eligibility for employee benefits. Each of our named executive officers has executed a form of our standard confidential information and inventions assignment agreement.

Our named executive officers are entitled to certain change in control and severance benefits pursuant to their employment letter agreements and our Change in Control and Severance Benefit Plan, the terms of which are described under the section titled “—Potential Payments and Benefits upon Termination or Change in Control” below.

Agreement with George Scangos, Ph.D.

In December 2016, we entered into an employment letter agreement with Dr. Scangos, our President and Chief Executive Officer. Pursuant to his letter agreement, Dr. Scangos was initially entitled to an annual base salary of \$500,000 and a discretionary annual target bonus equal to 50% of his base salary, contingent upon the achievement of performance

[Table of Contents](#)

objectives established by us. Dr. Scangos' letter agreement also provided that Dr. Scangos was entitled to a grant of 6,676,444 shares of restricted stock, that vest as follows: 25% on October 1, 2017 and the remainder in 36 equal monthly installments thereafter, subject to Dr. Scangos' continued employment through each such date. In lieu of the restricted stock grant for 6,676,444 shares, on January 7, 2017, Dr. Scangos was granted 3,338,222 shares of restricted stock under the 2016 Plan with 50% of these shares vesting on October 1, 2017 and the remainder of the shares vesting in 12 equal monthly installments thereafter, in each case subject to his continued service through the vesting dates. In addition, on January 7, 2017, Dr. Scangos purchased 3,338,222 shares of restricted stock pursuant to the 2016 Plan at the then-current fair market value of \$0.86 per share pursuant to a promissory note, subject to our right to repurchase the shares upon termination of his service for any reason at a purchase price equal to the lesser of fair market value or the amount Dr. Scangos paid for the shares that lapses in 24 equal monthly installments beginning November 1, 2018, subject to accelerated vesting as provided below under the section titled "Potential Payments and Benefits upon Termination or Change in Control." Dr. Scangos' letter agreement also provided that, if following the closing of our Series B convertible preferred stock financing, Dr. Scangos' ownership was greater than a 7% ownership of our company, then he would be required to automatically forfeit such number of shares causing his ownership to exceed 7%, and if his ownership was less than 7%, then he was entitled to an additional grant of restricted stock equal to such number of shares that would result in an ownership of 7%. Our Series B convertible preferred stock financing closed in January 2019 causing Dr. Scangos' ownership to be reduced to below 7%, and in March 2019, Dr. Scangos was granted an option to purchase 562,444 shares of our common stock that vest as follows: 25% on October 1, 2018 and the remainder in 36 equal monthly installments thereafter, subject to Dr. Scangos' continued employment through each such date, subject to accelerated vesting as provided below under the section titled "—Potential Payments and Benefits upon Termination or Change in Control." Dr. Scangos and our board of directors each approved Dr. Scangos receiving the stock option grant in lieu of the grant of restricted stock and in full satisfaction of the obligation noted above.

We amended and restated Dr. Scangos' letter agreement in August 2019. Pursuant to his amended and restated letter agreement, Dr. Scangos will continue to serve as our chief executive officer and as a member of our board of directors. Dr. Scangos is entitled to an annual base salary of \$517,500 and a discretionary annual target bonus equal to 50% of his base salary, contingent upon the achievement of performance objectives established by us. In addition to his previous equity awards, Dr. Scangos will be eligible to receive future equity award grants as determined by our board of directors or its compensation committee. The amended and restated letter agreement provides that Dr. Scangos is entitled to certain accelerated vesting of the equity awards granted prior to the date of the amended and restated letter agreement upon a change in control, and is eligible to participate in our Change in Control and Severance Benefit Plan, as described below under the section titled "—Potential Payments and Benefits upon Termination or Change in Control."

Agreement with Herbert (Skip) Virgin, M.D., Ph.D.

In October 2017, we entered into an employment letter agreement with Dr. Virgin, our current Executive Vice President, Research and Chief Scientific Officer. Pursuant to his letter agreement, Dr. Virgin was initially entitled to an annual base salary of \$600,000 and a discretionary annual target bonus equal to 40% of his base salary, contingent upon the achievement of performance objectives established by us. In addition, Dr. Virgin received a one-time sign-on bonus of \$600,000 in January 2018 and a housing allowance of \$7,000 per month for three years. Dr. Virgin's letter agreement also provided that Dr. Virgin was entitled to the grant of a stock option to purchase 555,555 shares of our common stock, which was granted in January 2018, that vests as follows: 25% on the anniversary of his start date and the remainder in 36 equal monthly installments thereafter, subject to Dr. Virgin's continued employment through each such date. The option granted to Dr. Virgin permits him to net exercise the option following the completion of this offering. Dr. Virgin's letter agreement also provided that he was eligible to receive an option to purchase 111,111 shares of our common stock on or following the one-year anniversary of his start date based on the achievement of performance goals determined by our board of directors and our chief executive officer. Dr. Virgin was also granted an option to purchase 133,332 shares of our common stock in July

[Table of Contents](#)

2019 that vest as follows: 25% on the one-year anniversary of July 12, 2019 and the remainder in 36 equal monthly installments thereafter, subject to Dr. Virgin's continued employment through each such date.

We amended and restated Dr. Virgin's letter agreement in September 2019. Pursuant to his amended and restated letter agreement, Dr. Virgin will continue to serve as our Executive Vice President, Research and Chief Scientific Officer. Dr. Virgin is entitled to an annual base salary of \$621,000 and a discretionary annual target bonus equal to 40% of his base salary, contingent upon the achievement of performance objectives established by us. Dr. Virgin's annual bonus payments are calculated in a manner that takes into consideration the amounts he receives in royalty payments relating to licensing fees paid by us to Washington University in St. Louis. Subject to his continued employment with us, Dr. Virgin is entitled to a housing allowance of \$7,000 per month through February 1, 2021 to maintain a residence in the San Francisco area. In addition to his previous equity awards, Dr. Virgin will be eligible to receive future equity grants as determined by our board of directors or its compensation committee. The amended and restated letter agreement provides that Dr. Virgin is eligible to participate in our Change in Control and Severance Benefit Plan as described below under the section titled "—Potential Payments and Benefits upon Termination or Change in Control."

Agreement with Phil Pang, M.D., Ph.D.

In December 2016, we entered into an employment letter agreement with Dr. Pang, our current Chief Medical Officer. Pursuant to his letter agreement, Dr. Pang held the position of Vice President, Clinical, and was initially entitled to an annual base salary of \$275,000 and a discretionary annual target bonus equal to 25% of his base salary, contingent upon the achievement of performance objectives established by us. In July 2017, Dr. Pang's annual base salary was increased to \$300,000, and his annual target performance bonus was increased to 30% of his base salary, contingent upon the achievement of performance objectives established by us. In September 2017, Dr. Pang was promoted to Senior Vice President, Development and his salary was increased to \$325,000, and his annual target performance bonus was increased to 40% of his base salary, contingent upon the achievement of performance objectives established by us. In July 2018, Dr. Pang's annual base salary was increased to \$425,000. In December 2018, Dr. Pang was promoted to Chief Medical Officer. Dr. Pang's letter agreement also provided that Dr. Pang was entitled to the grant of a stock option to purchase 111,111 shares of our common stock, which was granted in March 2017, that vest as follows: 25% on the one-year anniversary of his start date and the remainder in 36 equal monthly installments thereafter, subject to Dr. Pang's continued employment through each such date.

We amended and restated Dr. Pang's letter agreement in August 2019. Pursuant to his amended and restated letter agreement, Dr. Pang will continue to serve as our Chief Medical Officer. Dr. Pang is entitled to an annual base salary of \$442,000 and a discretionary annual target bonus equal to 40% of his base salary, contingent upon the achievement of performance objectives established by us. In addition to his previous equity awards, Dr. Pang will be eligible to receive future equity grants as determined by our board of directors or its compensation committee. The amended and restated letter agreement provides that Dr. Pang is eligible to participate in our Change in Control and Severance Benefit Plan as described below under the section titled "—Potential Payments and Benefits upon Termination or Change in Control."

Potential Payments and Benefits upon Termination or Change in Control

Regardless of the manner in which a named executive officer's employment with us terminates, the named executive officer is entitled to receive amounts earned during his term of service, including salary and accrued unused vacation pay.

Accelerated Vesting of Dr. Scangos' Equity Awards

Dr. Scangos' amended and restated employment letter agreement provides that in the event of a change in control (as defined in the 2016 Plan), all shares, options and other securities subject to unvested equity awards

[Table of Contents](#)

granted to Dr. Scangos prior to August 27, 2019 will become fully vested, except that the number of shares that would have vested within six months following the change in control will remain subject to the vesting schedule and will vest subject to Dr. Scangos continued employment during the six-month period; provided, however, any such remaining unvested shares will become fully vested in the event of his termination without cause or his resignation for good reason (each as defined in our Change in Control and Severance Benefit Plan) prior to the expiration of such six-month period.

Change in Control and Severance Benefit Plan

In March 2019, our board of directors approved the Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan, or the Severance Plan. The Severance Plan provides for severance benefits for certain of our executives and senior management, including our named executive officers, subject to the execution and effectiveness of a release of claims. In the event of a covered termination, which is either a termination by us without cause (and other than as a result of death or disability) or the employee's resignation for good reason, that occurs during the 12-month period following a change in control, or the change in control period, (i) Dr. Scangos will be entitled to a lump sum cash payment equal to 18 months of base salary plus his annual target cash bonus multiplied by 1.5, up to 18 months of payment for continued group health plan benefits and full vesting acceleration of all outstanding equity awards and (ii) Dr. Virgin and Dr. Pang will each be entitled to a lump sum cash payment equal to 12 months of base salary plus his annual target cash bonus, up to 12 months of payment for continued group health plan benefits and full vesting acceleration of all outstanding equity awards.

In addition, the Severance Plan provides that in the event of a covered termination that occurs outside of the change in control period, (i) Dr. Scangos will be entitled to a lump sum cash payment equal to 12 months of base salary plus a pro-rated annual target cash bonus and up to 12 months of payment for continued group health plan benefits and (ii) Dr. Virgin and Dr. Pang will each be entitled to a lump sum cash payment equal to nine months of base salary plus a pro-rated annual target cash bonus and up to nine months of payment for continued group health plan benefits.

For purposes of the Severance Plan, the following definitions are used:

- “cause” means, with respect to a particular employee, the occurrence of any of the following events: (i) the employee's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) the employee's attempted commission of, or participation in, a fraud or act of dishonesty against us; (iii) the employee's intentional, material violation of any contract or agreement between the employee and us or of any statutory duty owed to us; (iv) the employee's unauthorized use or disclosure of our confidential information or trade secrets; or (v) the employee's gross misconduct.
- “good reason” for an employee's resignation means the occurrence of any of the following events, conditions or actions taken by us without “cause” and without such employee's consent: (i) a material reduction of the employee's annual base salary, which is a reduction of at least 20% of such employee's base salary (unless pursuant to a salary reduction program applicable generally to our similarly situated employees); (ii) a material reduction in the employee's authority, duties or responsibilities; (iii) a relocation of the employee's principal place of employment with us (or our successor, if applicable) to a place that increases the employee's one-way commute by more than 50 miles as compared to the employee's then-current principal place of employment immediately prior to the relocation (excluding regular travel in the ordinary course of business); provided that if the employee's principal place of employment is his or her personal residence, this clause (iii) will not apply; or (iv) a material breach by us of any material agreement between the employee and us; provided, however, that in each case above, in order for the employee's resignation to be deemed to have been for “good reason,” the employee must first give us written notice of the action or omission giving rise to “good reason” within 30 days after the first occurrence thereof; we must fail to reasonably cure such action or omission within 30 days after receipt of notice, and the employee's resignation must be effective not later than 30 days after the expiration of this cure period.

[Table of Contents](#)

- “change of control” means: (i) any person becomes the owner, directly or indirectly, of our securities representing more than fifty percent (50%) of the combined voting power of our then outstanding securities other than by virtue of a merger, consolidation or similar transaction; provided that notwithstanding the foregoing, a “change in control” will not be deemed to occur (1) on account of the acquisition of our securities by any institutional investor or any other person that acquires our securities in a transaction or series of related transactions that are primarily a private financing transaction for us or (2) solely because the level of ownership held by any person exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by us reducing the number of shares outstanding, provided that if a “change in control” would occur but for this clause as a result of the acquisition of voting securities by us, and after such share acquisition, the person becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the person over the designated percentage threshold, then a “change in control” will be deemed to occur; (ii) the consummation of a merger, consolidation or similar transaction involving us, directly or indirectly, if, immediately after the consummation of such merger, consolidation or similar transaction, our stockholders immediately prior thereto do not own, directly or indirectly, either (1) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (2) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction; or (iii) the consummation of a sale, lease, license or other disposition of all or substantially all of our and our subsidiaries’ consolidated assets, other than a sale, lease, license or other disposition of all or substantially all of our and our subsidiaries’ consolidated assets to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by our stockholders in substantially the same proportion as their ownership immediately prior to such sale, lease, license or other disposition.

Health and Welfare and Retirement Benefits; Perquisites

Health and Welfare Benefits and Perquisites

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances, such as the housing allowance provided to Dr. Virgin, as described above under “—Employment Arrangements—Agreement with Herbert (Skip) Virgin, M.D., Ph.D.”

401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the U.S. Internal Revenue Code of 1986, or the Code. Contributions are allocated to each participant’s individual account and are then invested in selected investment alternatives according to the participants’ directions. We currently match 100% of employee contributions of the first three percent of compensation, and 50% of contributions on the next two percent of compensation. Employees are immediately and fully vested in all contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan’s related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Our board of directors may elect to adopt qualified or nonqualified benefit plans in the future, if it determines that doing so is in our best interests.

[Table of Contents](#)

Equity Incentive Plans

2019 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, our 2019 Plan in 2019. We do not expect to issue equity awards under our 2019 Plan until after the closing of this offering, except for certain other employee grants and grants to certain non-employee directors that were made upon the effectiveness of our 2019 Plan, as described in the section titled “—Director Compensation—Director IPO Option Grants.” Our 2019 Plan will provide for the grant of incentive stock options within the meaning of Section 422 of the Code to our employees and our parent and subsidiary corporations’ employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2019 Plan will also provide for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2019 Plan will not exceed 14,322,292 shares, which is the sum of (i) 3,926,497 new shares, plus (ii) 1,873,503 shares that remain available for the issuance of awards under our 2016 Plan at the time our 2019 Plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that were granted under our 2016 Plan that terminate or expire prior to exercise or settlement; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under our 2019 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2020 through January 1, 2029, in an amount equal to 5% of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued on the exercise of incentive stock options, or ISOs, under our 2019 Plan is 37,000,000 shares.

Shares subject to stock awards granted under our 2019 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under our 2019 Plan. If any shares of common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us for any reason, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2019 Plan. Any shares reacquired in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of a stock award will again become available for issuance under the 2019 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2019 Plan or otherwise during any one calendar year to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such calendar year for service on the board of directors, will not exceed \$750,000 in total value (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes), or, with respect to the calendar year in which a non-employee director is first appointed or elected to our board of directors, \$1,100,000.

Plan Administration. Our board of directors, or a duly authorized committee or subcommittee of our board of directors, will administer our 2019 Plan and is referred to as the “plan administrator” herein. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards, provided that the officer may not grant any such awards to himself. Our board of directors will specify the total number of shares of our common stock that may be subject to stock awards granted by such officer in this manner. Under our 2019 Plan, our board of directors has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

[Table of Contents](#)

Under the 2019 Plan, the board of directors also generally has the authority to effect, with the consent of any adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding award; (ii) the cancellation of any outstanding award and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles. Under the 2019 Plan, our board of directors also has the authority to submit any amendment to the 2019 Plan for stockholder approval.

Stock Options. ISOs and nonstatutory stock options, or NSOs, are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2019 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2019 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2019 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include: (i) cash, check, bank draft or money order; (ii) a broker- assisted cashless exercise; (iii) the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer in each case, (i) an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument and (ii) an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a

[Table of Contents](#)

restricted stock unit award. Except as otherwise provided in the applicable award agreement or other written agreement, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2019 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. The appreciation distribution may be made in shares of our stock, in cash, in any combination of the two, or in any other form of consideration, as determined by our board of directors and contained in the applicable award agreements.

The plan administrator determines the term of stock appreciation rights granted under the 2019 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service, or any other period set by the applicable award agreement, so long as such period complies with applicable law. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death, or any other period set by the applicable award agreement, so long as such period complies with applicable law. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2019 Plan permits the grant of performance-based stock and cash awards. Our compensation committee may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (i) sales; (ii) revenue; (iii) assets; (iv) expenses; (v) market penetration or expansion; (vi) earnings from operations; (vii) earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization, incentives, service fees or extraordinary or special items, whether or not on a continuing operations or an aggregate or per share basis; (viii) net income or net income per common share (basic or diluted); (ix) return on equity, investment, capital or assets; (x) one or more operating ratios; (xi) borrowing levels, leverage ratios or credit rating; (xii) market share; (xiii) capital expenditures; (xiv) cash flow, free cash flow, cash flow return on investment, or net cash provided by operations; (xv) stock price, dividends or total stockholder return; (xvi) development of new technologies or products; (xvii) sales of particular products or services; (xviii) economic value created or added; (xix) operating margin or profit margin; (xx) customer acquisition or retention; (xxi) raising or refinancing of capital; (xxii) successful hiring of key individuals; (xxiii) resolution of significant litigation; (xxiv) acquisitions and

[Table of Contents](#)

divestitures (in whole or in part); (xxv) joint ventures and strategic alliances; (xxvi) spin-offs, split-ups and the like; (xxvii) reorganizations; (xxviii) recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; (xxix) or strategic business criteria, consisting of one or more objectives based on the following goals: achievement of timely development, design management or enrollment, meeting specified market penetration or value added, payor acceptance, patient adherence, peer reviewed publications, issuance of new patents, establishment of or securing of licenses to intellectual property, product development or introduction (including, without limitation, any clinical trial accomplishments, regulatory or other filings, approvals or milestones, discovery of novel products, maintenance of multiple products in pipeline, product launch or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals, or goals relating to acquisitions, divestitures or other business combinations (in whole or in part), joint ventures or strategic alliances; and (xxx) other measures of performance selected by the board of directors.

The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Our board of directors is authorized at any time in its sole discretion, to adjust or modify the calculation of a performance goal for such performance period in order to prevent the dilution or enlargement of the rights of participants, (i) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event or development; (ii) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting us, or our financial statements in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions; or (iii) in view of the board of director's assessment of our business strategy, performance of comparable organizations, economic and business conditions, and any other circumstances deemed relevant. Specifically, the board of directors is authorized to make adjustment in the method of calculating attainment of performance goals and objectives for a performance period as follows: (1) to exclude the dilutive effects of acquisitions or joint ventures; (2) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; and (3) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends. In addition, the board of directors is authorized to make adjustment in the method of calculating attainment of performance goals and objectives for a performance period as follows: (A) to exclude restructuring and/or other nonrecurring charges; (B) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated net sales and operating earnings; (C) to exclude the effects of changes to generally accepted accounting standards required by the Financial Accounting Standards Board; (D) to exclude the effects of any items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (E) to exclude the effects to any statutory adjustments to corporate tax rates; and (F) to make other appropriate adjustments selected by the board of directors.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class(es) and maximum number of shares reserved for issuance under the 2019 Plan; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and maximum number of shares that may be issued on the exercise of ISOs; and (iv) the class(es) and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

[Table of Contents](#)

Corporate Transactions. Our 2019 Plan provides that in the event of certain specified significant corporate transactions (or a change in control, as defined below), unless otherwise provided in an award agreement or other written agreement between us and the award holder, the plan administrator may take one or more of the following actions with respect to such stock awards:

- arrange for the assumption, continuation, or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting, in whole or in part, of the stock award and provide for its termination if not exercised (if applicable) at or before the effective time of the transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us;
- cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised before the effective time of the transaction, in exchange for a cash payment, if any; or
- make a payment in any form determined by our board of directors equal to the excess, if any, of (A) the value of the property the participant would have received on exercise of the award immediately before the effective time of the transaction, over (B) any exercise price payable by the participant in connection with the exercise.

The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

Under the 2019 Plan, a corporate transaction is generally the consummation of: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) a merger or consolidation where we do not survive the transaction; or (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. In the event of a change in control, the plan administrator may take any of the above-mentioned actions. Awards granted under the 2019 Plan may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur. Under the 2019 Plan, a change in control is generally: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock (unless made in connection with this offering or to allow us to obtain financing through the issuance of equity securities); (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; (iv) a complete dissolution or liquidation of the company; or (v) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2019 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts our 2019 Plan. No stock awards may be granted under our 2019 Plan while it is suspended or after it is terminated.

[Table of Contents](#)

2016 Equity Incentive Plan

General. Our board of directors adopted and our stockholders approved our 2016 Plan in September 2016. We have subsequently amended our 2016 Plan in January 2017 and July 2018, the purpose of which was to increase the number of shares available for issuance under our 2016 Plan. Our stockholders approved the amendment in January 2017 and August 2018, respectively. Our 2016 Plan was terminated prior to the completion of this offering in connection with our adoption of our 2019 Plan; however, awards outstanding under our 2016 Plan continue in full effect in accordance with their existing terms.

Share Reserve. 18,444,444 shares of our common stock were reserved for issuance under our 2016 Plan. As of June 30, 2019, options to purchase 5,544,976 shares of common stock, at exercise prices ranging from \$0.86 to \$5.18 per share, or a weighted-average exercise price of \$2.36 per share, and 9,139,413 shares of restricted common stock were outstanding under our 2016 Plan.

Administration. Our board of directors administers our 2016 Plan. Our board of directors has full authority and discretion to take any actions it deems necessary or advisable for the administration of our 2016 Plan. Our board of directors may modify, extend or renew outstanding option or may accept the cancellation of outstanding options (whether granted by us or another issuer) in return for the grant of new options for the same or a different number of shares and at the same or a different exercise price.

Types of Awards. Our 2016 Plan provides for the grant of incentive stock options and nonstatutory stock options to purchase shares of our common stock, restricted stock awards and other stock-based awards to employees, members of our board of directors and consultants. Incentive stock options may be granted only to employees.

Options. The exercise price of options granted under our 2016 Plan may not be less than 100% (or 110% in the case of incentive stock options granted to certain stockholders) of the fair market value of our common stock on the grant date. Options expire at the time determined by the administrator, but in no event more than 10 years after they are granted, and generally expire earlier if the optionholder's service terminates.

Change of Control. Unless otherwise expressly provided in the applicable award agreement governing an award, upon a change of control, our board of directors (or a committee thereof) may:

- accelerate the vesting or lapse of restrictions with respect to, all or any portion of an award;
- cancel an award for a cash payment equal to the value of the consideration to be paid in the change of control transaction to holders of the same number of shares of common stock and, in the case of options, less the subject to the options over the aggregate exercise price;
- continue, assume or substitute award; or
- cancel an appreciation award for no consideration if the exercise price is greater than the value of an underlying share of our common stock in the transaction.

In general, a "change of control" means: (i) the acquisition of the company by another entity by means of any transaction or series of related transactions, unless our stockholders of record immediately prior to such transaction or series of related transactions hold, immediately after such transaction or series of related transactions, at least 50% of the voting power of the surviving or acquiring entity; (ii) a change in control of two-thirds of our board of directors; or (iii) a sale of all or substantially all of our assets, subject to certain exceptions.

Transferability. A participant may not transfer stock awards under our 2016 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2016 Plan.

[Table of Contents](#)

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2016 Plan, provided that such action is approved by our stockholders to the extent stockholder approval is necessary. As described above, our 2016 Plan terminated upon the effective date of our 2019 Plan.

2019 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders approved, our 2019 Employee Stock Purchase Plan, or ESPP, in 2019. The ESPP became effective immediately prior to and contingent upon the date of the underwriting agreement related to this offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code for U.S. employees. In addition, we may make grants of purchase rights that do not comply with Section 423 of the Code, or Non-423 Grants.

Share Reserve. Following this offering, the ESPP authorizes the issuance of 1,280,000 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2020 through January 1, 2029, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase and (ii) 2,700,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors administers the ESPP and may delegate its authority to administer the ESPP to our compensation committee, which may further delegate its authority to administer the ESPP to a subcommittee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. The administrator will establish for each offering, one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date of an offering or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code. The board of directors may exclude employees from receiving Non-423 Grants if the board of directors determines that these grants would not be practical or advisable.

[Table of Contents](#)

Changes to Capital Structure. In the event that there occurs a change in our capital structure that affects the shares of our stock subject to the ESPP through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under the ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately.

Under the ESPP, a corporate transaction is generally the consummation of: (i) a sale of all or substantially all of our assets, as determined by the board; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) a merger or consolidation where we do not survive the transaction; and (iv) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

ESPP Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Director Compensation

In October 2017, our board of directors adopted a compensation policy applicable to all of our non-employee directors that are not affiliated with our stockholders. This compensation policy provided that each such director would receive annual cash compensation of \$35,000 for service on our board of directors. We have reimbursed our non-employee directors for direct expenses incurred in connection with attending meetings of our board of directors or its committees, and occasionally granted stock options and restricted stock.

In addition, in 2016 we entered into a non-executive chairman agreement with Dr. Sato pursuant to which Dr. Sato agreed to serve as the chairman of the Board, act as a liaison between our senior management and the Board and advise our senior management on company operations. The agreement was terminated in September 2019. In addition, Dr. Sato is eligible to receive any cash fees payable to non-employee directors generally as determined by the Board from time to time, and was eligible for a grant of 1,907,555 restricted shares of common stock. Pursuant to this agreement, on January 6, 2017, Dr. Sato was granted 1,621,422 shares of restricted stock. 476,889 of these shares vested on August 1, 2017 and the remainder of the shares are eligible to vest in 29 equal monthly installments thereafter, provided that 100% of the unvested shares are eligible to vest in full upon a change in control (as defined in the 2016 Plan), in each case subject to her continued service through the vesting dates. In addition, on January 6, 2017, Dr. Sato purchased 286,133 shares of restricted stock at the then-current fair market value of \$0.86 per share pursuant to a promissory note, subject to our right to repurchase the shares upon termination of her service for any reason at a purchase price equal to the lesser of fair market value or the amount Dr. Sato paid for the shares that lapses in seven equal monthly installments beginning February 1, 2020 and ending on August 1, 2020, provided that the repurchase right lapses as to all of the shares upon a change in control (as defined in the 2016 Plan), subject to her continued service through the vesting dates. Dr. Sato's chairman agreement also provided that, if following the closing of our Series B

[Table of Contents](#)

convertible preferred stock financing, Dr. Sato's ownership was greater than a 2% ownership of our company, then she would be required to automatically forfeit such number of shares causing her ownership to exceed 2%, and if her ownership was less than 2%, then she was entitled to an additional grant of restricted stock equal to such number of shares that would result in an ownership of 2%. Our Series B convertible preferred stock financing closed in January 2019 causing Dr. Sato's ownership to be reduced to below 2%, and in March 2019, Dr. Sato was granted an option to purchase 160,666 shares of our common stock that vest as follows: 25% on August 1, 2018 and the remainder in 36 equal monthly installments thereafter, subject to Dr. Sato's continued employment through each such date. Dr. Sato and our board of directors each approved Dr. Sato receiving the stock option grant in lieu of the grant of restricted stock, in full satisfaction of the above.

In August 2019, our board of directors approved a new non-employee director compensation policy, which superseded and replaced our former policy and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. Under this policy, we will pay each of our non-employee directors a cash retainer for service on the board of directors and an additional cash retainer for service on each committee on which the director is a member. The chairperson of each committee will receive a higher retainer than other members of each committee for such service. These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors. No retainers will be paid in respect of any period prior to the completion of this offering. The retainers to be paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

Name	Annual Service Retainer	Chairperson Retainer (Inclusive of Annual Service Retainer)
Board of Directors	\$40,000	\$ 70,000
Audit Committee	\$ 8,000	\$ 16,000
Compensation Committee	\$ 6,000	\$ 12,000
Nominating and Corporate Governance Committee	\$ 5,000	\$ 10,000

In addition, under our non-employee director compensation policy each non-employee director elected to our board of directors after the completion of this offering will receive an option to purchase 57,777 shares of our common stock on the first trading day on or after his or her election or appointment to our board of directors. One-third of the shares subject to each such stock option will vest on the one-year anniversary of such director's initial election or appointment and thereafter the remainder of the shares subject to each such stock option will vest monthly over a two-year period, subject to the director's continued service as a director. Further, on the first market trading day after each annual meeting of stockholders held after the completion of this offering, each non-employee director that continues to serve as a non-employee member on our board of directors will receive an option to purchase 28,888 shares of our common stock. The shares subject to each such stock option will vest in full on the one-year anniversary of the grant date, subject to the director's continued service as a director. The exercise price of all options will equal the fair market value of our common stock on the date of grant. The options granted pursuant to our non-employee director compensation policy will vest in full upon the occurrence of a change in control (as defined in the 2019 Plan) prior to the termination of the director's continuous service.

We will also continue to reimburse each non-employee director for travel expenses incurred in connection with attending each board or committee meeting. This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

[Table of Contents](#)
2018 Director Compensation Table

The following table sets forth information regarding the compensation earned for service on our board of directors by our non-employee directors during the year ended December 31, 2018. Dr. Scangos also served on our board of directors, but did not receive any additional compensation for his service as a director and therefore is not included in the table below. The compensation for Dr. Scangos, as a named executive officer, is set forth above under “— Summary Compensation Table.”

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$(1)(2)	All Other Compensation \$(3)	Total (\$)
Vicki Sato, Ph.D.	35,000	—	—	35,000
Kristina Burow	—	—	—	—
Thomas Daniel, M.D.(4).	35,000	—	—	35,000
Klaus Frueh, Ph.D.	35,000	—	150,000	185,000
Robert More	—	—	—	—
Robert Nelsen	—	—	—	—
Dipchand Nishar	—	—	—	—
Robert Perez	35,000	—	—	35,000
Phillip Sharp, Ph.D.	35,000	—	—	35,000

- (1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during fiscal year 2018 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 12 to our audited consolidated financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.
- (2) The following table provides information regarding the number of shares of common stock underlying stock options granted to our non-employee directors that were outstanding as of December 31, 2018 and the number of shares of restricted common stock granted to our non-employee directors that were subject to our repurchase rights as of December 31, 2018.

Name	Option Awards Outstanding at Year-End (#)	Stock Awards Outstanding at Year-End Subject to Repurchase Rights (#)
Vicki Sato, Ph.D.	42,377	799,199
Kristina Burow	—	—
Thomas Daniel, M.D.	42,377	—
Klaus Frueh, Ph.D.	42,377	—
Robert More	—	—
Robert Nelsen	—	—
Dipchand Nishar	—	—
Robert Perez	42,377	—
Phillip Sharp, Ph.D.	25,897	—

- (3) The dollar amount in this column for Dr. Frueh represents consulting fees paid to Dr. Frueh during 2018 for certain consulting, advisory and other services provided to us related to immune programming. For more information, see description of our consulting arrangement with Dr. Frueh below under “Certain Relationships and Related Party Transactions—Relationships with Klaus Frueh.”
- (4) Dr. Daniel resigned from our board of directors in September 2019.

Director IPO Option Grants

Upon the effectiveness of our 2019 Plan, our board of directors granted an option to purchase 22,222 shares of our common stock to each of Dr. Sato, Mr. Perez and Dr. Sharp, with an exercise price per share equal to the initial public offering price per share. One-third of the shares underlying each of these options will vest on the first anniversary of the date of grant and the remaining shares will vest in 24 equal installments thereafter, subject to the director’s continuous service with us at each vesting date.

[Table of Contents](#)**Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

[Table of Contents](#)

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since April 7, 2016 (our date of inception) and any currently proposed transactions, to which we were or are to be a participant, in which (1) the amount involved exceeded or will exceed \$120,000, and (2) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive and Director Compensation.”

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm’s-length transactions.

Common Stock Issuance

In April 2016, we entered into a stock subscription agreement pursuant to which we issued 444,444 shares of our common stock at a price of \$0.00000002 per share to ARCH Venture Fund VIII, L.P., or ARCH VIII. In September 2016, ARCH VIII transferred all such shares to ARCH Venture Fund IX, L.P., or ARCH IX.

The table below sets forth the number of shares of our common stock acquired by entities affiliated with ARCH Venture Partners, L.P., who is a holder of more than 5% of our capital stock and the approximate purchase price such stockholder paid for such shares.

Name	Common Stock (#)	Aggregate Cash Purchase Price (\$)
Entities affiliated with ARCH Venture Partners, L.P.(1)	444,444	0.01

- (1) Kristina Burow and Robert Nelsen, members of our board of directors, were designated to our board by ARCH IX, which is an affiliate of ARCH Venture Fund IX Overage, L.P., or ARCH Overage, and their affiliated funds. ARCH Venture Partners IX, L.P., or ARCH IX LP, is the sole general partner of ARCH IX, and ARCH Venture Partners IX Overage, L.P., or ARCH IX Overage LP, is the sole general partner of ARCH Overage. Mr. Nelsen is a managing director of ARCH Venture Partners IX, LLC, or ARCH IX LLC, the sole general partner of ARCH IX LP and ARCH IX Overage LP. Ms. Burow holds an interest in each of ARCH IX LP and ARCH IX Overage LP. Thomas Daniel, M.D., a former member of our board of directors, is a venture partner of ARCH Venture Partners, L.P., or ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds. Jay Parrish, Ph.D., our Chief Business Officer, is a venture partner of ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds.

Convertible Preferred Stock Financings

Series A-1 Convertible Preferred Stock Financing

In September 2016, we entered into a Series A-1 preferred stock purchase agreement with various investors, pursuant to which we issued an aggregate of 1,777,777 shares of our Series A-1 convertible preferred stock at a price per share of \$4.50 for gross cash proceeds of \$8.0 million. In December 2016, we entered into a Series A-1 and Series B preferred stock purchase agreement, or the Series A-1/B Purchase Agreement, with various investors, pursuant to which we issued an aggregate of 36,767,773 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross cash proceeds of \$165.5 million in five closings. The first closing occurred in December 2016, at which time we issued an additional 2,222,222 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$10.0 million. The second closing occurred in March 2017, at which time we issued an additional 3,333,333 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$15.0 million. Two additional closings occurred in June 2017, at which time we issued an aggregate of 24,571,107 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$110.6 million. The fifth closing occurred in July 2017, at which time we issued an additional 6,641,111 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$29.9 million.

Table of Contents

In August 2017, the Series A-1/B Purchase Agreement was amended and restated, or the A&R Purchase Agreement, pursuant to which we issued an aggregate of 25,843,330 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$116.3 million in five closings. The first two closings occurred in August 2017, at which time we issued an aggregate of 21,111,110 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$95.0 million. Two additional closings occurred in September 2017, at which time we issued an aggregate of 3,968,270 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$17.9 million. The fifth closing occurred in October 2017, at which time we issued an aggregate of 763,950 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$3.4 million. In June 2018, the A&R Purchase Agreement was amended, or the Amended A&R Purchase Agreement, pursuant to which we issued an aggregate of 3,222,220 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$14.5 million in two closings. The first closing occurred in June 2018, at which time we issued an additional 2,777,776 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$12.5 million. The second closing occurred in July 2018, at which time we issued an additional 444,444 shares of our Series A-1 convertible preferred stock for gross cash proceeds of \$2.0 million.

The table below sets forth the number of shares of our Series A-1 convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series A-1 convertible preferred stock in the table below will convert into one share of our common stock upon the completion of this offering.

Name	Series A-1 Convertible Preferred Stock (#)	Aggregate Cash Purchase Price (\$)
Entities affiliated with ARCH Venture Partners(1)	24,444,442	110,000,000
SoftBank Vision Fund (AIV M1) L.P.(2)	15,555,555	70,000,000
Alta Partners NextGen Fund I, L.P. (3)	1,666,666	7,500,000

- (1) Ms. Burow and Mr. Nelsen, members of our board of directors, were designated to our board by ARCH IX, which is an affiliate of ARCH Overage, and their affiliated funds. ARCH IX LP is the sole general partner of ARCH IX, and ARCH IX Overage LP is the sole general partner of ARCH Overage. Mr. Nelsen is a managing director of ARCH IX LLC, the sole general partner of ARCH IX LP and ARCH IX Overage LP. Ms. Burow holds an interest in each of ARCH IX LP and ARCH IX Overage LP. Dr. Daniel, a former member of our board of directors, is a venture partner of ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds. Dr. Parrish, our Chief Business Officer, is a venture partner of ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds.
- (2) Dipchand Nishar, a member of our board of directors, was designated to our board by SoftBank Vision Fund (AIV M1) L.P., or SVF. Mr. Nishar is Senior Managing Partner at SoftBank Investment Advisers, an affiliate of SVF.
- (3) Robert More, a member of our board of directors, is a managing director of Alta Partners NextGen Fund I Management, LLC, or APNG I Management. APNG I Management is the general partner of Alta Partners NextGen Fund I, L.P., or APNG I.

Series B Convertible Preferred Stock Financing

In January 2019, we issued an aggregate of 18,202,213 shares of Series B convertible preferred stock at \$18.00 per share for gross proceeds of \$327.6 million in two closings pursuant to the Amended A&R Purchase Agreement. Both closings occurred in January 2018.

[Table of Contents](#)

The table below sets forth the number of shares of our Series B convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series B convertible preferred stock in the table below will convert into one share of our common stock upon the completion of this offering.

Name	Series B Convertible Preferred Stock (#)	Aggregate Cash Purchase Price (\$)
Entities affiliated with ARCH Venture Partners ⁽¹⁾	2,777,777	50,000,000
SoftBank Vision Fund (AIV M1) L.P. ⁽²⁾	6,111,111	110,000,000
Alta Partners NextGen Fund I, L.P. ⁽³⁾	277,777	5,000,000

- (1) Ms. Burow and Mr. Nelsen, members of our board of directors, were designated to our board by ARCH IX, which is an affiliate of ARCH Overage, and their affiliated funds. ARCH IX LP is the sole general partner of ARCH IX, and ARCH IX Overage LP is the sole general partner of ARCH Overage. Mr. Nelsen is a managing director of ARCH IX LLC, the sole general partner of ARCH IX LP and ARCH IX Overage LP. Ms. Burow holds an interest in each of ARCH IX LP and ARCH IX Overage LP. Dr. Daniel, a former member of our board of directors, is a venture partner of ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds. Dr. Parrish, our Chief Business Officer, is a venture partner of ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds.
- (2) Mr. Nishar, a member of our board of directors, was designated to our board by SVF. Mr. Nishar is Senior Managing Partner at SoftBank Investment Advisers, an affiliate of SVF.
- (3) Mr. More, a member of our board of directors, is a managing director of APNG I Management. APNG I Management is the general partner of APNG I.

Relationships with Klaus Frueh

Klaus Frueh, Ph.D., a member of our board of directors and a stockholder, was the former President of TomegaVax, Inc., or TomegaVax. In September 2016, we entered into an agreement and plan of merger to acquire all equity interest of TomegaVax. As purchase consideration, we issued an aggregate of 1,555,550 shares of Series A-2 convertible preferred stock to former stockholders of TomegaVax, including 218,400 shares of Series A-2 convertible preferred stock to Dr. Frueh.

In June 2016, we entered into a consulting agreement with Dr. Frueh, pursuant to which Dr. Frueh agreed to provide certain consulting, advisory and related services within the field of immune programming on an exclusive basis, in exchange for a consulting fee of \$150,000 per year. Unless we terminate the agreement earlier, the consulting agreement will terminate on the fifth anniversary of the closing date of our acquisition of TomegaVax. We paid Dr. Frueh an aggregate of \$150,000 pursuant to the consulting agreement during 2018.

Relationships with Robert More

Mr. More, a member of our board of directors and a stockholder, was a former director and stockholder of TomegaVax. In connection with the acquisition of TomegaVax, we issued 60,822 shares of Series A-2 convertible preferred stock to Mr. More.

Investors' Rights, Management Rights, Voting and Co-Sale Agreements

In connection with our convertible preferred stock financings, we entered into investors' rights, management rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, rights of first offer, voting rights and rights of first refusal, among other things, with certain holders of our capital stock. The holders of more than 5% of our capital stock that are party to these agreements are entities affiliated with ARCH Venture Partners and SVF. In connection with our acquisition of TomegaVax, former stockholders of TomegaVax became parties to the investors' rights, voting and right of first refusal and co-sale agreements. Our directors who are parties to these agreements are Dr. Frueh and Mr. More.

[Table of Contents](#)

These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors' rights agreement, which will terminate upon the earliest of (1) the closing of a deemed liquidation event, as defined in our amended and restated certificate of incorporation as currently in effect; (2) with respect to each stockholder, the date when such stockholder can sell all of its registrable shares without limitation during a three-month period without registration pursuant to Rule 144 of the Securities Act, or Rule 144, or another similar exemption under the Securities Act; and (3) five years after the completion of this offering. For a description of the registration rights, see the section titled "Description of Capital Stock—Registration Rights."

Certain Loan Transactions

In June 2016, we entered into a promissory note, or the ARCH Loan, with ARCH VIII. Under the terms of the ARCH Loan, we drew down an aggregate of \$0.3 million from ARCH VIII, with an interest rate of 5% per annum. The ARCH Loan was repaid in September 2016.

In January 2017, we issued two promissory notes to Dr. Scangos, our President, Chief Executive Officer and a member of our board of directors, and Vicki Sato, Ph.D., Chairman of our board of directors, for principal amounts of \$2.9 million and \$0.2 million, respectively, with an interest rate of 1.97% per annum, to allow Dr. Scangos and Dr. Sato to purchase 3,338,222 shares and 286,133 shares of our restricted stock, respectively, pursuant to their respective restricted stock purchase agreements. The principal and accrued interest outstanding on each of these promissory notes was approximately \$3.0 million and \$0.3 million for Dr. Scangos and Dr. Sato, respectively, as of July 31, 2019. Dr. Scangos' loan and Dr. Sato's loan were repaid in full in August 2019.

Employment of an Immediate Family Member

Jennifer Scangos, the daughter of Dr. Scangos, our President, Chief Executive Officer and a member of our board of directors, is employed by us as a legal counsel. For the years ended December 31, 2017 and 2018, Ms. Scangos earned \$9,394 and \$153,282, respectively, in base salary and bonus which was in line with similar roles at the Company. Ms. Scangos's 2019 base salary and bonus opportunity are \$139,000 and \$20,850, respectively. Ms. Scangos has received and continues to be eligible to receive equity awards and benefits on the same general terms and conditions as applicable to unrelated employees in similar positions.

Collaboration with Bria Biosciences

In May 2018, we entered into an option and license agreement with Bria Bio Parent and Bria Bio, pursuant to which we granted, and were granted, an exclusive option with respect to up to four collaboration programs for the development and commercialization of therapeutic products for infectious diseases. Dr. Scangos, our President, Chief Executive Officer and a member of our board of directors, and Mr. Nelsen, a member of our board of directors, served at the time and currently serve as directors of Bria Bio Parent and Bria Bio. We agreed to pay Bria Bio an option exercise fee for each licensed Bria Bio program up to \$50.0 million, and milestone payments and royalties for net sales of licensed products in the United States arising from the selected collaboration programs. Bria Bio agreed to pay us an option exercise fee for each licensed Vir program up to \$20.0 million, and milestone payments and royalties for net sales of licensed products in greater China arising from the selected collaboration programs. For a description of the option and license agreement, see the section titled "Business—Our Collaboration, License and Grant Agreements."

Other Transactions

We have entered into offer letter agreements with our executive officers that, among other things, provide for certain compensatory and change in control benefits, as well as severance benefits. For a description of these agreements with our named executive officers, see the section titled "Executive and Director Compensation—Employment Arrangements."

[Table of Contents](#)

We have also granted stock options and restricted stock to our executive officers and certain of our directors. For a description of these equity awards, see the section titled “Executive and Director Compensation.”

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and executive officers, and intend to enter into new indemnification agreements with each of our current directors and executive officers before the completion of this offering. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by applicable law. See the section titled “Management—Limitations on Liability and Indemnification Matters.”

Other than as described above under this section “Certain Relationships and Related Party Transactions,” since April 7, 2016, we have not entered into any transactions, nor are there any currently proposed transactions, between us and a related person where the amount involved exceeds, or would exceed, \$120,000, and in which any related person had or will have a direct or indirect material interest. We believe the terms of the transactions described above were comparable to terms we could have obtained in arm’s length dealings with unrelated third parties.

Policies and Procedures for Related Party Transactions

In connection with this offering, we intend to adopt a written related party transactions policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. This policy became effective upon the effectiveness of the registration statement of which this prospectus is a part. For purposes of this policy only, a “related person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are participants involving an amount that exceeds \$120,000. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A “related person” is any executive officer, director, nominee to become a director or a holder of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee or, where review by our audit committee would be inappropriate due to a conflict of interest, to another independent body of our board of directors, for review. The presentation must include a description of, among other things, all of the parties, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management’s recommendation. To identify related-party transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties under the same or similar circumstances.

[Table of Contents](#)

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest in the agreement or transaction were disclosed to our board of directors. Our board of directors considered this information when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

[Table of Contents](#)**PRINCIPAL STOCKHOLDERS**

The following table sets forth, as of September 15, 2019, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information under the column titled “Before Offering” is based on 102,439,115 shares of common stock outstanding as of September 15, 2019 assuming the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 88,112,733 shares of common stock upon the completion of this offering. The percentage ownership information under the column titled “After Offering” is based on the sale of 7,142,858 shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters’ option to purchase additional shares and no purchases of any shares of common stock in this offering by the beneficial owners identified in the table below.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security. In addition, the rules include shares of common stock issuable upon the exercise of stock options or warrants that are currently exercisable or exercisable within 60 days of September 15, 2019. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table does not necessarily indicate beneficial ownership for any other purpose. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

[Table of Contents](#)

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Vir Biotechnology, Inc., 499 Illinois Street, Suite 500, San Francisco, CA 94158.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
Greater than 5% Stockholders:			
Entities affiliated with ARCH Venture Partners(1)	27,666,663	27.0	25.2
SoftBank Vision Fund (AIV M1) L.P.(2)	21,666,666	21.2	19.8
Named Executive Officers and Directors:			
George Scangos, Ph.D.(3)	6,913,827	6.7	6.3
Herbert (Skip) Virgin, M.D., Ph.D.(4)	254,629	*	*
Phil Pang, M.D., Ph.D.(5)	157,405	*	*
Vicki Sato, Ph.D.(6)	1,788,912	1.7	1.6
Kristina Burow	—	*	*
Klaus Frueh, Ph.D.(7)	470,050	*	*
Robert More(8)	2,005,265	2.0	1.8
Robert Nelsen(9)	27,666,663	27.0	25.2
Dipchand (Deep) Nishar	—	*	*
Robert Perez(10)	29,428	*	*
Saira Ramasastry	—	*	*
Phillip Sharp, Ph.D.(11)	251,648	*	*
All executive officers and directors as a group (15 persons)	40,417,453	39.0	36.5

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 444,444 shares of common stock held by ARCH Venture Fund IX, L.P., or ARCH IX, (ii) 11,111,110 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by ARCH IX, (iii) 555,555 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by ARCH IX, (iv) 13,333,332 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by ARCH Venture Fund IX Overage, L.P., or ARCH Overage, and (v) 2,222,222 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by ARCH Overage. ARCH Venture Partners IX, L.P., or the ARCH IX LP, as the sole general partner of ARCH IX, may be deemed to beneficially own certain of the shares held by ARCH IX. ARCH IX LP disclaims beneficial ownership of all shares held by ARCH IX. ARCH Venture Partners IX Overage, L.P., or ARCH IX Overage LP, as the sole general partner of ARCH Overage, may be deemed to beneficially own certain of the shares held by ARCH Overage. ARCH IX Overage LP disclaims beneficial ownership of all shares held by ARCH Overage. ARCH Venture Partners IX, LLC, or ARCH IX LLC, as the sole general partner of ARCH IX LP and ARCH IX Overage LP, may be deemed to beneficially own the shares held by ARCH IX and ARCH Overage. ARCH IX LLC disclaims beneficial ownership of all shares held by ARCH IX and ARCH Overage. As managing directors of ARCH IX LLC, each of Keith Crandell, Clinton Bybee, Mr. Nelsen (one of the designees of ARCH IX to our board of directors), or collectively the ARCH Managing Directors, may be deemed to share voting and investment power over, and therefore to beneficially own, the shares held by ARCH IX and ARCH Overage. The ARCH Managing Directors disclaim beneficial ownership of all shares held by ARCH IX and ARCH Overage. Ms. Burow, one of the designees of ARCH IX to our board of directors, owns an interest in ARCH IX LP and ARCH IX Overage LP but does not have voting or investment power over the shares held by ARCH IX and ARCH Overage. Ms. Burow disclaims all beneficial ownership of all shares held by ARCH IX and ARCH Overage except to the extent of her pecuniary interest therein. Jay Parrish, Ph.D., our Chief Business Officer, is a venture partner of ARCH Venture Corporation, or ARCH, which is an affiliate of ARCH IX and ARCH Overage, and their affiliated funds, but does not have voting or investment power over the shares held by ARCH IX and ARCH Overage. The address of each of ARCH, ARCH IX, ARCH Overage, ARCH IX LP, ARCH IX Overage LP, ARCH IX LLC, the ARCH Managing Directors and Ms. Burow is 8755 West Higgins Road, Suite 1025, Chicago, Illinois 60631.
- (2) Consists of (i) 15,555,555 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by SoftBank Vision Fund (AIV M1) L.P., or SVF, and (ii) 6,111,111 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by SVF. SVF GP (Jersey) Limited, or SVF GP, is the general partner of SVF. SB Investment Advisers (UK) Limited, or SBIA UK, has been appointed as alternative investment fund manager, or AIFM, and is exclusively responsible for managing SVF in accordance with the Alternative Investment Fund Managers Directive and is authorized and regulated by the UK Financial Conduct Authority accordingly. As AIFM of SVF, SBIA UK is exclusively responsible for making all decisions related to the acquisition, structuring, financing, voting and disposal of SVF's investments. SVF GP and SBIA UK are both wholly owned by SoftBank Group Corp. Mr. Nishar, a member of our board of directors, is a Senior Managing Partner at SB Investment Advisers (US) Inc., an affiliate of SBIA UK, but does not have voting or investment power over the shares held by SVF. The address of SVF is 251 Little Falls Drive, Wilmington, Delaware 19808.

Table of Contents

- (3) Consists of (i) 4,398,666 shares of common stock held directly by Dr. Scangos, (ii) 2,222,222 shares of common stock held by the George A. Scangos 2018 Annuity Trust, dated August 30, 2018, over which Dr. Scangos and his wife share voting and investment power as trustees and (iii) 292,939 shares of common stock issuable upon exercise of stock options held by Dr. Scangos that are exercisable within 60 days of September 15, 2019.
- (4) Consists of 254,629 shares of common stock issuable upon exercise of stock options held by Dr. Virgin that are exercisable within 60 days of September 15, 2019.
- (5) Consists of (i) 7,777 shares of common stock, and (ii) 149,628 shares of common stock issuable upon exercise of stock options held by Dr. Pang that are exercisable within 60 days of September 15, 2019.
- (6) Consists of (i) 1,669,110 shares of common stock, and (ii) 119,802 shares of common stock issuable upon exercise of stock options held by Dr. Sato that are exercisable within 60 days of September 15, 2019.
- (7) Consists of (i) 222,222 shares of common stock, (ii) 218,400 shares of common stock issuable upon the conversion of Series A-2 convertible preferred stock, and (iii) 29,428 shares of common stock issuable upon exercise of stock options held by Dr. Frueh that are exercisable within 60 days of September 15, 2019.
- (8) Consists of (i) 1,666,666 shares of common stock issuable upon the conversion of Series A-1 convertible preferred stock held by Alta Partners NextGen Fund I, L.P., or APNG I, (ii) 60,822 shares of common stock issuable upon the conversion of Series A-2 convertible preferred stock held by Mr. More, and (iii) 277,777 shares of common stock issuable upon the conversion of Series B convertible preferred stock held by APNG I. The shares directly held by APNG I are indirectly held by Alta Partners NextGen Fund I Management, LLC, or APNG I Management, which is the general partner of APNG I. The individual managing directors of APNG I Management are Mr. More, Peter Hudson and Daniel Janney. The managing directors of APNG I Management exercise sole voting and investment control with respect to the shares held by APNG I. The individual managing directors of APNG I Management disclaim beneficial ownership of all shares held by APNG I, except to the extent of their pecuniary interests therein.
- (9) Consists of the shares held by ARCH IX and ARCH Overage disclosed in footnote (1) above. Mr. Nelsen is a managing director of GPLLC and may be deemed to beneficially own the shares held by ARCH IX and ARCH Overage as disclosed in footnote (1).
- (10) Consists of 29,428 shares of common stock issuable upon exercise of stock options held by Mr. Perez that are exercisable within 60 days of September 15, 2019.
- (11) Consists of (i) 16,480 shares of common stock held directly by Dr. Sharp, (ii) 88,888 shares of Series A-1 convertible preferred stock held directly by Dr. Sharp, (iii) an aggregate of 133,332 shares of Series A-1 convertible preferred stock held by the Phillip A. Sharp Irrevocable Trusts 11/04/08, over which Dr. Sharp holds voting and investment power as trustee, and (iv) 12,948 shares of common stock issuable upon exercise of stock options held by Dr. Sharp that are exercisable within 60 days of September 15, 2019.

[Table of Contents](#)

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation, the amended and restated bylaws and the amended and restated investors' rights agreement, which are filed as exhibits to the registration statement of which this prospectus is a part.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 300,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share.

Common Stock

Outstanding Shares

As of June 30, 2019, we had 102,254,338 shares of common stock outstanding, held of record by 162 stockholders, assuming the conversion of all of our outstanding shares of convertible preferred stock into 88,112,733 shares of common stock upon the completion of this offering.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Upon the completion of this offering, all of our currently outstanding shares of convertible preferred stock will convert into common stock and we will not have any preferred stock outstanding. Immediately after the

[Table of Contents](#)

completion of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Stock Options

As of June 30, 2019, 5,544,976 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of \$2.36 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive and Director Compensation—Equity Incentive Plans.”

Warrant

As of June 30, 2019, we had one warrant to purchase 244,444 shares of our Series A-1 convertible preferred stock, at an exercise price of \$4.50 per share. The warrant will automatically convert into a warrant to purchase an equivalent number of shares of our common stock upon the completion of this offering. The warrant is held by Takeda Ventures, Inc. and was issued in connection with the termination of the certain sponsored research agreements with Takeda Ventures, Inc. and TomegaVax in September 2016 in connection with our acquisition of TomegaVax. If unexercised, the warrant will expire on the tenth anniversary of the issue date. The warrant has a cashless exercise provision pursuant to which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. The warrant also provides for adjustments in the event of specified stock dividends, stock splits, reclassifications, and consolidations. The warrant will neither expire nor be automatically exercised upon the closing of this offering.

Registration Rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors’ rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and

[Table of Contents](#)

Form S-3 registration rights described below will expire no later than five years after the completion of this offering, or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act during any three-month period.

Demand Registration Rights

Upon the completion of this offering, holders of up to approximately 66.0 million shares of our common stock issuable upon conversion of outstanding convertible preferred stock, will be entitled to certain demand registration rights. Beginning 180 days following the effectiveness of the registration statement of which this prospectus is a part, certain major investors holding, collectively, a majority of registrable securities may, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions. If any of these holders exercises its demand registration rights, then holders of approximately 88.2 million shares of our common stock issuable upon the shares of our convertible preferred stock in connection with this offering, will be entitled to register their shares, subject to specified conditions and limitations, in the corresponding offering.

Piggyback Registration Rights

In connection with this offering, holders of up to approximately 88.2 million shares of our common stock issuable upon conversion of outstanding preferred stock are entitled to their rights to notice of this offering and to include their shares of registrable securities in this offering. The requisite percentage of these stockholders have waived all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 Registration Rights

Upon the completion of this offering, the holders of approximately 66.0 million shares of our common stock issuable upon conversion of outstanding convertible preferred stock will initially be entitled to certain Form S-3 registration rights. Certain major investors holding at least 10% of registrable securities may, on not more than two registrations on Form S-3 within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds \$5.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not

[Table of Contents](#)

the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of our board of directors;
- provide that our board of directors will be classified into three classes of directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least 66 2/3% of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;

Table of Contents

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors, and not by our stockholders; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and (v) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Nothing in our amended and restated certificate of incorporation precludes stockholders that assert claims under the Securities Act from bringing such claims in state or federal court, subject to applicable law. Our amended and restated certificate of incorporation will further provide that the federal district courts of the United States will be

[Table of Contents](#)

the exclusive forum for resolving any complaint asserting a cause of action under the Securities Act, unless we consent in writing to the selection of an alternative forum.

Limitation on Liability and Indemnification

See the section titled “Management—Limitation on Liability and Indemnification Matters.”

Listing

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “VIR.”

Transfer Agent and Registrar

Upon completion of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent’s address is 250 Royall Street, Canton, Massachusetts 02021.

[Table of Contents](#)

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of our common stock, including shares issued upon the exercise of outstanding options and an outstanding warrant, in the public market after the completion of this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock from time to time or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of June 30, 2019, upon the closing of this offering and assuming (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 88,112,733 shares of our common stock upon the completion of this offering, (ii) no exercise of the underwriters’ option to purchase additional shares of common stock, if any, and (iii) no exercise of outstanding options or an outstanding warrant, we will have outstanding an aggregate of approximately 109,397,196 shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our “affiliates” as such term is defined in Rule 144 or subject to lock-up agreements. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be “restricted securities,” as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 of the Securities Act, or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, based on the number of shares of our common stock outstanding (calculated as of June 30, 2019 on the basis of the assumptions described above and assuming no exercise of the underwriter’s option to purchase additional shares, if any, and no exercise of outstanding options or an outstanding warrant), the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

<u>Approximate Number of Shares</u>	<u>First Date Available for Sale into Public Market</u>
102,254,338 shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2019 Plan became eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

[Table of Contents](#)

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144.

Under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our “affiliates” for purposes of Rule 144 at any time during the 90 days preceding a sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our “affiliates,” is entitled to sell those shares in the public market (subject to the lock-up agreement referred to below, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 1,093,971 shares of common stock immediately upon the completion of this offering (calculated as of June 30, 2019 on the basis of the assumptions described above and assuming no exercise of the underwriter’s option to purchase additional shares, if any, and no exercise of outstanding options or an outstanding warrant); or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our “affiliates” as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our “affiliates” may resell those shares beginning 90 days after the date of this prospectus without compliance with minimum holding period requirements under Rule 144 (subject to the terms of the lock-up agreement referred to below, if applicable).

[Table of Contents](#)**Lock-Up Agreements**

In connection with this offering, we, our directors, our executive officers and holders of all of our other outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock outstanding upon the completion of this offering, have agreed, subject to certain limited exceptions, with the underwriters not to directly or indirectly offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives of the underwriters, and certain other limited exceptions. These agreements are described in the section titled “Underwriting.”

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors’ rights agreement, our standard form of option agreement, our standard form of restricted stock agreement and our standard form of restricted stock purchase agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the completion of this offering, the holders of up to approximately 88.2 million shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described under “—Lock-Up Agreements” above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. The requisite percentage of these stockholders have waived all such stockholders’ rights to notice of this offering and to include their shares of registrable securities in this offering. See the section titled “Description of Capital Stock—Registration Rights.”

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under our 2019 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

[Table of Contents](#)

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax consequences applicable to non-U.S. holders (as defined herein) with respect to their purchase, ownership and disposition of shares of our common stock issued pursuant to this offering. All prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (ii) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any estate or gift tax consequences, or any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt or governmental organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders subject to the alternative minimum tax or the Medicare contribution tax on net investment income, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction, synthetic security or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, controlled foreign corporations, passive foreign investment companies, accrual method taxpayers subject to special tax accounting rules under Section 451(b) of the Code, and U.S. expatriates and certain former U.S. citizens or long-term residents.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold their common stock through such partnerships. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner, the activities of the partnership and certain determinations made at the partner level. Such partners and partnerships should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that a court or the IRS will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

Distributions on Our Common Stock

As described in the section titled "Dividend Policy," we do not currently intend to pay any cash dividends in the foreseeable future. If we do make distributions of cash or property on our common stock, such distributions

[Table of Contents](#)

generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock." Any distributions will also be subject to the discussion below under the heading "Foreign Accounts."

Dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to "United States persons" (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

To claim a reduction or exemption from withholding, a non-U.S. holder of our common stock generally will be required to provide (i) a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or successor form, and satisfy applicable certification and other requirements to claim the benefit of an applicable income tax treaty between the United States and such holder's country of residence, or (ii) a properly executed IRS Form W-8ECI stating that dividends are not subject to withholding because they are effectively connected with such non-U.S. holder's conduct of a trade or business within the United States. The tax forms referred to above must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. In the case of a non-U.S. holder that is an entity, Treasury Regulations and any relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding, in general, a non-U.S. holder will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally

[Table of Contents](#)

will be taxed at the graduated U.S. federal income tax rates applicable to “United States persons” (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” may also apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder’s holding period, if shorter) a U.S. real property holding corporation. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus the fair market value of its other assets used or held for use in a trade or business. We do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. However, because the determination of whether we are a U.S. real property holding corporation depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded, as defined by applicable Treasury Regulations, on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, actually or constructively, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to “United States persons” (as defined in the Code). No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a “United States person” (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. A non-U.S. holder generally will not be subject to U.S. backup withholding with respect to payments of dividends on our common stock if it certifies its non-U.S. status by providing a valid IRS Form W-8BEN (in the case of individuals), IRS Form W-8BEN-E (in the case of entities) or IRS Form W-8ECI, or successor form, or otherwise establishes an exemption; provided the applicable withholding agent does not have actual knowledge or reason to know such non-U.S. holder is a “United States person,” as defined in the Code.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner

[Table of Contents](#)

similar to dispositions effected through a U.S. office of a broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns that are filed with the IRS may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is incorporated.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends on our common stock paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends on our common stock paid to a "non-financial foreign entity" (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity, or otherwise qualifies for an exemption from these rules. The withholding provisions described above currently apply to dividends paid on our common stock. Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA would have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, although under recently proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on such proposed regulations pending finalization), no withholding applies with respect to payments of gross proceeds. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAWS.

[Table of Contents](#)

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, Cowen and Company, LLC and Barclays Capital Inc. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	2,321,429
J.P. Morgan Securities LLC	2,321,429
Cowen and Company, LLC	1,428,571
Barclays Capital Inc.	1,071,429
Total	7,142,858

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,071,428 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Paid by Us	No Exercise	Full Exercise
Per Share	\$ 1.40	\$ 1.40
Total	\$ 10,000,001.20	\$ 11,500,000.40

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$0.84 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our directors, our executive officers and holders of substantially all of our other outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock outstanding upon the completion of this offering have agreed with the underwriters, subject to certain limited exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, were our historical performance, estimates of the business potential and our earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

[Table of Contents](#)

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “VIR.”

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the New York Stock Exchange, The Nasdaq Global Select Market or relevant exchange, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$5.5 million. We will reimburse the underwriters for certain of their expenses incurred in connection with this offering in an amount up to \$40,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve

[Table of Contents](#)

or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relative Member State”) an offer to the public of our common shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of our common shares may be made at any time under the following exemptions under the Prospectus Directive:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer or shares of our common stock shall result in a requirement for the publication by us or any Brazilian placement agent of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to public” in relation to our common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common shares to be offered so as to enable an investor to decide to purchase our common shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (as amended), including by Directive 2010/73/EU and includes any relevant implementing measure in the Relevant Member State.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed as qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

[Table of Contents](#)

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this offering memorandum (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for six months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

[Table of Contents](#)

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for six months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32.

Singapore Securities and Futures Act Product Classification—Solely for the purposes of its obligations pursuant to Sections 309B(1)(a) and 309B(1)(c) of the SFA, we have determined, and hereby notify all relevant persons (as defined in Section 309A of the SFA) that the common shares are “prescribed capital markets products” (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (“Addressed Investors”); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 – 1968, subject to certain conditions (“Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 – 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 – 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 – 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to

[Table of Contents](#)

exemptions available under the Israeli Securities Law, 5728 – 1968: (1) for its own account; (2) for investment purposes only; and (3) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 – 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Switzerland

The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

[Table of Contents](#)

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Cooley LLP, Palo Alto, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, Menlo Park, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2017 and 2018, and for each of the two years in the period ended December 31, 2018, as set forth in their report. We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review on the web site of the SEC referred to above. We also maintain a website at www.vir.bio, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
Audited Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2017 and 2018	F-3
Consolidated Statements of Operations for the years ended December 31, 2017 and 2018	F-4
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2017 and 2018	F-5
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit for the years ended December 31, 2017 and 2018	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2018	F-7
Notes to Consolidated Financial Statements	F-8
Unaudited Condensed Consolidated Financial Statements	
Condensed Consolidated Balance Sheets as of December 31, 2018 and June 30, 2019	F-44
Condensed Consolidated Statements of Operations for the six months ended June 30, 2018 and 2019	F-45
Condensed Consolidated Statements of Comprehensive Loss for the six months ended June 30, 2018 and 2019	F-46
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit for the six months ended June 30, 2018 and 2019	F-47
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and 2019	F-48
Notes to Unaudited Condensed Consolidated Financial Statements	F-49

[Table of Contents](#)**Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors
of Vir Biotechnology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vir Biotechnology, Inc. (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Redwood City, California

June 26, 2019, except for the third paragraph of Note 1, as to which the date is September 27, 2019.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Consolidated Balance Sheets**
(in thousands, except share and per share data)

	December 31,	
	2017	2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 187,918	\$ 47,598
Short-term investments	—	50,845
Restricted cash and cash equivalents, current	—	10,761
Prepaid expenses and other current assets	4,432	8,579
Total current assets	192,350	117,783
Intangible assets, net	35,882	36,917
Goodwill	16,937	16,937
Property and equipment, net	5,138	12,290
Restricted cash and cash equivalents, noncurrent	1,003	1,003
Other assets	256	6,666
TOTAL ASSETS	\$ 251,566	\$ 191,596
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	\$ 4,898	\$ 6,473
Accrued liabilities	7,540	14,534
Deferred revenue, current portion	—	8,761
Advanced proceeds from preferred stock financing	—	10,140
Total current liabilities	12,438	39,908
Deferred revenue, noncurrent	888	6,561
Convertible preferred stock warrant liability	929	1,024
Contingent consideration	9,000	9,250
Deferred tax liability	3,305	3,305
Other long-term liabilities	1,397	1,588
TOTAL LIABILITIES	27,957	61,636
Commitments and contingencies (Note 8)		
Convertible preferred stock, \$0.0001 par value; 408,100,000 and 421,450,000 shares authorized; 65,944,430 and 69,910,520 shares issued and outstanding as of December 31, 2017 and 2018, respectively; aggregate liquidation preference of \$305,609 and \$333,058 as of December 31, 2017 and 2018, respectively	292,525	309,137
STOCKHOLDERS' DEFICIT:		
Common stock, \$0.0001 par value; 525,000,000 and 558,350,000 shares authorized; 6,210,325 and 8,858,799 shares issued and outstanding as of December 31, 2017 and 2018, respectively	1	1
Additional paid-in capital	9,035	14,672
Accumulated other comprehensive loss	—	(14)
Accumulated deficit	(77,952)	(193,836)
TOTAL STOCKHOLDERS' DEFICIT	(68,916)	(179,177)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	\$ 251,566	\$ 191,596

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2017	2018
Revenue:		
Grant revenue	\$ 2,559	\$ 9,800
Contract revenue	149	868
Total revenue	2,708	10,668
Operating expenses:		
Research and development	62,512	100,229
General and administrative	21,693	29,131
Total operating expenses	84,205	129,360
Loss from operations	(81,497)	(118,692)
Other income (expense):		
Interest income	638	2,540
Other income (expense), net	83	(212)
Total other income (expense), net	721	2,328
Loss before benefit from income taxes	(80,776)	(116,364)
Benefit from income taxes	10,924	480
Net loss	\$ (69,852)	\$ (115,884)
Net loss per share, basic and diluted	\$ (32.45)	\$ (15.12)
Weighted-average shares outstanding, basic and diluted	2,152,273	7,666,463
Pro forma net loss per share, basic and diluted (unaudited)		\$ (1.52)
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)		76,050,495

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2017	2018
Net loss	\$ (69,852)	\$ (115,884)
Other comprehensive loss:		
Changes in unrealized gains (losses) on investments	—	(14)
Other comprehensive loss	—	(14)
Comprehensive loss	<u>\$ (69,852)</u>	<u>\$ (115,898)</u>

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit***(in thousands, except share amounts)*

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2016	5,555,549	\$ 21,242	446,108	\$ —	\$ 128	\$ —	\$ (8,100)	\$ (7,972)
Issuance of Series A-1 convertible preferred stock, net of issuance costs of \$467	60,388,881	271,283	—	—	—	—	—	—
Issuance of common stock in connection with business acquisition	—	—	1,666,656	—	2,475	—	—	2,475
Issuance of common stock in connection with acquisition of research and development license	—	—	1,111,111	—	1,651	—	—	1,651
Vesting of restricted common stock	—	—	2,986,450	1	(1)	—	—	—
Stock-based compensation	—	—	—	—	4,782	—	—	4,782
Net loss	—	—	—	—	—	—	(69,852)	(69,852)
Balance at December 31, 2017	65,944,430	292,525	6,210,325	1	9,035	—	(77,952)	(68,916)
Issuance of Series A-1 convertible preferred stock, net of issuance costs of \$232	3,222,220	14,269	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred stock as consideration in asset acquisition	743,870	2,343	—	—	—	—	—	—
Vesting of restricted common stock	—	—	2,247,673	—	—	—	—	—
Exercise of stock options	—	—	400,801	—	584	—	—	584
Stock-based compensation	—	—	—	—	5,053	—	—	5,053
Other comprehensive loss	—	—	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	—	—	(115,884)	(115,884)
Balance at December 31, 2018	<u>69,910,520</u>	<u>\$ 309,137</u>	<u>8,858,799</u>	<u>\$ 1</u>	<u>\$ 14,672</u>	<u>\$ (14)</u>	<u>\$ (193,836)</u>	<u>\$ (179,177)</u>

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2017	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (69,852)	\$ (115,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of property and equipment	—	198
Depreciation and amortization	255	1,618
Amortization of intangible assets	177	1,138
Accretion of discounts on investments	—	(328)
Change in fair value of contingent consideration	2,750	250
Change in estimated fair value of convertible preferred stock warrant liability	(82)	95
Preferred stock issued in connection with asset acquisition	—	1,750
Common stock issued in connection with acquisition of research and development license	1,651	—
Change in long-term deferred income taxes	(10,924)	(480)
Stock-based compensation	4,782	5,053
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,600)	(4,172)
Other assets	(246)	151
Accounts payable	2,011	1,471
Deferred revenue	888	7,873
Accrued liabilities and other long-term liabilities	4,809	7,171
Net cash used in operating activities	(66,381)	(94,096)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,742)	(8,192)
Purchases of short-term investments	—	(123,105)
Maturities of short-term investments	—	72,574
Proceeds from sale of property and equipment	—	25
Asset acquisitions	—	(1,743)
Business acquisition, net of cash acquired	(27,252)	—
Net cash used in investing activities	(29,994)	(60,441)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	—	584
Advanced proceeds from convertible preferred stock financing	—	10,140
Proceeds from issuance of convertible preferred stock, net of issuance costs	271,182	14,254
Net cash provided by financing activities	271,182	24,978
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	174,807	(129,559)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	14,114	188,921
Cash, cash equivalents and restricted cash and cash equivalents at end of period	\$ 188,921	\$ 59,362
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Common stock issued in connection with business acquisition	\$ 2,475	\$ —
Contingent consideration recorded in connection with business acquisitions	\$ 6,250	\$ —
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 1,885	\$ 1,996
Issuance costs for convertible preferred stock in accounts payable and accrued liabilities	\$ 15	\$ —
Receipt of promissory note from related parties for purchase of common stock	\$ 3,159	\$ —
Preferred stock issued in connection with asset acquisition	\$ —	\$ 593
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH TO THE CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	\$ 187,918	\$ 47,598
Restricted cash and cash equivalents, current	—	10,761
Restricted cash and cash equivalents, noncurrent	1,003	1,003
Total cash, cash equivalents and restricted cash	\$ 188,921	\$ 59,362

The accompanying notes are an integral part of these consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

1. Organization

Vir Biotechnology, Inc. (“Vir” or the “Company”) is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are one of the leading causes of death worldwide and the cause of hundreds of billions of dollars of economic burden each year. The Company believes that now is the time to apply the recent advances in immunology to combat infectious diseases. The Company’s approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. The Company then brings to bear powerful technologies that the Company believes, individually or in combination, will lead to effective therapies.

Need for Additional Capital

The Company has incurred net losses since inception and expects such losses to continue over the next several years. At December 31, 2018, the Company had an accumulated deficit of \$193.8 million. Management expects to incur additional losses in the future to conduct research and development and recognizes the need to raise additional capital to fully implement its business plan. Through December 31, 2018, the Company has financed its operations primarily through the sale and issuance of convertible preferred stock. The Company intends to raise additional capital through the issuance of equity or strategic alliances with third parties. The Company had \$47.6 million of cash and cash equivalents at December 31, 2018 and raised additional funding through the issuance of equity after December 31, 2018. See Note 16—Subsequent Events, for additional information. Based on the Company’s business plans, management believes it has sufficient capital to meet its obligations for the next twelve months from the issuance date of these consolidated financial statements.

Reverse Stock Split

On September 16, 2019, the Company’s board of directors approved an amendment to the Company’s amended and restated certificate of incorporation to effect a 1-for-4.5 reverse split (“Reverse Split”) of shares of the Company’s common and convertible preferred stock, which was effected on September 27, 2019. The par value per share and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information included in the accompanying consolidated financial statements has been adjusted to reflect the Reverse Split.

2. Summary of Significant Accounting Policies
Basis of Presentation

The Company’s consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented. The consolidated financial statements include the accounts of Vir and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Foreign Currency

The functional currency of the Company’s foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. Transaction gains and losses are included in other income (expense), net on the consolidated statements of operations and were immaterial for the years ended December 31, 2017 and 2018.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reporting periods. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates. The most significant estimates in the Company's consolidated financial statements relate to business combinations, accrued expenses, defined benefit pension plans, the valuation of convertible preferred stock and common stock, the valuation of stock options and the valuation allowance for deferred tax assets.

Unaudited Pro Forma Information

Immediately prior to the completion of the Company's planned initial public offering ("IPO"), all outstanding shares of convertible preferred stock will convert into common stock. The unaudited pro forma net loss per share for the year ended December 31, 2018 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock and the conversion of the convertible preferred stock warrant into a warrant to purchase common stock, as if such conversions had occurred at the beginning of the period, or their issuance dates if later. The numerator of the pro forma net loss per share excludes the impact of the remeasurement of the convertible preferred stock warrant liability as the related convertible preferred stock warrant liability will be reclassified to additional paid-in capital upon the completion of an IPO. Pro forma net loss per share does not include the shares expected to be sold in the IPO.

Segments

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for purposes of allocating resources.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents are deposited in checking and sweep accounts at a financial institution. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and short-term investments and issuers of the short-term investments to the extent recorded on the consolidated balance sheets. As of December 31, 2018, the Company has no off-balance sheet concentrations of credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Investments

Investments include available-for-sale securities and are carried at estimated fair value. The Company's valuations of marketable securities are generally derived from independent pricing services based on quoted prices in active markets for similar securities at period end. Generally, investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from, the consolidated balance sheet date are considered short-term investments. Unrealized gains and losses deemed temporary in nature are reported as a component of accumulated comprehensive loss. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, on the consolidated statements of operations.

The Company's Swiss subsidiary holds short-term structured deposits which include a feature that provides for the instrument to be settled in U.S. dollars or Swiss Francs (CHF) depending on the strike level set at the onset of the instrument compared to the U.S. dollars to CHF exchange rate at the settlement date. The Company has elected to account for these instruments using the fair value option with gains and losses recognized in earnings.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents represent money market funds to secure a standby letter of credit issued pursuant to an office lease entered into in March 2017, and a holdback retained by the Company pursuant to the acquisition of Agenovir Corporation ("Agenovir") in 2018. Additionally, funds received from certain grants are restricted as to their use and are therefore classified as restricted cash and cash equivalents.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over the lesser of their useful lives or the remaining life of the lease. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

Acquired Intangible Assets

Indefinite-lived intangible assets represent the estimated fair value assigned to in-process research and development ("IPR&D") acquired in a business combination. The Company reviews indefinite-lived intangible assets for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of an indefinite-lived intangible asset exceeds its fair value, then it is written down to its adjusted fair value. As of December 31, 2018, there have been no such impairments. For IPR&D, if a product candidate derived from the indefinite-lived intangible asset is developed and commercialized, the useful life will be determined, and the carrying value will be amortized.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

prospectively over that estimated useful life. Alternatively, if a product candidate is abandoned, the carrying value of the intangible asset will be charged to research and development expenses.

Finite-lived intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date. Finite-lived intangible assets acquired in a transaction that is accounted for as an acquisition of assets rather than a business combination are initially recognized in accordance with other applicable GAAP. Any consideration transferred in excess of the fair value of the assets acquired is allocated to each asset acquired on a relative fair value basis. Amortization is computed using the straight-line method over the estimated useful lives of the respective finite-lived intangible assets, generally three to twelve years. Intangible assets are reviewed for impairment at least annually or more frequently if indicators of potential impairment exist.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net tangible and intangible assets acquired in a business combination. The Company tests goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that this asset may be impaired.

Convertible Preferred Stock Warrant Liability

A freestanding warrant to purchase shares of Series A-1 convertible preferred stock at a future date was determined to be a freestanding instrument that is accounted for as a liability due to the variable number of shares to be issued upon exercise. At initial recognition, the Company recorded the convertible preferred stock warrant liability on the consolidated balance sheet at its estimated fair value. The warrant liability is subject to remeasurement at each reporting period, with changes in estimated fair value recognized as a component of other income (expense), net until the exercise of the convertible preferred stock warrant or conversion of such warrant into a warrant to purchase shares of common stock. Upon the completion of the IPO, the warrant will automatically convert into a warrant to purchase shares of common stock.

Revenue Recognition

The Company's revenue primarily consists of research funding received from grants and contract revenue related to research services provided to customers. The Company has not had any product revenue since inception. Additionally, while the Company has entered into various collaboration arrangements, the Company has not recognized any revenue from licenses, milestones or royalties under such agreements.

Grant Revenue

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have been met.

Contract Revenue

Effective January 1, 2017, the Company early adopted on a full retrospective basis Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). In accordance with ASC 606, the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

For collaborative arrangements that fall within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”), the Company applies the revenue recognition model under ASC 606 to part or all of the arrangement, as deemed appropriate. The Company has entered into a number of license and collaboration agreements that fall within the scope of ASC 606. The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to our intellectual property.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These agreements may include the following types of consideration: non-refundable upfront payments, reimbursement for research services, research, development or regulatory milestone payments, and royalty and commercial sales milestone payments.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on their estimated standalone selling prices. For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligation and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Research and Development Expenses

To date, research and development expenses have related primarily to discovery efforts and preclinical and clinical development of product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Research and development expenses include expenses related to license and collaboration agreements; personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel contributing to research and development activities; expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants; clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and other allocated expenses, including expenses for rent, facilities maintenance, and depreciation and amortization.

The Company has and may continue to acquire the rights to develop and commercialize new product candidates from third parties. The upfront payments made to acquire license, product or rights, or payments made related to

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Consolidated Financial Statements**

future milestone payments from transactions that are not considered to be business combinations, are immediately recognized as research and development expenses provided that there is no alternative future use of the rights in other research and development projects, up to the point of regulatory approval. Milestone payments are expensed when the specific milestone has been achieved.

Stock-based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. The Company calculates the fair value measurement of stock options using the Black-Scholes valuation model. Stock-based compensation is recognized using the straight-line method for awards that vest only upon the employee's or non-employee's continued service to the Company. Forfeitures are recognized as they occur.

Business Combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's consolidated financial statements. Any excess fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with the business combination are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in the consolidated statements of operations.

When the Company determines that assets acquired do not meet the definition of a business under the acquisition method of accounting, acquired IPR&D is expensed, no goodwill is recorded, and any contingent consideration is recognized only when it becomes payable or is paid.

Pension Benefits

Accounting for the defined pension benefit plan for the Company's Swiss subsidiary requires actuarial valuations based on significant assumptions for discount rates and expected long-term rates of return on plan assets. These and other assumptions such as salary growth, retirement, and mortality rates are evaluated and selected based on expectations or actual experience during each remeasurement date. Pension expense could vary within a range of outcomes and have a material effect on reported earnings, projected benefit obligations and future cash funding. Actual results in any given year may differ from those estimated because of economic and other factors. The Company recognizes a liability for the underfunded status of its defined benefit pension plan as a component of other long-term liabilities and recognizes actuarial gains or losses and prior service costs or credits in the consolidated statements of operations.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating losses and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Consolidated Financial Statements**

The Company's tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on several factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as any related net interest and penalties.

Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus any potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. Diluted net loss per share is the same as basic net loss per share since the effect of potentially dilutive securities is anti-dilutive.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued a new standard on revenue recognition codified in ASC 606, *Revenue from Contracts with Customers*. Under this standard, revenue is recognized by applying the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill contracts with customers. The Company adopted this Standard on January 1, 2017, using the full retrospective method. The adoption of ASC 606 did not have a significant impact on the Company's consolidated results of operations as the Company's revenue is primarily from grants which are not considered contracts with customers.

In August 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-18, *Restricted Cash, Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 in fiscal 2018 and retrospectively presented fiscal 2017.

In March 2017, the FASB issued ASU No. 2017-07, *Compensation—Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost* ("ASU 2017-07"). ASU 2017-07 requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other current compensation costs for related employees in the income statement and (2) present the other components elsewhere in the income statement and outside of income from operations if that subtotal is presented. The Company adopted ASU 2017-07 as of January 1, 2018. The impact of adopting ASU 2017-07 did not have any impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

conditions of a share-based payment award as a modification. Under ASU 2017-09, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted ASU 2017-09 as of January 1, 2018. The effect of the adoption on the consolidated financial statements was not material.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted ASU 2018-07 as of January 1, 2018. The effect of the adoption on the consolidated financial statements was not material.

In June 2018, the FASB issued ASU No. 2018-08, *Not-For-Profit Entities (Topic 958): Clarifying the Scope of the Accounting Guidance for Contributions Received and Contribution Made* (“ASU 2018-08”). ASU 2018-08 assists entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transactions) within the scope of Topic 958, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. The Company adopted ASU 2018-08 as of January 1, 2018. The adoption of ASU 2018-08 did not have an impact on the consolidated financial statements.

Recent Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instrument—Overall (Subtopic 825-10)* (“ASU 2016-01”), which requires entities to measure equity instruments at fair value and recognize any changes in fair value within the statement of operations. ASU 2016-01 is effective for the Company for the annual period beginning January 1, 2019, and the interim period beginning January 1, 2020. The Company is currently evaluating the impact of adopting ASU 2016-01 on the consolidated financial statements and disclosures.

In February 2016, the FASB issued Accounting Standards Update 2016-02, *Leases (Topic 842)*. Topic 842 requires lessees to recognize all leases, including operating leases, on the balance sheet as a right-of-use asset and lease liability, unless the lease is a short-term lease. In July 2018, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10 *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Targeted Improvements—Leases (Topic 842)*. This update provides an alternative transition method that allows entities to elect to apply the standard retrospectively as of the beginning of the latest period presented versus retrospectively as of the beginning of the earliest period presented. The standard is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. For all other entities, this standard is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The Company plans to adopt the standard on January 1, 2020 and has not yet evaluated the impact of adopting Topic 842 on the consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, which includes the Company’s financial instruments. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* (“ASU 2019-04”). ASU 2019-04 modified the accounting for available-for-sale debt securities, which must be individually assessed for credit losses when fair value is less than the amortized cost basis. For public business entities that are U.S. Securities and Exchange

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Commission filers, this standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other public business entities, this standard is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. For all other entities, this standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company will adopt this standard on January 1, 2020 and has not yet evaluated the impact of adopting this standard on the consolidated financial statements and disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment* (“ASU 2017-04”), which simplifies the current requirements for testing goodwill for impairment by eliminating the second step of the two-step impairment test to measure the amount of an impairment loss. ASU 2017-04 is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-04 will have on its consolidated financial statements and related disclosures. The Company does not expect the adoption of ASU 2017-04 to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-14, *Compensation—Retirement Benefits—Defined Benefit Plans—General (Subtopic 715-20): Disclosure Framework—Changes to the Disclosure Requirements for Defined Benefit Plans* (“ASU 2018-14”). ASU 2018-14 added, removed and clarified disclosure requirements related to defined benefit pension and other postretirement plans. The standard is effective for public business entities for fiscal years ending after December 15, 2020. For all other entities, this standard is effective for fiscal years ending after December 15, 2021. Early adoption is permitted for all entities. The Company is still evaluating the effect that ASU 2018-14 may have on its notes to consolidated financial statements.

3. Fair Value Measurements and Short-Term Investments

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company’s financial instruments, including accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Level 3 liabilities consist of contingent consideration and convertible preferred stock warrant liability. The estimated fair value of the contingent consideration was determined by calculating the probability-weighted milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved. The fair value of the contingent consideration was estimated using discount rates between 15.0% to 16.2% as of December 31, 2017 and 16.8% to 20.3% as of December 31, 2018. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. The increase in the estimated fair value of contingent consideration is primarily due to the shorter time period over which such milestones are expected to be achieved. See Note 4—Acquisitions.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The convertible preferred stock warrant liability is valued using the Black-Scholes option pricing model. The assumptions used to calculate the convertible preferred stock warrant liability are as follows:

	Year Ended December 31,	
	2017	2018
Exercise price	\$4.50	\$4.50
Expected term	8.7	7.7
Expected stock price volatility	92.5%	83.5%
Risk-free interest rate	2.4%	2.6%
Expected dividend yield	—	—

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

		December 31, 2017			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
(in thousands)					
Assets:					
Money market funds(1)	Level 1	\$ 184,404	\$ —	\$ —	\$ 184,404
Total financial assets		<u>\$ 184,404</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 184,404</u>
Liabilities:					
Convertible preferred stock warrant liability	Level 3	\$ 929	\$ —	\$ —	\$ 929
Contingent consideration	Level 3	9,000	—	—	9,000
Total financial liabilities		<u>\$ 9,929</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 9,929</u>

(1) Includes \$1.0 million of restricted cash equivalents.

		December 31, 2018			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
(in thousands)					
Assets:					
Money market funds(1)	Level 1	\$ 43,600	\$ —	\$ —	\$ 43,600
Structured deposits	Level 2	1,000	—	—	1,000
U.S. government treasuries	Level 2	49,859	—	(14)	49,845
Total financial assets		<u>\$ 94,459</u>	<u>\$ —</u>	<u>\$ (14)</u>	<u>\$ 94,445</u>
Liabilities:					
Convertible preferred stock warrant liability	Level 3	\$ 1,024	\$ —	\$ —	\$ 1,024
Contingent consideration	Level 3	9,250	—	—	9,250
Total financial liabilities		<u>\$ 10,274</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,274</u>

(1) Includes \$11.8 million of restricted cash equivalents.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

As of December 31, 2018, some of the Company's short-term investments were in an unrealized loss position. The Company determined that it does have the ability and intent to hold the investments that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment in the year ended December 31, 2018. Total unrealized losses of \$14,000 were recorded in accumulated other comprehensive loss during the year ended December 31, 2018.

No securities have contractual maturities of longer than one year. There were no transfers between Levels 1, 2, or 3 for any of the periods presented.

The following table sets forth the changes in the estimated fair value of the Company's Level 3 financial liabilities (in thousands):

	Contingent Consideration	Warrant Liability	Total
Balance at December 31, 2016	\$ —	\$ 1,011	\$ 1,011
Additions	6,250	—	6,250
Changes in fair value	2,750	(82)	2,668
Balance at December 31, 2017	9,000	929	9,929
Changes in fair value	250	95	345
Balance at December 31, 2018	<u>\$ 9,250</u>	<u>\$ 1,024</u>	<u>\$ 10,274</u>

4. Acquisitions
Acquisition of TomegaVax

In September 2016, the Company entered into an agreement and plan of merger ("TomegaVax Merger Agreement") to acquire all of the equity interests of TomegaVax, Inc. ("TomegaVax"). The primary asset purchased in the acquisition was an in-process CMV vector-based vaccine platform for use in hepatitis B virus ("HBV"), human immunodeficiency virus ("HIV"), and tuberculosis ("TB"). The acquisition was accounted for as an asset purchase and the Company recorded the entire purchase price of \$5.2 million in research and development expenses in 2016.

As purchase consideration the Company issued an aggregate of 1,555,550 shares of Series A-2 convertible preferred stock, valued at \$3.6 million on the transaction date, to the former TomegaVax stockholders. In addition to the equity, the Company paid liabilities of \$1.1 million and incurred transaction costs of \$0.5 million.

In connection with the entry into the TomegaVax Merger Agreement, the Company also entered into a letter agreement with TomegaVax (the "TomegaVax Letter Agreement"), which provides for certain payments to TomegaVax's former stockholders prior to September 2024, in each case so long as the Company is continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, the Company will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of \$30.0 million if the per share price of the Company's publicly traded common stock, or implied price per share of the Company's Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least \$45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and the stage of the Company's clinical development at the time of the relevant event triggering the payment. The share price of the Company's publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of the Company's common stock for each trading day during a consecutive

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the Company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the Company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of the Company's common stock, at the discretion of the Company's board of directors. None of the milestones have been achieved as of December 31, 2018, therefore no amounts were recognized relating to the contingent consideration during 2017 or 2018.

Acquisition of Humabs

In August 2017, the Company entered into a securities purchase agreement (the "Humabs SPA") with Humabs Biomed SA ("Humabs") and its securities holders, pursuant to which the Company purchased all equity interests of Humabs. Humabs, based in Switzerland, discovers and develops monoclonal antibodies derived from individuals whose immune systems have successfully responded to major diseases. The Company paid \$30.0 million in cash and issued 1,666,656 shares of common stock, valued at \$2.5 million as of the date of the transaction based on a valuation determined by the Company with the assistance of a third-party valuation specialist, to former Humabs securities holders. Additionally, the Company is required to pay up to \$135.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for an HBV product, and up to \$105.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for another product. Pursuant to the Humabs SPA, the Company is required to use commercially reasonable efforts to achieve such milestones during a specified period following the closing of the Humabs acquisition. In addition, Humabs' securities holders are also entitled to receive certain pass-through payments that Humabs receives under certain license agreements following deduction of certain expenses incurred by the Company or Humabs thereunder. The estimated fair value of this contingent consideration was \$6.3 million at the date of acquisition.

This transaction was accounted for as an acquisition of a business. The elements of the purchase consideration are as follows (in thousands):

Cash paid	\$ 30,000
Common stock issued(1)	2,475
Net working capital	3,563
Fair value of contingent consideration(2)	6,250
Total consideration	<u>\$ 42,288</u>

(1) Based on the share purchase agreement, the purchase consideration included 1,666,656 shares of the Company's common stock.

(2) The estimated fair value of the contingent consideration was determined by calculating the probability-weighted milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The estimated fair value of assets acquired and liabilities assumed as of acquisition date are as follows (in thousands):

Net working capital	\$ 4,037
Fixed assets	531
Non-current liabilities	(1,047)
Deferred tax liabilities	(14,229)
Finite-lived intangible assets	4,826
Indefinite-lived intangible assets	31,233
Goodwill	16,937
Total consideration transferred	<u>\$ 42,288</u>

Finite-lived intangible assets consisted of developed technologies related to an internally developed platform for isolating and identifying monoclonal antibodies. The developed technologies are amortized on a straight-lined basis over their estimated remaining useful lives, generally between seven to twelve years. The amortization expense for the years ended December 31, 2017 and 2018 was \$0.2 million and \$0.5 million, respectively.

The indefinite-lived intangible assets consisted of in-process research and development related to research and development projects focused on developing antibodies to treat a variety of diseases, including HBV, respiratory syncytial virus ("RSV"), murine pneumonia virus ("MPV"), Zika, and Dengue. The in-process research and development are classified as indefinite-lived intangible assets until they become finite-lived intangible assets upon the successful completion or the abandonment of the associated research and development effort. Accordingly, during the development period after the date of acquisition, these assets will not be amortized until regulatory approval is obtained in a major market, typically either the United States or the European Union, subject to management judgment. At that time, the Company will determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned, the related in-process research and development assets will be written-off and an impairment charge recorded. As of December 31, 2018, there have been no such impairments.

The estimated fair value of the intangible assets was determined using the replacement cost method. Under this method, the Company estimated the cost to recreate the intangible asset as a basis of estimating their fair values. The excess of the purchase price over the estimated fair value of the net assets acquired was recorded as goodwill. The goodwill recognized as a result of the Humabs acquisition is primarily attributable to the fact that the acquisition furthers the Company's strategy of investing in programs focused in infectious diseases. The acquisition adds multiple antibody development candidates, including promising pre-clinical antibodies for the treatment of HBV, RSV/MPV, Zika, and Dengue. None of the goodwill is expected to be deductible for income tax purposes. As of December 31, 2018, no goodwill impairment was identified.

The Company incurred approximately \$0.7 million of direct transaction costs related to the Humabs acquisition. These costs were included in general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2017. The amounts of revenue and pretax loss of Humabs included in the Company's consolidated statement of operations from the acquisition date in August 2017 through December 31, 2017 are \$0.9 million and \$2.7 million, respectively.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The following unaudited pro forma financial information summarizes the combined results of operations for the Company and Humabs, as though the companies were combined as of the beginning of 2017 (in thousands):

	Year Ended December 31, 2017
Total revenue	\$ 4,437
Pretax loss	(84,448)
Net loss	(73,524)

The pro forma financial information for the period presented above has been calculated after adjusting the results of Humabs to reflect the business combination accounting effects resulting from this acquisition, including the amortization expense from acquired intangible assets. The pro forma financial information is for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of the Company's fiscal 2017.

Acquisition of Agenovir

In January 2018, the Company entered into an agreement and plan of merger (the "Agenovir Merger Agreement") with Agenovir Corporation ("Agenovir"), pursuant to which the Company purchased all equity interests of Agenovir. The primary assets purchased in the acquisition were in-process research and development programs in human papillomavirus ("HPV") and HBV using CRISPR/Cas9. The Company concluded that the assets acquired and liabilities assumed did not meet the definition of a business as a limited number of inputs were acquired but no substantive processes were acquired. As such, the acquisition was accounted for as an asset purchase.

As purchase consideration, the Company agreed to pay cash of \$11.5 million and issued an aggregate of 555,537 shares of Series A-2 convertible preferred stock, valued at \$1.8 million on the transaction date, to the former Agenovir stockholders. The Company also assumed certain liabilities of \$1.3 million. The estimated fair value of the Company's Series A-2 convertible preferred stock was \$3.15 per share as of the date of the transaction and was determined by management with the assistance of a third-party valuation specialist. The Company has retained \$2.0 million of the cash consideration as holdback to satisfy claims for indemnification which expires in April 2019. The holdback is recorded in the Company's consolidated balance sheet as restricted cash, current. In addition to the equity, the Company incurred transaction costs of \$0.7 million.

The Company allocated the purchase price of \$15.3 million between property and equipment of \$0.8 million and in-process research and development of \$14.5 million, which was expensed as research and development expenses in the accompanying consolidated statement of operations in the year ended December 31, 2018.

During a specified period following the closing of the Agenovir acquisition, the Company will be required to pay Agenovir's former stockholders up to \$45.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first HBV product, and if the Company elects to progress the HPV program, the Company will owe up to \$45.0 million in the aggregate for the achievement of development and regulatory milestones for the first HPV product. In addition, during a specified period following the closing of the Agenovir acquisition, if the Company successfully commercializes one or more products arising from the HBV program or the HPV program, the Company will owe milestone payments for the achievement of specified levels of worldwide annual net sales of up to \$90.0 million for products arising from each program, or up to \$180.0 million in the aggregate, if the Company were to commercialize products from both the HBV program and the HPV program.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

None of the milestones have been achieved as of December 31, 2018, therefore no amounts were recognized relating to the contingent consideration during 2018.

Acquisition of Statera

In February 2018, the Company entered into an agreement and plan of reorganization with Statera Health, LLC (“Statera”), pursuant to which the Company acquired all equity interests of Statera. The Company paid \$0.9 million in cash and issued an aggregate of 188,333 shares of Series A-2 Convertible Preferred Stock, valued at \$0.6 million on the transaction date, to the former Statera stockholders as purchase consideration. The estimated fair value of the Company’s Series A-2 convertible preferred stock was \$3.15 per share as of the date of the transaction and was determined by management with the assistance of a third party valuation specialist. The transaction was accounted for as an asset acquisition. The Company incurred transaction costs of \$0.2 million.

The primary asset purchased was a cloud-based predictive analytics platform that translates clinical data into casual hypotheses of disease pathophysiology. The cloud-based predictive analytics platform was accounted for as developed technology and is classified as finite-lived intangible assets and is being amortized on a straight-lined basis over an estimated useful life of three years. The amortization expense for the year ended December 31, 2018 was \$0.6 million.

5. Goodwill and Intangible Assets

Goodwill

Goodwill of \$16.9 million represents the excess of the purchase price over the estimated fair value of the net assets acquired from Humabs. The Company tests goodwill for impairment on an annual basis or sooner, if deemed necessary. There was no impairment for the year ended December 31, 2018.

Intangible Assets

The following table summarizes the carrying amount of the Company’s finite-lived intangible assets (in thousands):

	December 31,		Weighted-Average Remaining Useful Life (Years)
	2017	2018	
Developed technology	\$4,826	\$ 7,000	6.4
Less accumulated amortization	(177)	(1,316)	
Developed technology, net	<u>\$4,649</u>	<u>\$ 5,684</u>	

Finite-lived intangible assets are carried at cost less accumulated amortization. Amortization expense related to finite-lived intangible assets, included in research and development expenses in the consolidated statement of operations, totaled \$0.2 million and \$1.1 million for the years ended December 31, 2017 and 2018, respectively.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Based on the finite-lived intangible assets recorded as of December 31, 2018, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31:	Amount
2019	\$ 1,223
2020	1,223
2021	584
2022	499
2023	499
Total	<u>\$ 4,028</u>

Indefinite-Lived Intangible Assets

As of December 31, 2018, the Company had indefinite-lived intangible assets of \$31.2 million of purchased IPR&D from the Humabs acquisition. No impairment losses have been recorded for the years ended December 31, 2017 and 2018.

6. Grant, License and Collaboration Agreements

The Company is a party to various grant and customer contract agreements. Descriptions of the material agreements are included below.

Bill & Melinda Gates Foundation Grants

Campylo/EPEC/EAEC Grant

As part of the Company's acquisition of Humabs in August 2017, the Company acquired a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$4.7 million (the "2017 Grant"). The 2017 Grant supported the Company's discovery, characterization and selection of human monoclonal antibodies with pre-clinical efficacy against three enteric pathogens responsible for life-threatening diarrhea in neonates. The 2017 Grant expired on May 31, 2019.

Payments received in advance that were related to future research activities were deferred and recognized as revenue when the donor-imposed conditions were met, which was as the research and development activities were performed. The Company recognized grant revenue of \$0.8 million and \$2.0 million for the years ended December 31, 2017 and 2018, respectively.

Human Immunodeficiency Virus ("HIV") Grant

On January 26, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$12.2 million for its HIV program (the "HIV Grant"). The HIV Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of \$4.4 million for the year ended December 31, 2018.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Tuberculosis (“TB”) Grant

On March 16, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$14.9 million for its TB program (the “TB Grant”). The TB Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company’s breach, failure to progress the funded project, in the event of the Company’s change of control, change in the Company’s tax status, or significant changes in the Company’s leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of \$2.3 million for the year ended December 31, 2018.

National Institutes of Health

As part of the Company’s acquisition of TomegaVax in September 2016, the Company acquired grant agreements related to TomegaVax’s research effort in infectious diseases and cancer that entitled them to several awards under the Small Business Innovation Research Program from the National Institutes of Health (“NIH”). Through December 31, 2018, the Company has acquired or been awarded grants from NIH totaling \$4.1 million. These grants are cost plus fixed fee agreements in which the Company is reimbursed for its direct and indirect costs. Only costs that are allowable under certain government regulations and NIH’s supplemental policy and procedure manual may be claimed for reimbursement, subject to government audit.

The Company recognized \$1.8 million and \$1.1 million in grant revenue for the years ended December 31, 2017 and 2018, respectively, related to the NIH grants.

Brii Biosciences

In May 2018, the Company entered into an option and license agreement (the “Brii Agreement”) with Brii Biosciences Limited (previously named BiiG Therapeutics Limited) (“Brii Bio Parent”) and Brii Biosciences Offshore Limited (“Brii Bio”), pursuant to which the Company granted to Brii Bio, with respect to up to four of the Company’s programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau (collectively, the “China Territory”) for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection (the “Field of Use”). The Company’s HBV siRNA program being developed under the Alnylam Agreement (described below) is included within the Brii Agreement as a program for which Brii Bio may exercise one of its options. In partial consideration for the options granted by the Company to Brii Bio, Brii Bio Parent and Brii Bio granted the Company, with respect to up to four of Brii Bio Parent’s or Brii Bio’s programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that the Company may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a Vir program. As of December 31, 2018, no license option had been exercised.

As partial consideration for the Company’s entry into the Brii Agreement, upon closing of Brii Bio Parent’s Series A preferred stock financing, the Company received ordinary shares equal to 9.9% of the outstanding shares in Brii Bio Parent. As a result of Brii Bio’s right to exercise one of its options for the Company’s HBV siRNA program, under the terms of the Alnylam Agreement, as amended by a letter agreement with Alnylam, the Company will transfer to Alnylam a specified percentage of such equity consideration allocable to such program.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Consolidated Financial Statements**

The Company also received an option to purchase additional ordinary shares of Brie Bio Parent at a purchase price of \$0.0001 per share in connection with additional Series A preferred stock issuances by Brie Bio Parent and an option to acquire shares of Brie Bio Parent's Series B preferred stock ("Series B Closing Option") upon the occurrence of a Series B financing at the same purchase price paid by the other Series B investors.

With respect to programs for which Brie Bio exercises its options, Brie Bio will be required to pay the Company an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to \$20.0 million, determined based on the commercial potential of the licensed program. Brie Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to \$30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brie Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of \$175.0 million per licensed program. Brie Bio also will pay royalties to the Company that range from the mid-teens to the high-twenties, as described below.

Upon exercise of each option for a Brie Bio program, the Company will be required to pay to Brie Bio an option exercise fee ranging from the low tens of millions to up to \$50.0 million, determined based on the commercial potential of the licensed program. The Company will be required to make regulatory milestone payments to Brie Bio on a licensed product-by-licensed product basis ranging from the low tens of millions up to \$100.0 million, also determined based on the commercial potential of such program. The Company will also be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products in the United States arising from each licensed program, up to an aggregate of \$175.0 million per licensed program.

In addition, the Company is obligated under the Brie Agreement to pay Brie Bio tiered royalties based on net sales of products arising from the licensed programs in the United States, and Brie Bio is obligated to pay the Company tiered royalties based on net sales of products arising from the licensed programs in the China Territory. The rates of royalties payable by the Company to Brie Bio, and by Brie Bio to the Company, on net sales range from mid-teens to high-twenties. Each party's obligations to pay royalties expires, on a product-by-product and territory-by-territory basis, on the latest of 10 years after the first commercial sale of such licensed product in the United States or China Territory, as applicable; the expiration or abandonment of licensed patent rights that cover such product in the United States or China Territory, as applicable; and the expiration of regulatory exclusivity in the United States or the China Territory, as applicable. Royalty rates are subject to specified reductions and offsets.

The Brie Agreement will remain in force until expiration of all options or, if any option is exercised, expiration of all royalty payment obligations for all licensed products within such licensed program, unless terminated in its entirety or on a program-by-program basis by either party. Each party may terminate for convenience all rights and obligations with respect to any program for which it has an option, with 30 days' written notice (if the terminating party has not exercised an option for such program) or 180 days' notice (following the exercise of an option for such program). The Brie Agreement may also be terminated by either party for insolvency of the other party, and either party may terminate the Brie Agreement in its entirety or on a program-by-program basis for the other party's uncured material breach on 60 days' written notice (or 30 days' notice following failure to make payment).

The Company has determined that Brie Bio Parent and its wholly owned subsidiary Brie Bio are variable interest entities due to their reliance on future financing and having insufficient equity at risk. However, the Company does not have the power to direct activities which most significantly impact the economic success of these entities and is not considered the primary beneficiary of these entities. Therefore, the Company does not

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Consolidated Financial Statements**

consolidate Bii Bio Parent or Bii Bio. The Company also determined that it does not exercise significant influence over Bii Bio Parent or Bii Bio. The investment in Bii Bio Parent was recorded at its initial estimated fair value of \$6.6 million within other assets on the consolidated balance sheet and is subsequently accounted for under the cost method. The Company also recorded a contract liability of \$6.6 million within deferred revenue which represents the four options that the Company granted to Bii Bio. Revenue will be recognized when Bii Bio exercises its options or the options expire.

The Company's maximum exposure to loss under the Bii Agreement is represented by options to acquire licenses to develop and commercialize potential products and future milestone payments. The ultimate expense that the Company incurs under the Bii Agreement cannot be quantified at this time as the amount will vary based on the timing and outcome of research activities.

Alnylam

In October 2017, the Company entered into a collaboration and license agreement (the "Alnylam Agreement") with Alnylam Pharmaceuticals, Inc. ("Alnylam") for the development of siRNA products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA therapeutic products directed to up to four other infectious disease targets selected by the Company. The technology licensed under the Alnylam Agreement forms the basis of the Company's siRNA technology platform.

Pursuant to the Alnylam Agreement, the Company obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such as excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to the Company's selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. On a product-by-product basis for each product arising from the HBV and, following the Company's option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

The Company and Alnylam are jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept studies. Prior to the exercise of the Company's option for each siRNA program directed to one of the Company's selected infectious disease targets, Alnylam is responsible for conducting all development activities, at the Company's expense, in accordance with an agreed upon development plan. Following the Company's exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, the Company is solely responsible, at the Company's expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program. If Alnylam exercises a profit-sharing option for a product, the Company will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

Pursuant to the Alnylam Agreement, the Company paid Alnylam an upfront fee of \$10.0 million and issued to Alnylam 1,111,111 shares of the Company's common stock. Both the upfront fee and the estimated fair value of the common stock were recognized as research and development expenses for the year ended December 31,

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Consolidated Financial Statements**

2017. Additionally, the receipt of consideration from Brii Bio as discussed above triggered a requirement under the Alnylam Agreement to transfer a portion of the consideration, consisting of equity in Brii Bio, to Alnylam. Accordingly, the Company recognized a liability of \$0.8 million as of December 31, 2018 and a corresponding charge to research and development expenses.

Upon the achievement of a certain development milestone, the Company will also issue shares of the Company's common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on the Company's stock price at the time such milestone is achieved. The Company will be required to pay Alnylam up to \$190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to \$115.0 million for the achievement of specified development and regulatory milestones by the first product directed to the target of each infectious disease siRNA program for which the Company exercised its option. Following commercialization, the Company will be required to pay to Alnylam up to \$250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to \$100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which the Company exercised its option. The Company may also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. No such liabilities have been recorded as of December 31, 2018.

The term of the Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Alnylam Agreement. If the Company does not exercise its option for an infectious disease program directed to one of its selected targets, the Alnylam Agreement will expire upon the expiration of the applicable option period with respect to such program. However, if Alnylam exercises its profit-sharing option for any product, the term of the Alnylam Agreement will continue until the expiration of the profit-sharing arrangement for such product. The Company may terminate the Alnylam Agreement on a program-by-program basis or in its entirety for any reason on 90 days' written notice. Either party may terminate the agreement for cause for the other party's uncured material breach on 60 days' written notice (or 30 days' notice for payment breach), or if the other party challenges the validity or enforceability of any patent licensed to it under the Alnylam Agreement on 30 days' notice.

The Company incurred \$1.1 million and \$8.3 million of expenses for the joint funding of development activities for the proof of concept study under the Alnylam Agreement during the years ended December 31, 2017 and 2018, respectively.

Visterra

In August 2017, the Company entered into a collaboration, license and option agreement (the "Visterra Agreement") with Visterra, Inc. ("Visterra") to license Visterra's proprietary technology and to research, develop, and commercialize certain product candidates. Under the Visterra Agreement, the Company paid an upfront fee of \$25.0 million, which was recognized as research and development expenses in the year ended December 31, 2017. The Company incurred \$0.9 million and \$2.6 million for the research and development activities under the Visterra Agreement during the years ended December 31, 2017 and 2018, respectively.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Rockefeller University

In July 2018, the Company entered into an exclusive license agreement with The Rockefeller University (“Rockefeller”), which was amended in May 2019 (the “Rockefeller Agreement”). Pursuant to the Rockefeller Agreement, Rockefeller granted the Company a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The Company uses technology licensed under the Rockefeller Agreement in the Company’s antibody platform and in the Company’s product candidate VIR-3434.

The Company paid Rockefeller an upfront fee of \$0.3 million for entry into the Rockefeller Agreement, and is required to pay annual license maintenance fees of \$1.0 million, which will be creditable against royalties following commercialization. In addition, for achievement of specified development and regulatory milestone events, the Company will be required to pay up to \$8.5 million with respect to the first infectious disease product for the HIV indication, up to \$7.0 million with respect to each of the first four other infectious disease products with specified projected peak worldwide annual net sales, and up to \$3.6 million with respect to any other infectious disease product. Following regulatory approval, the Company will be required to pay commercial success milestones of up to \$40.0 million in the aggregate for the achievement of specified aggregate worldwide annual net sales of the first infectious disease product for the HIV indication and the first four infectious disease products with specified projected peak worldwide annual net sales. The Company will also be required to pay to Rockefeller a royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. The Company’s obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction.

The Rockefeller Agreement will remain in force, absent earlier termination, until the expiration of all of the Company’s obligations to pay royalties to Rockefeller in all jurisdictions. The Company has the right to terminate the Rockefeller Agreement in its entirety, or in part, for any reason on 60 days’ written notice to Rockefeller. Rockefeller may terminate the Rockefeller Agreement on 90 days’ written notice for the Company’s uncured material breach, or if the Company challenges the validity or enforceability of any of the licensed patents, or immediately in the event of the Company’s insolvency. Rockefeller may also terminate the Rockefeller Agreement if the Company ceases to carry on business with respect to the rights granted to the Company under the agreement.

MedImmune

In September 2018, the Company entered into a license agreement (“2018 MedImmune Agreement”) with MedImmune, Inc. (“MedImmune”), pursuant to which the Company obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The Company is developing VIR-2482 using technology licensed under the 2018 MedImmune Agreement.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, the Company made an upfront payment to MedImmune of \$10.0 million. The upfront fee was recognized as research and development expenses in the year ended December 31, 2018.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The Company will be obligated to make development, regulatory, and commercial milestone payments of up to \$343.3 million in the aggregate relating to influenza A and influenza B products. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits.

The 2018 MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of the Company's obligations to pay royalties to MedImmune. The Company may terminate the 2018 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 2018 MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party. Additionally, MedImmune may terminate the 2018 MedImmune Agreement for cause on 30 days' written notice if the Company challenges the validity or enforceability of the patents to which the Company has obtained a license under the 2018 MedImmune Agreement.

7. Balance Sheet Components
Property and Equipment, net

Property and equipment, net consists of the following:

	December 31,	
	2017	2018
	(in thousands)	
Lab equipment	\$2,840	\$ 7,538
Computer equipment	21	518
Furniture and fixtures	347	943
Leasehold improvements	2,010	3,114
Construction in progress	186	1,893
Property and equipment, gross	5,404	14,006
Less accumulated depreciation and amortization	(266)	(1,716)
Total property and equipment, net	<u>\$5,138</u>	<u>\$12,290</u>

Depreciation and amortization expenses were \$0.3 million and \$1.6 million for the years ended December 31, 2017 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2017	2018
	(in thousands)	
Payroll and related expenses	\$3,680	\$ 6,165
Research and development expenses	1,838	5,016
Other professional and consulting expenses	1,355	694
Other accrued expenses	667	2,659
Total accrued liabilities	<u>\$7,540</u>	<u>\$14,534</u>

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

8. Commitments and Contingencies***Facility Leases***

The Company has two lease arrangements for office and laboratory space located in San Francisco, California and Bellinzona, Switzerland with contractual lease periods expiring between 2024 and 2028. Rent expense is recognized on a straight-line basis over the terms of the leases accordingly and the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability.

The following are minimum future lease payments owed under these leases (in thousands):

Year Ending December 31:	
2019	\$ 3,436
2020	3,524
2021	3,622
2022	3,722
2023 and thereafter	7,559
Total	<u>\$ 21,863</u>

Rent expense for the years ended December 31, 2017 and 2018 was \$2.6 million and \$4.0 million, respectively.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with its directors and certain officers that may require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no demands have been made upon the Company to provide indemnification under these agreements, and thus, there are no indemnification claims that the Company is aware of that could have a material effect on the Company's consolidated balance sheets, consolidated statements of operations, or consolidated statements of cash flows.

9. Related Party Transactions

In January 2017, the Company issued a promissory note to an executive officer and a promissory note to a director for an aggregate principal amount of \$3.1 million with an interest rate of 1.97% per annum. Principal and interest under these notes are due the earlier of (i) December 31, 2025 or (ii) in an event of default. The entire principal amount was used to purchase 3,624,355 shares of restricted stock. The outstanding balance of these notes was approximately \$3.2 million as of December 31, 2017 and 2018. As the promissory notes are non-recourse in nature, they are accounted for as in-substance stock options. See further discussion in Note 12—Stock-Based Awards.

As a result of the Brie Agreement in May 2018, the Company holds a minority equity interest in Brie Bio through its parent company, Brie Bio Parent. Additionally, the Company's Chief Executive Officer and member of the board of directors as well as another member of the Company's board of directors serve on Brie Bio Parent's board of directors.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

10. Convertible Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of shares: preferred stock and common stock. The preferred stock is issuable in series.

The Company entered into a Series A-1 Preferred Stock Purchase Agreement with certain investors in September 2016 (the "Initial Closing") and sold an aggregate of 1,777,777 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross cash proceeds of \$8.0 million. On the same day as the Initial Closing, the Company issued 1,555,550 shares of Series A-2 convertible preferred stock in connection with an acquisition of TomegaVax, Inc.

In December 2016, the Company entered into a Series A-1 and Series B Preferred Stock Purchase Agreement (the "Series A-1 and B Purchase Agreement") and sold an aggregate of 36,767,773 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$165.5 million in five closings: (i) 2,222,222 shares in December 2016; (ii) 3,333,333 shares in March 2017; (iii) 24,571,107 shares in two closings in June 2017; and (iv) 6,641,111 shares in July 2017.

In August 2017, the Series A-1 and B Purchase Agreement was amended and restated (the "A&R Series A-1 and B Purchase Agreement"), pursuant to which the Company sold an aggregate of 25,843,330 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$116.3 million in five closings: (i) 21,111,110 shares in two closings in August 2017; (ii) 3,968,270 shares in two closings in September 2017; and (iii) 763,950 shares in October 2017.

In June 2018, the A&R Series A-1 and B Purchase Agreement was amended (as amended, the "Amended A&R Series A-1 and B Purchase Agreement"), pursuant to which the Company sold an aggregate of 3,222,220 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$14.5 million in three closings (the "Additional Closings"): (i) 2,777,776 shares in two closings in June 2018; and (ii) 444,444 shares in July 2018. Pursuant to the Amended A&R Series A-1 and B Purchase Agreement, after the Additional Closings, the Company is authorized to sell up to 1,111,121 additional shares of Series A-1 convertible preferred stock in one or more additional closings.

Pursuant to the Amended A&R Series A-1 and B Purchase Agreement, the Company may sell, and certain purchasers of Series A-1 convertible preferred stock shall purchase, up to an aggregate of 22,222,222 shares of Series B convertible preferred stock in one or more additional closings and on the terms and conditions set forth in the Amended A&R Series A-1 and B Purchase Agreement and at a purchase price of \$18.00 per share ("Series B Closing"). As of December 31, 2018, certain purchasers of Series A-1 convertible preferred stock had committed to purchase 18,202,213 shares of Series B convertible preferred stock. Upon 25 calendar days' notice by the Company prior to any Series B Closing, the purchasers were obligated purchase shares of Series B convertible preferred stock at the Series B Closing.

The Company effected a Series B Closing with the consent of supermajority of the Company's board of directors in December 2018. In January 2019, the Company issued and sold 18,202,213 shares of Series B convertible preferred stock in two closings. See Note 16—Subsequent Events, for more details.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

At December 31, 2017, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

			2017		
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	301,100,000	64,388,880	\$ 4.50	\$ 288,955	\$ 298,189
Series A-2	7,000,000	1,555,550	\$ 2.30	3,570	7,420
Series B	100,000,000	—	—	—	—
	<u>408,100,000</u>	<u>65,944,430</u>		<u>\$ 292,525</u>	<u>\$ 305,609</u>

At December 31, 2018, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

			2018		
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	310,350,000	67,611,100	\$ 4.50	\$ 303,224	\$ 322,100
Series A-2	11,100,000	2,299,420	\$ 2.57	5,913	10,958
Series B	100,000,000	—	—	—	—
	<u>421,450,000</u>	<u>69,910,520</u>		<u>\$ 309,137</u>	<u>\$ 333,058</u>

The Company recorded its convertible preferred stock at the issuance price on the dates of issuance, net of issuance costs. Certain purchasers of Series A-1 convertible preferred stock committed to purchase a pre-determined number of shares of Series B convertible preferred stock at a purchase price of \$18.00 per share. In the event that any purchaser of Series A-1 convertible preferred stock does not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Series A-1 convertible preferred stock and Series B convertible preferred stock (collectively, "Senior Preferred Stock") originally purchased by such purchaser shall automatically be converted into 5% of the number of shares of common stock that would otherwise be issuable upon conversion of such shares should the purchaser have elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion shall be canceled by the Company for no consideration.

The convertible preferred stock is an equity instrument with various features, including convertibility and dividends. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative. The Company did not separately account for the purchase rights of the shares of Series B convertible preferred stock described above as they were not freestanding from the associated shares of Series A-1 convertible preferred stock.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The holders of the convertible preferred stock have the following rights and preferences:

Dividend Rights

The holders of preferred stock are entitled to receive dividends, if and when declared by the Company's board of directors, at the rate of \$0.27 per share per annum for each of Series A-1 convertible preferred stock and Series A-2 convertible preferred stock and \$1.08 per share per annum for Series B convertible preferred stock, from and after the date of issuance of such shares. As of December 31, 2017 and 2018, no such dividends were declared or accrued.

Conversion Rights

Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock is convertible, at the option of the holder, into one share of common stock, subject to certain adjustments for dilution, if any, resulting from future stock issuances. Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock shall automatically be converted into shares of common stock at the then-effective conversion rate for such share either: (i) upon the closing of a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in gross proceeds to the Company of not less than \$200.0 million; or (ii) by vote or written consent of the holders of at least 60% of the then outstanding shares of Senior Preferred Stock. Additionally, in the event that any purchaser of Series A-1 convertible preferred stock does not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Senior Preferred Stock originally purchased by such purchaser shall automatically be converted into 5% of the number of shares of common stock that would otherwise be issuable upon conversion of such shares should the purchaser have elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion shall be canceled by the Company for no consideration.

The conversion price for each series of preferred stock will be subject to an adjustment in the event of stock split, stock dividend, combination or other similar recapitalization with respect to the common stock.

Voting Rights

Each holder of outstanding shares of preferred stock has voting rights equal to the whole number of shares of common stock into which such shares could be converted as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Company's amended and restated certificate of incorporation, the holders of the Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock shall vote together with the holders of common stock as a single class. Holders of shares of Series A-1 convertible preferred stock, voting as a separate class, are entitled to elect three directors of the Company prior to the date shares of Series B convertible preferred stock are issued (the "Series B Issuance Date") and two directors of the Company after the Series B Issuance Date. The holders of shares of Series A-2 convertible preferred stock, voting as a separate class, are entitled to elect one director of the Company. From and after the Series B Issuance Date, holders of shares of Series B convertible preferred stock, voting as a separate class, are entitled to elect one director of the Company. Holders of a majority of the outstanding shares of common stock and preferred stock, voting as a single class on an as-converted basis, are entitled to elect any remaining directors.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, as further defined in the Company's amended and restated certificate of incorporation, the holders of shares of Senior Preferred Stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders, on a *pari passu* basis and before any payment shall be made to the holders of Series A-2 convertible preferred stock and common stock, an amount per share equal to the greater of: (i) the original issue price of Senior Preferred Stock held plus any dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid thereon; or (ii) such amount per share as would have been payable if all shares of Senior Preferred Stock had been converted to common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation event. If assets of the Company available are insufficient to pay holders of Senior Preferred Stock the full amount they are entitled to, the holders of Senior Preferred Stock would have shared ratably in any distribution of the assets available for distribution in proportion to the amounts due such holders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock, the remaining assets of the Company will be distributed among the holders of the shares of Series A-2 convertible preferred stock using the same distribution method as the Senior Preferred Stock holders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock and Series A-2 convertible preferred stock, the remaining assets of the Company available for distribution will be distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each such holder.

Redemption

The preferred stock is not redeemable at the option of the holder.

Classification

The Company has classified the convertible preferred stock as temporary equity on the consolidated balance sheets as the shares can be redeemed upon the occurrence of certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation will occur.

11. Convertible Preferred Stock Warrant Liability

In September 2016, the Company issued a warrant to purchase an aggregate of 244,444 shares of the Company's Series A-1 convertible preferred stock with an exercise price of \$4.50 per share in connection with the termination of a sponsor research agreement. The warrant was fully vested upon the issuance date and expires on September 11, 2026. The initial fair value of the warrant was calculated using the Black-Scholes pricing model and the following assumptions: volatility of 99.32%, expected term of 10 years, risk-free interest rate of 1.68%, exercise price of \$4.50 and dividend rate of 0%. The fair value of the warrant was determined to be \$0.9 million and \$1.0 million as of December 31, 2017 and 2018, respectively.

12. Stock-Based Awards
2016 Equity Incentive Plan

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the "2016 Plan") for the issuance of stock options, non-qualified stock options, stock appreciation rights, restricted stock and other stock awards, to

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

employees, non-employee directors, and consultants under terms and provisions established by the Company's board of directors and approved by the stockholders.

Awards granted under the 2016 Plan expire no later than ten years from the date of grant. For incentive stock options and non-statutory stock options, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. For all stock options granted between July and December 2018, the Company incorporated reassessed fair values using hindsight for calculating stock-based compensation expense.

As of December 31, 2018, there were 3,859,178 shares available for the Company to grant under the 2016 Plan.

Stock Option Activity

The following table summarizes option award activity under the 2016 Plan:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding at December 31, 2017	2,479,141	\$ 1.44	9.74	
Granted	3,082,226	1.55		
Exercised	(400,801)	1.46		
Canceled	(115,642)	1.50		
Outstanding at December 31, 2018	<u>5,044,924</u>	1.50	9.13	\$ 18,520
Vested and expected to vest at December 31, 2018	<u>5,044,924</u>	1.50	9.13	18,520
Vested and exercisable at December 31, 2018	<u>545,063</u>	\$ 1.40	8.72	\$ 2,056

Aggregate intrinsic value represents the difference between the Company's reassessed fair value of its common stock and the exercise price of outstanding options. The aggregate intrinsic value of options vested during 2018 was \$3.3 million.

During the years ended December 31, 2017 and 2018, the estimated weighted-average grant date fair value of the options granted was \$1.08 and \$1.72 per share, respectively.

As of December 31, 2018, the Company expects to recognize the remaining unamortized stock-based compensation expense of \$6.1 million related to stock options, over an estimated weighted average period of 2.9 years.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Stock Options Granted to Employees

The fair value of stock options granted to employees was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Year Ended December 31,	
	2017	2018
Expected term of options (in years)	5.9 – 6.0	6.0
Expected stock price volatility	86.5% – 87.3%	86.4% – 88.0%
Risk-free interest rate	1.4% – 2.2%	2.5% – 3.0%
Expected dividend yield	—	—

The valuation assumptions were determined as follows:

Expected Term—The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility—The expected volatility was determined by examining the historical volatilities for industry peers and using an average of historical volatilities of Company's industry peers as the Company's stock is not actively traded on any public markets.

Risk-Free Interest Rate—The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend Rate—The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its profit interest units in the foreseeable future.

Restricted Stock Activity

The following table summarizes restricted stock activity:

	Number of Shares	Weighted Average Fair Value at Date of Grant per Share
Unvested as of December 31, 2017	7,062,406	\$ 1.15
Vested	(2,247,673)	1.15
Unvested as of December 31, 2018	<u>4,814,733</u>	<u>\$ 1.15</u>

The shares of restricted stock have not been included in the shares issued and outstanding.

In January 2017, the Company entered into a restricted stock purchase agreement with an executive officer and a restricted stock purchase agreement with a director whereby the executive officer and the director purchased an aggregate of 3,624,355 shares of restricted stock. The consideration for the restricted stock was the issuance of promissory notes which are non-recourse in nature and are accounted for as in-substance stock options. The Company measured compensation cost for these in-substance options based on their estimated fair value on the grant date using the Black-Scholes pricing model. The Company is recognizing compensation cost over the requisite service period with an offsetting credit to additional paid-in capital.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

As of December 31, 2018, there was \$3.0 million of total unrecognized compensation cost related to unvested restricted stock, all of which is expected to be recognized over a remaining weighted-average period of 1.7 years.

Stock-Based Compensation Expense

The following table sets forth the total stock-based compensation expense for all awards granted to employees and non-employees, including shares sold through the issuance of non-recourse promissory notes of which all the shares are considered to be options for accounting purposes in the Company's statement of operations:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Research and development	\$ 445	\$ 1,056
General and administrative	4,337	3,997
Total stock-based compensation	<u>\$ 4,782</u>	<u>\$ 5,053</u>

13. Net Loss and Unaudited Pro Forma Net Loss Per Share

As the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common securities outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of December 31,	
	2017	2018
Convertible preferred stock	65,944,430	69,910,520
Options issued and outstanding	2,479,141	5,044,924
Restricted shares subject to future vesting	7,062,406	4,814,733
Warrants to purchase convertible preferred stock	244,444	244,444
Total	<u>75,730,421</u>	<u>80,014,621</u>

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share of common stock:

	Year Ended December 31, 2018 (in thousands, except share and per share data)
Numerator:	
Net loss	\$ (115,884)
Add: change in fair value of convertible preferred stock warrant liability	95
Net loss used in calculating pro forma earnings per share, basic and diluted	<u>\$ (115,789)</u>
Denominator:	
Conversion of convertible preferred stock	68,384,032
Weighted average common shares outstanding	<u>76,050,495</u>
Net loss per share, basic and diluted	<u>\$ (1.52)</u>

14. Defined Benefit Pension and Other Postretirement Plans
Defined Contribution Plan

In October 2017, the Company began to sponsor a 401(k) retirement savings plan for the benefit of its employees. Eligible employees may contribute a percentage of their compensation to this plan, subject to statutory limitations. The Company made contributions to the plan for eligible participants, and recorded contribution expenses of \$0.2 million and \$0.7 million for the years ended December 31, 2017 and 2018, respectively.

Postretirement Benefits (Pension Plans) for Humabs

The Company's subsidiary, Humabs, provides its Swiss employees with mandatory cash balance pension benefits whereby employer and employee contributions are accumulated in individual accounts with interest to retirement or withdrawal, if earlier. The benefits are financed through the Swiss Life Collective BVG Foundation with Swiss Life Asset Management through two separate plans. The plans insured base salary and annual incentives up to an aggregate maximum of CHF 0.9 million (\$0.9 million as of December 31, 2018). In addition to retirement benefits, the plans provide benefits on death or long-term disability of its employees.

The first plan is a defined normal benefit plan which is funded 65% by the Company and 35% by employee contribution to a collective foundation with Swiss Life Asset Management. On retirement, the plan participant will receive his/her accumulated savings, which consist of all contributions paid by the employer and the employees, net of any withdrawals, and the interest granted on those savings at the discretion of the pension foundation. At that time, the plan participant has the right to choose between a lump-sum payment and an annuity, or a combination thereof. The annuity is calculated using a fixed conversion rate determined by the pension foundation. The pension fund's plan assets are pooled and the Company's share is calculated based on its share of retirement savings. Additional funding requirements may be determined by the pension foundation in case of a severe underfunding. Should the Company withdraw from the plan, the withdrawal may qualify as a partial liquidation/settlement under Swiss law, which may trigger an obligation to fund any proportionate deficit or a right to any overfunding in existence at that time.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The second plan is a defined management plan. This plan is set up as a collective foundation with Swiss Life Asset Management, for which contributions are split up as 40% paid by the employees and 60% paid by the Company. The purpose of this plan is to allow higher saving opportunity (in a tax effective manner) and risk benefits for management.

Contributions are expressed as an age-related percentage of pensionable salary between limits and are shared between Humabs and its employees. The Company paid contributions of approximately \$0.2 million and employees paid approximately \$0.1 million for the year ended December 31, 2018.

The following table sets forth the net liability recognized in the consolidated balance sheets (in thousands):

	December 31,	
	2017	2018
	(in thousands)	
Projected benefit obligation	\$ (3,576)	\$ (3,887)
Fair value of plan assets	2,409	2,770
Net unfunded status	<u>\$ (1,167)</u>	<u>\$ (1,117)</u>

The key assumptions used to measure the liabilities are as follows:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Discount rate	0.67%	0.85%
Salary increase	1.00%	1.00%
Expected rate of return on assets	0.80%	0.80%
Mortality	BVG2015	BVG2015

The expected rate of return on assets corresponds to the return on benefits expected to be provided under the insurance contract. Net periodic pension cost includes the following components (in thousands):

	August 22, 2017 to December 31, 2017
Service cost	\$ 99
Interest cost	7
Expected return on plan assets	(6)
Net funded status at December 31, 2017	<u>\$ 100</u>
	Year Ended December 31, 2018
Service cost	\$ 261
Interest cost	23
Expected return on plan assets	(20)
Net funded status at December 31, 2018	<u>\$ 264</u>

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

The benefits expected to be paid over the next 10 years are as follows (in thousands):

Year Ending December 31,	
2019	\$ 180
2020	180
2021	180
2022	175
2023	172
2024-2028	833
	<u>\$1,720</u>

15. Income Taxes

Loss before benefit from income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2017	2018
Domestic	\$ (77,947)	\$ (110,399)
Foreign	(2,829)	(5,965)
Total loss before benefit from income taxes	<u>\$ (80,776)</u>	<u>\$ (116,364)</u>

The components of income tax expense (benefit) consist of the following (in thousands):

	Year Ended December 31,	
	2017	2018
Current:		
Federal	\$ —	\$ —
State	—	—
Foreign	—	20
	<u>—</u>	<u>20</u>
Deferred:		
Federal	(10,924)	(445)
State	—	(55)
Foreign	—	—
	<u>(10,924)</u>	<u>(500)</u>
Benefit from income taxes	<u>\$ (10,924)</u>	<u>\$ (480)</u>

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

A reconciliation between the expected income tax provision at the federal statutory rate and the reported income tax benefit is as follows:

	Year Ended December 31,	
	2017	2018
U.S. federal statutory income tax rate	34.0%	21.0%
Foreign tax at less than federal statutory rate	(0.5)	(0.1)
Effect of Tax Act	(6.8)	—
State taxes, net of federal benefit	5.0	2.0
Research and development tax credit	1.0	2.2
Acquired IPR&D	—	(2.9)
Permanent items	(0.1)	(0.4)
Changes in valuation allowance	(19.0)	(21.4)
Other	(0.1)	—
Effective income tax rate	<u>13.5%</u>	<u>0.4%</u>

The tax effects of temporary differences that give rise to significant portions of the Company's deferred tax assets and liabilities as of December 31, 2017 and 2018, are related to the following:

	December 31,	
	2017	2018
	(in thousands)	
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 13,468	\$ 36,358
Research and development tax credit carryforward	735	3,357
Reserves and accruals	27	1,331
Property and equipment	8,550	7,761
IPR&D	(8,647)	(8,647)
Net deferred tax assets	14,133	40,160
Valuation allowance	(17,438)	(43,465)
Net deferred tax liabilities	<u>\$ (3,305)</u>	<u>\$ (3,305)</u>

The Company has incurred significant tax losses since inception. Based on the available objective evidence, the Company cannot conclude it is more likely than not that the net deferred tax assets will be fully realizable. Accordingly, the Company has provided a valuation allowance against its net deferred tax assets. For the years ended December 31, 2017 and 2018, the valuation allowance increased by approximately \$15.8 million and \$26.0 million, respectively. For the year ended December 31, 2018, the Company has net operating loss carryforwards of approximately \$141.2 million for federal purposes and approximately \$77.4 million for state tax purposes. If not utilized, these carryforwards will begin expiring in 2034 for federal and in 2031 for state tax purposes. The federal net operating losses ("NOLs") generated after December 31, 2017, have an infinite carryforward period and subject to 80% deduction limitation based upon pre-NOL deduction taxable income. As of December 31, 2018, the Company also has net operating loss carryforwards of \$9.3 million for Swiss tax purposes, which begin expiring in 2024 and no net operating loss carryforward for Australian tax purposes.

Staff Accounting Bulletin No. 118 addresses the application of GAAP in situations when an entity does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act and allows the registrant to record

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company has completed the analysis with no change to the provisional amounts previously recorded.

Under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. The impact of any limitations that may be imposed due to such ownership changes has not yet been determined.

As of December 31, 2018, the Company has research tax credit carryforwards of approximately \$2.5 million and \$1.6 million for federal and state tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2036. The California credits can be carried forward indefinitely. If not utilized, Oregon carryforward will expire starting 2021. The Company has not undertaken a detailed analysis of all amounts claimed as research credits for federal or state tax purposes. As a result, amounts ultimately realized for research credits were included in the Company's consideration of uncertain tax benefits.

Uncertain Tax Positions

As of December 31, 2018, the Company had an unrecognized tax benefit of approximately \$2.4 million related to transfer pricing and research and development tax credits. No amount of unrecognized tax benefits as of December 31, 2018, if recognized, would reduce the Company's effective tax rate because the benefits would be in the form of tax credit carryforwards, which would attract a full valuation allowance. There are no provisions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date. Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statutes are still open on calendar years ending December 31, 2018 forward for federal and state purposes.

The Company did not recognize any expense for interest and penalties related to uncertain tax positions during 2018 and 2017, and the Company does not have any amounts related to interest and penalties accrued at December 31, 2018. The Company files U.S. federal, state and Switzerland tax returns. The Company's tax years remain open for all years. As of December 31, 2018, the Company was not under examination by the Internal Revenue Service or any state or foreign tax jurisdiction.

A reconciliation of the beginning and ending amounts of the liability for uncertain tax positions is as follows:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Gross unrecognized tax benefits at January 1	\$ 18	\$ 272
Addition for tax positions taken in the prior years	—	32
Reduction for tax positions taken in the prior years	—	(215)
Addition for tax positions taken in current year	253	2,315
Gross unrecognized tax benefits at December 31	<u>\$ 271</u>	<u>\$ 2,404</u>

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

16. Subsequent Event

In January 2019, the Company sold an aggregate of 18,202,213 shares of Series B convertible preferred stock at \$18.00 per share for estimated net cash proceeds of \$327.5 million, which includes the \$10.1 million in advanced proceeds received in December 2018.

F-43

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Condensed Consolidated Balance Sheets**
(in thousands, except share and per share data)

	December 31, 2018	June 30, 2019	Pro Forma Stockholders' Equity as of June 30, 2019
		(unaudited)	(unaudited)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 47,598	\$ 80,678	
Short-term investments	50,845	275,869	
Restricted cash and cash equivalents, current	10,761	11,620	
Prepaid expenses and other current assets	8,579	9,232	
Total current assets	117,783	377,399	
Intangible assets, net	36,917	36,305	
Goodwill	16,937	16,937	
Property and equipment, net	12,290	15,418	
Restricted cash and cash equivalents, noncurrent	1,003	1,003	
Other assets	6,666	9,787	
TOTAL ASSETS	\$ 191,596	\$ 456,849	
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)			
CURRENT LIABILITIES:			
Accounts payable	\$ 6,473	\$ 4,078	
Accrued liabilities	14,534	18,374	
Deferred revenue, current portion	8,761	11,663	
Advanced proceeds from preferred stock financing	10,140	—	
Contingent consideration, current portion	—	6,605	
Total current liabilities	39,908	40,720	
Deferred revenue, noncurrent	6,561	6,561	
Convertible preferred stock warrant liability	1,024	1,808	\$ —
Contingent consideration, noncurrent	9,250	2,995	
Deferred tax liability	3,305	3,305	
Other long-term liabilities	1,588	1,815	
TOTAL LIABILITIES	61,636	57,204	
Commitments and contingencies (Note 8)			
Convertible preferred stock, \$0.0001 par value; 421,450,000 shares authorized; 69,910,520 and 88,112,733 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), respectively; aggregate liquidation preference of \$333,058 and \$670,606 as of December 31, 2018 and June 30, 2019 (unaudited), respectively; no actual shares issued and outstanding as of June 30, 2019, pro forma (unaudited)			
	309,137	636,612	—
STOCKHOLDERS' EQUITY (DEFICIT):			
Common stock, \$0.0001 par value; 558,350,000 shares authorized as of December 31, 2018 and June 30, 2019 (unaudited); 8,858,799 and 9,722,838 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), respectively; 300,000,000 shares authorized and 97,835,571 shares issued and outstanding as of June 30, 2019, pro forma (unaudited)			
	1	1	10
Additional paid-in capital	14,672	19,226	657,637
Accumulated other comprehensive income (loss)	(14)	240	240
Accumulated deficit	(193,836)	(256,434)	(256,434)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(179,177)	(236,967)	\$ 401,453
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	\$ 191,596	\$ 456,849	

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Condensed Consolidated Statements of Operations**
(in thousands, except share and per share amounts)
(unaudited)

	Six Months Ended June 30,	
	2018	2019
Revenues:		
Grant revenue	\$ 3,909	\$ 5,605
Contract revenue	748	103
Total revenue	4,657	5,708
Operating expenses:		
Research and development	48,419	55,677
General and administrative	13,788	16,570
Total operating expenses	62,207	72,247
Loss from operations	(57,550)	(66,539)
Other income (expense):		
Interest income	1,207	4,552
Other income (expense), net	(192)	(592)
Total other income (expense), net	1,015	3,960
Loss before benefit from (provision for) income taxes	(56,535)	(62,579)
Benefit from (provision for) income taxes	500	(19)
Net loss	\$ (56,035)	\$ (62,598)
Net loss per share, basic and diluted	\$ (8.04)	\$ (6.83)
Weighted-average shares outstanding, basic and diluted	6,973,460	9,165,311
Pro forma net loss per share, basic and diluted		\$ (0.64)
Pro forma weighted-average shares outstanding, basic and diluted		96,912,507

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	2019
Net loss	\$ (56,035)	\$ (62,598)
Other comprehensive loss:		
Unrealized gains (losses) on investments	(16)	254
Other comprehensive income (loss)	(16)	254
Comprehensive loss	<u>\$ (56,051)</u>	<u>\$ (62,344)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.**

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	65,944,430	\$292,525	6,210,325	\$ 1	\$ 9,035	\$ —	\$ (77,952)	\$ (68,916)
Issuance of Series A-1 convertible preferred stock, net of issuance costs of \$182	2,777,776	12,318	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred shares as consideration in asset acquisition	743,870	2,343	—	—	—	—	—	—
Vesting of restricted common stock	—	—	1,295,336	—	—	—	—	—
Exercise of stock options	—	—	9,721	—	14	—	—	14
Stock-based compensation	—	—	—	—	2,652	—	—	2,652
Other comprehensive loss	—	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	—	(56,035)	(56,035)
Balance at June 30, 2018	<u>69,466,076</u>	<u>\$307,186</u>	<u>7,515,382</u>	<u>\$ 1</u>	<u>\$ 11,701</u>	<u>\$ (16)</u>	<u>\$ (133,987)</u>	<u>\$ (122,301)</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	69,910,520	\$309,137	8,858,799	\$ 1	\$ 14,672	\$ (14)	\$ (193,836)	\$ (179,177)
Issuance of Series B convertible preferred stock, net of issuance costs of \$165	18,202,213	327,475	—	—	—	—	—	—
Vesting of restricted common stock	—	—	395,966	—	—	—	—	—
Exercise of stock options	—	—	468,073	—	702	—	—	702
Stock-based compensation	—	—	—	—	3,852	—	—	3,852
Other comprehensive income	—	—	—	—	—	254	—	254
Net loss	—	—	—	—	—	—	(62,598)	(62,598)
Balance at June 30, 2019	<u>88,112,733</u>	<u>\$636,612</u>	<u>9,722,838</u>	<u>\$ 1</u>	<u>\$ 19,226</u>	<u>\$ 240</u>	<u>\$ (256,434)</u>	<u>\$ (236,967)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (56,035)	\$ (62,598)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of property and equipment.	198	—
Depreciation and amortization	589	1,533
Amortization of intangible assets	527	612
Accretion of discounts on investments	(200)	(1,220)
Change in fair value of contingent consideration	2,030	350
Change in estimated fair value of convertible preferred stock warrant liability	(67)	784
Preferred stock issued in connection with asset acquisition	1,750	—
Change in deferred income taxes	(500)	—
Stock-based compensation	2,652	3,852
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(314)	(653)
Other assets	(157)	(212)
Accounts payable	1,250	(833)
Deferred revenue	13,144	2,902
Accrued liabilities and other long-term liabilities	5,149	1,691
Net cash used in operating activities	<u>(29,984)</u>	<u>(53,792)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3,868)	(6,131)
Purchases of short-term investments	(100,291)	(360,021)
Maturities of short-term investments	10,963	136,471
Proceeds from sale of property and equipment	25	—
Asset acquisitions	(1,743)	—
Net cash used in investing activities	<u>(94,914)</u>	<u>(229,681)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of offering costs related to initial public offering	—	(625)
Proceeds from exercise of stock options	14	702
Proceeds from issuance of convertible preferred stock, net of issuance costs	12,314	317,335
Net cash provided by financing activities	<u>12,328</u>	<u>317,412</u>
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	(112,570)	33,939
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	188,921	59,362
Cash, cash equivalents and restricted cash and cash equivalents at end of period	<u>\$ 76,351</u>	<u>\$ 93,301</u>
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued liabilities	\$ 432	\$ 526
Preferred stock issued in connection with asset acquisition	\$ 593	\$ —
Deferred offering costs in accounts payable and accrued liabilities	\$ —	\$ 2,284
Advanced proceeds applied to convertible preferred stock issuance	\$ —	\$ 10,140
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	\$ 59,316	\$ 80,678
Restricted cash and cash equivalents, current	16,032	11,620
Restricted cash and cash equivalents, noncurrent	1,003	1,003
Total cash, cash equivalents and restricted cash and cash equivalents	<u>\$ 76,351</u>	<u>\$ 93,301</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
1. Organization

Vir Biotechnology, Inc. (“Vir” or the “Company”) is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. The Company’s approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. The Company then brings to bear powerful technologies that the Company believes, individually or in combination, will lead to effective therapies.

Need for Additional Capital

The Company has incurred net losses since inception and expects such losses to continue over the next several years. At June 30, 2019, the Company had an accumulated deficit of \$256.4 million. Management expects to incur additional losses in the future to conduct research and development and recognizes the need to raise additional capital to fully implement its business plan. Through June 30, 2019, the Company has financed its operations primarily through the sale and issuance of convertible preferred stock. The Company intends to raise additional capital through the issuance of equity or strategic alliances with third parties. The Company had \$356.5 million of cash, cash equivalents and short-term investments at June 30, 2019. Based on the Company’s business plans, management believes it has sufficient capital to meet its obligations for the next twelve months from the issuance date of these condensed consolidated financial statements.

Reverse Stock Split

On September 16, 2019, the Company’s board of directors approved an amendment to the Company’s amended and restated certificate of incorporation to effect a 1-for-4.5 reverse split (“Reverse Split”) of shares of the Company’s common and convertible preferred stock, which was effected on September 27, 2019. The par value per share and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the Reverse Split. All of the share and per share information included in the accompanying condensed consolidated financial statements has been adjusted to reflect the Reverse Split.

2. Summary of Significant Accounting Policies
Basis of Presentation

The Company’s condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented. The condensed consolidated financial statements include the accounts of Vir and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Foreign Currency

The functional currency of the Company’s foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. Transaction gains and losses are included in other income (expense), net on the condensed consolidated statements of operations and were immaterial for the six months ended June 30, 2018 and 2019.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Use of Estimates***

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expense during the reporting periods. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates. The most significant estimates in the Company's condensed consolidated financial statements relate to business combinations, accrued expenses, defined benefit pension plans, the valuation of convertible preferred stock and common stock, the valuation of stock options and the valuation allowance for deferred tax assets.

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of June 30, 2019, and the condensed consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the six months ended June 30, 2018 and 2019 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial position as of June 30, 2019 and its results of operations, convertible preferred stock and stockholders' deficit, and cash flows for the six months ended June 30, 2018 and 2019. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the six-month periods are also unaudited. The condensed consolidated results of operations for the six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ended December 31, 2019 or for any other future annual or interim period. The consolidated balance sheet as of December 31, 2018 included herein was derived from the audited consolidated financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Information

The unaudited pro forma stockholders' equity as of June 30, 2019 gives effect to the conversion of all outstanding shares of convertible preferred stock into shares of common stock and the conversion of the convertible preferred stock warrant into a warrant to purchase common stock, and the related reclassification of convertible preferred stock warrant liability to additional paid-in-capital upon the completion of the Company's planned initial public offering ("IPO"). The shares expected to be sold in the IPO and the proceeds expected to be received in the IPO are excluded from such pro forma financial information.

The unaudited pro forma net loss per share for the six months ended June 30, 2019 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later. The numerator of the pro forma net loss per share excludes the impact of the remeasurement of the convertible preferred stock warrant liability as the related convertible preferred stock warrant liability will be reclassified to additional paid-in capital upon the completion of an IPO. Pro forma net loss per share does not include the shares expected to be sold in the IPO.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Segments***

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for purposes of allocating resources.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents are deposited in checking and sweep accounts at a financial institution. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and short-term investments and issuers of the short-term investments to the extent recorded on the condensed consolidated balance sheets. As of June 30, 2019, the Company has no off-balance sheet concentrations of credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value.

Investments

Investments include available-for-sale securities and are carried at estimated fair value. The Company's valuations of marketable securities are generally derived from independent pricing services based on quoted prices in active markets for similar securities at period end. Generally, investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from, the consolidated balance sheet date are considered short-term investments. Unrealized gains and losses deemed temporary in nature are reported as a component of accumulated comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, on the condensed consolidated statements of operations.

The Company's Swiss subsidiary holds short-term structured deposits which include a feature that provides for the instrument to be settled in U.S. dollars or Swiss Francs (CHF) depending on the strike level set at the onset of the instrument compared to the U.S. dollars to CHF exchange rate at the settlement date. The Company has elected to account for these instruments using the fair value option with gains and losses recognized in earnings.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents represent money market funds to secure a standby letter of credit issued pursuant to an office lease entered into in March 2017, and a holdback retained by the Company pursuant to the acquisition of Agenovir Corporation ("Agenovir") in 2018, which was paid to Agenovir in the second quarter of 2019. Additionally, funds received from certain grants are restricted as to their use and are therefore classified as restricted cash and cash equivalents.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Deferred Offering Costs***

Deferred offering costs, consisting of legal, accounting and filing fees relating to an IPO, are capitalized. The deferred offering costs will be offset against offering proceeds upon the completion of the offering. In the event the offering is terminated, or delayed, deferred offering costs will be expensed. The Company has incurred \$2.9 million in deferred offering costs relating to the planned IPO as of June 30, 2019. There are no deferred offering costs capitalized as of December 31, 2018.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over the lesser of their useful lives or the remaining life of the lease. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

Acquired Intangible Assets

Indefinite-lived intangible assets represent the estimated fair value assigned to in-process research and development ("IPR&D") acquired in a business combination. The Company reviews indefinite-lived intangible assets for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of an indefinite-lived intangible asset exceeds its fair value, then it is written down to its adjusted fair value. As of June 30, 2019, there have been no such impairments. For IPR&D, if a product candidate derived from the indefinite-lived intangible asset is developed and commercialized, the useful life will be determined, and the carrying value will be amortized prospectively over that estimated useful life. Alternatively, if a product candidate is abandoned, the carrying value of the intangible asset will be charged to research and development expenses.

Finite-lived intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date. Finite-lived intangible assets acquired in a transaction that is accounted for as an acquisition of assets rather than a business combination are initially recognized in accordance with other applicable GAAP. Any consideration transferred in excess of the fair value of the assets acquired is allocated to each asset acquired on a relative fair value basis. Amortization is computed using the straight-line method over the estimated useful lives of the respective finite-lived intangible assets, generally three to twelve years. Intangible assets are reviewed for impairment at least annually or more frequently if indicators of potential impairment exist.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Goodwill***

Goodwill represents the excess of the purchase price over the estimated fair value of the net tangible and intangible assets acquired in a business combination. The Company tests goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that this asset may be impaired.

Convertible Preferred Stock Warrant Liability

A freestanding warrant to purchase shares of Series A-1 convertible preferred stock at a future date was determined to be a freestanding instrument that is accounted for as a liability due to the variable number of shares to be issued upon exercise. At initial recognition, the Company recorded the convertible preferred stock warrant liability on the consolidated balance sheet at its estimated fair value. The warrant liability is subject to remeasurement at each reporting period, with changes in estimated fair value recognized as a component of other income (expense), net until the exercise of the convertible preferred stock warrant or conversion of such warrant into a warrant to purchase shares of common stock. Upon the completion of the IPO, the warrant will automatically convert into a warrant to purchase shares of common stock.

Revenue Recognition

The Company's revenue primarily consists of research funding received from grants and contract revenue related to research services provided to customers. The Company has not had any product revenue since inception. Additionally, while the Company has entered into various collaboration arrangements, the Company has not recognized any revenue from licenses, milestones or royalties under such agreements.

Grant Revenue

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have been met.

Contract Revenue

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

For collaborative arrangements that fall within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808"), the Company applies the revenue recognition model under ASC 606 to part or all of the arrangement, as deemed appropriate. The Company has entered into a number of license and collaboration agreements that fall within the scope of ASC 606. The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to our intellectual property.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements**

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These agreements may include the following types of consideration: non-refundable upfront payments, reimbursement for research services, research, development or regulatory milestone payments, and royalty and commercial sales milestone payments.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on their estimated standalone selling prices. For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligation and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Research and Development Expenses

To date, research and development expenses have related primarily to discovery efforts and preclinical and clinical development of product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Research and development expenses include expenses related to license and collaboration agreements; personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel contributing to research and development activities; expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants; clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and other allocated expenses, including expenses for rent, facilities maintenance, and depreciation and amortization.

The Company has and may continue to acquire the rights to develop and commercialize new product candidates from third parties. The upfront payments made to acquire license, product or rights, or payments made related to future milestone payments from transactions that are not considered to be business combinations, are immediately recognized as research and development expenses provided that there is no alternative future use of the rights in other research and development projects, up to the point of regulatory approval. Milestone payments are expensed when the specific milestone has been achieved.

Stock-based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. The Company calculates the fair value measurement of stock options using the Black-Scholes valuation model. Stock-based compensation is recognized using the straight-line method for awards that vest only upon the employee's or non-employee's continued service to the Company. Forfeitures are recognized as they occur.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Business Combinations***

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's consolidated financial statements. Any excess fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with the business combination are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in the condensed consolidated statements of operations.

When the Company determines that assets acquired do not meet the definition of a business under the acquisition method of accounting, acquired IPR&D is expensed, no goodwill is recorded, and any contingent consideration is recognized only when it becomes payable or is paid.

Pension Benefits

Accounting for the defined pension benefit plan for the Company's Swiss subsidiary requires actuarial valuations based on significant assumptions for discount rates and expected long-term rates of return on plan assets. These and other assumptions such as salary growth, retirement, and mortality rates are evaluated and selected based on expectations or actual experience during each remeasurement date. Pension expense could vary within a range of outcomes and have a material effect on reported earnings, projected benefit obligations and future cash funding. Actual results in any given year may differ from those estimated because of economic and other factors. The Company recognizes a liability for the underfunded status of its defined benefit pension plan as a component of other long-term liabilities and recognizes actuarial gains or losses and prior service costs or credits in the consolidated statements of operations.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating losses and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized. The Company's tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on several factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as any related net interest and penalties.

Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net

[Table of Contents](#)

VIR BIOTECHNOLOGY, INC.

Notes to Unaudited Condensed Consolidated Financial Statements

loss per common share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus any potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. Diluted net loss per share is the same as basic net loss per share since the effect of potentially dilutive securities is anti-dilutive.

3. Fair Value Measurements and Short-Term Investments

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of the Company’s financial instruments, including accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Level 3 liabilities consist of contingent consideration and convertible preferred stock warrant liability. The estimated fair value of the contingent consideration was determined by calculating the probability-weighted milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved. The fair value of the contingent consideration was estimated using discount rates between 16.8% to 20.3% as of December 31, 2018 and 16.5% to 20.9% as of June 30, 2019. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. The increase in the estimated fair value of contingent consideration is primarily due to the shorter time period over which such milestones are expected to be achieved. See Note 4—Acquisitions.

The convertible preferred stock warrant liability is valued using the Black-Scholes option pricing model. The assumptions used to calculate the convertible preferred stock warrant liability are as follows:

	Year Ended December 31, 2018	Six Months Ended June 30, 2019
Exercise price	\$ 4.50	\$ 4.50
Expected term	7.7	7.2
Expected stock price volatility	83.5%	103.2%
Risk-free interest rate	2.6%	1.9%
Expected dividend yield	—	—

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

		December 31, 2018			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
(in thousands)					
Assets:					
Money market funds(1)	Level 1	\$ 43,600	\$ —	\$ —	\$ 43,600
Structured deposits	Level 2	1,000	—	—	1,000
U.S. government treasuries	Level 2	49,859	—	(14)	49,845
Total financial assets		<u>\$ 94,459</u>	<u>\$ —</u>	<u>\$ (14)</u>	<u>\$ 94,445</u>
Liabilities:					
Convertible preferred stock warrant liability	Level 3	\$ 1,024	\$ —	\$ —	\$ 1,024
Contingent consideration	Level 3	9,250	—	—	9,250
Total financial liabilities		<u>\$ 10,274</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,274</u>

(1) Includes \$11.8 million of restricted cash equivalents.

		June 30, 2019			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
(in thousands)					
Assets:					
Money market funds(1)	Level 1	\$ 85,228	\$ —	\$ —	\$ 85,228
U.S. government treasuries	Level 2	272,628	240	—	272,868
Bank time deposits	Level 2	4,000	—	—	4,000
Total financial assets		<u>\$ 361,856</u>	<u>\$ 240</u>	<u>\$ —</u>	<u>\$ 362,096</u>
Liabilities:					
Convertible preferred stock warrant liability	Level 3	\$ 1,808	\$ —	\$ —	\$ 1,808
Contingent consideration	Level 3	9,600	—	—	9,600
Total financial liabilities		<u>\$ 11,408</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,408</u>

(1) Includes \$12.6 million of restricted cash equivalents.

As of December 31, 2018, some of the Company's short-term investments were in an unrealized loss position. The Company determined that it does have the ability and intent to hold the investments that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment in the year ended December 31, 2018. Total unrealized losses of \$14,000 were recorded in accumulated other comprehensive income (loss) at December 31, 2018.

As of June 30, 2019, all of the Company's short-term investments were in an unrealized gain position. Total unrealized gains of \$0.3 million were recorded in accumulated other comprehensive income (loss) at June 30, 2019.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

No securities have contractual maturities of longer than one year. There were no transfers between Levels 1, 2, or 3 for any of the periods presented.

The following table sets forth the changes in the estimated fair value of the Company's Level 3 financial liabilities (in thousands):

	Contingent Consideration	Warrant Liability	Total
Balance at December 31, 2018	\$ 9,250	\$ 1,024	\$ 10,274
Changes in fair value	350	784	1,134
Balance at June 30, 2019	<u>\$ 9,600</u>	<u>\$ 1,808</u>	<u>\$ 11,408</u>

4. Acquisitions
Acquisition of TomegaVax

In September 2016, the Company entered into an agreement and plan of merger ("TomegaVax Merger Agreement") to acquire all of the equity interests of TomegaVax, Inc. ("TomegaVax"). The primary asset purchased in the acquisition was an in-process CMV vector-based vaccine platform for use in hepatitis B virus ("HBV"), human immunodeficiency virus ("HIV"), and tuberculosis ("TB"). The acquisition was accounted for as an asset purchase and the Company recorded the entire purchase price of \$5.2 million in research and development expenses in 2016.

As purchase consideration, the Company issued an aggregate of 1,555,550 shares of Series A-2 convertible preferred stock, valued at \$3.6 million on the transaction date, to the former TomegaVax stockholders. In addition to the equity, the Company paid liabilities of \$1.1 million and incurred transaction costs of \$0.5 million.

In connection with the entry into the TomegaVax Merger Agreement, the Company also entered into a letter agreement with TomegaVax (the "TomegaVax Letter Agreement"), which provides for certain payments to TomegaVax's former stockholders prior to September 2024, in each case so long as the Company is continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, the Company will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of \$30.0 million if the per share price of the Company's publicly traded common stock, or implied price per share of the Company's Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least \$45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and the stage of the Company's clinical development at the time of the relevant event triggering the payment. The share price of the Company's publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of the Company's common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the Company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the Company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of the Company's common stock, at the discretion of the Company's board of directors. None of the milestones have been achieved as of June 30, 2019, therefore no amounts were recognized relating to the contingent consideration during the six months ended June 30, 2019.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
Acquisition of Humabs

In August 2017, the Company entered into a securities purchase agreement (the “Humabs SPA”) with Humabs Biomed SA (“Humabs”) and its securities holders, pursuant to which the Company purchased all equity interests of Humabs. Humabs, based in Switzerland, discovers and develops monoclonal antibodies derived from individuals whose immune systems have successfully responded to major diseases. The Company paid \$30.0 million in cash and issued 1,666,656 shares of common stock, valued at \$2.5 million as of the date of the transaction based on a valuation determined by the Company with the assistance of a third-party valuation specialist, to former Humabs securities holders. Additionally, the Company is required to pay up to \$135.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for an HBV product, and up to \$105.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for another product. Pursuant to the Humabs SPA, the Company is required to use commercially reasonable efforts to achieve such milestones during a specified period following the closing of the Humabs acquisition. In addition, Humabs’ securities holders are also entitled to receive certain pass-through payments that Humabs receives under certain license agreements following deduction of certain expenses incurred by the Company or Humabs thereunder. The estimated fair value of this contingent consideration was \$6.3 million at the date of acquisition.

This transaction was accounted for as an acquisition of a business. The elements of the purchase consideration are as follows (in thousands):

Cash paid	\$ 30,000
Common stock issued(1)	2,475
Net working capital	3,563
Fair value of contingent consideration(2)	6,250
Total consideration	\$ 42,288

- (1) Based on the share purchase agreement, the purchase consideration included 1,666,656 shares of the Company’s common stock.
- (2) The estimated fair value of the contingent consideration was determined by calculating the probability- weighted milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved.

The estimated fair value of assets acquired and liabilities assumed as of the acquisition date are as follows (in thousands):

Net working capital	\$ 4,037
Fixed assets	531
Non-current liabilities	(1,047)
Deferred tax liabilities	(14,229)
Finite-lived intangible assets	4,826
Indefinite-lived intangible assets	31,233
Goodwill	16,937
Total consideration transferred	\$ 42,288

Finite-lived intangible assets consisted of developed technologies related to an internally developed platform for isolating and identifying monoclonal antibodies. The developed technologies are amortized on a straight-lined

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

basis over their estimated remaining useful lives, generally between seven to twelve years. The amortization expense for the six months ended June 30, 2018 and 2019 was \$0.2 million.

The indefinite-lived intangible assets consisted of in-process research and development related to research and development projects focused on developing antibodies to treat a variety of diseases, including HBV, respiratory syncytial virus ("RSV"), murine pneumonia virus ("MPV"), Zika, and Dengue. The in-process research and development are classified as indefinite-lived intangible assets until they become finite-lived intangible assets upon the successful completion or the abandonment of the associated research and development effort. Accordingly, during the development period after the date of acquisition, these assets will not be amortized until regulatory approval is obtained in a major market, typically either the United States or the European Union, subject to management judgment. At that time, the Company will determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned, the related in-process research and development assets will be written-off and an impairment charge recorded. As of June 30, 2019, there have been no such impairments.

The estimated fair value of the intangible assets was determined using the replacement cost method. Under this method, the Company estimated the cost to recreate the intangible asset as a basis of estimating their fair values. The excess of the purchase price over the estimated fair value of the net assets acquired was recorded as goodwill. The goodwill recognized as a result of the Humabs acquisition is primarily attributable to the fact that the acquisition furthers the Company's strategy of investing in programs focused in infectious diseases. The acquisition adds multiple antibody development candidates, including promising pre-clinical antibodies for the treatment of HBV, RSV/MPV, Zika, and Dengue. None of the goodwill is expected to be deductible for income tax purposes. As of June 30, 2019, no goodwill impairment was identified.

Acquisition of Agenovir

In January 2018, the Company entered into an agreement and plan of merger (the "Agenovir Merger Agreement") with Agenovir Corporation ("Agenovir"), pursuant to which the Company purchased all equity interests of Agenovir. The primary assets purchased in the acquisition were in-process research and development programs in human papillomavirus ("HPV") and HBV using CRISPR/Cas9. The Company concluded that the assets acquired and liabilities assumed did not meet the definition of a business as a limited number of inputs were acquired but no substantive processes were acquired. As such, the acquisition was accounted for as an asset purchase.

As purchase consideration, the Company agreed to pay cash of \$11.5 million and issued an aggregate of 555,537 shares of Series A-2 convertible preferred stock, valued at \$1.8 million on the transaction date, to the former Agenovir stockholders. The Company also assumed certain liabilities of \$1.3 million. The estimated fair value of the Company's Series A-2 convertible preferred stock was \$3.15 per share as of the date of the transaction and was determined by management with the assistance of a third-party valuation specialist. The Company retained \$2.0 million of the cash consideration as holdback to satisfy claims for indemnification, of which, \$1.8 million was paid to Agenovir in April 2019. In addition to the equity, the Company incurred transaction costs of \$0.7 million.

The Company allocated the purchase price of \$15.3 million between property and equipment of \$0.8 million and in-process research and development of \$14.5 million, which was expensed as research and development expenses in the accompanying condensed consolidated statement of operations for the six months ended June 30, 2018.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

During a specified period following the closing of the Agenovir acquisition, the Company will be required to pay Agenovir's former stockholders up to \$45.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first HBV product, and if the Company elects to progress the HPV program, the Company will owe up to \$45.0 million in the aggregate for the achievement of development and regulatory milestones for the first HPV product. In addition, during a specified period following the closing of the Agenovir acquisition, if the Company successfully commercializes one or more products arising from the HBV program or the HPV program, the Company will owe milestone payments for the achievement of specified levels of worldwide annual net sales of up to \$90.0 million for products arising from each program, or up to \$180.0 million in the aggregate, if the Company were to commercialize products from both the HBV program and the HPV program.

None of the milestones have been achieved as of June 30, 2019, therefore no amounts were recognized relating to the contingent consideration.

Acquisition of Statera

In February 2018, the Company entered into an agreement and plan of reorganization with Statera Health, LLC ("Statera"), pursuant to which the Company acquired all equity interests of Statera. The Company paid \$0.9 million in cash and issued an aggregate of 188,333 shares of Series A-2 convertible preferred stock, valued at \$0.6 million on the transaction date, to the former Statera stockholders as purchase consideration. The estimated fair value of the Company's Series A-2 convertible preferred stock was \$3.15 per share as of the date of the transaction and was determined by management with the assistance of a third party valuation specialist. The transaction was accounted for as an asset acquisition. The Company incurred transaction costs of \$0.2 million.

The primary asset purchased was a cloud-based predictive analytics platform that translates clinical data into casual hypotheses of disease pathophysiology. The cloud-based predictive analytics platform was accounted for as developed technology and is classified as finite-lived intangible assets and is being amortized on a straight-lined basis over an estimated useful life of three years. The amortization expense for the six months ended June 30, 2018 and 2019 was \$0.3 million and \$0.4 million, respectively.

5. Goodwill and Intangible Assets
Goodwill

Goodwill of \$16.9 million represents the excess of the purchase price over the estimated fair value of the net assets acquired from Humabs. The Company tests goodwill for impairment on an annual basis or sooner, if deemed necessary. There was no impairment as of June 30, 2019.

Intangible Assets

The following table summarizes the carrying amount of the Company's finite-lived intangible assets (in thousands):

	December 31, 2018	June 30, 2019	Weighted Average Remaining Useful Life (Years)
Developed technology	\$ 7,000	\$ 7,000	6.2
Less accumulated amortization	(1,316)	(1,928)	
Developed technology, net	<u>\$ 5,684</u>	<u>\$ 5,072</u>	

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Finite-lived intangible assets are carried at cost less accumulated amortization. Amortization expense related to finite-lived intangible assets, included in research and development expenses in the condensed consolidated statements of operations, totaled \$0.5 million and \$0.6 million for the six months ended June 30, 2018 and 2019, respectively.

Indefinite-Lived Intangible Assets

As of June 30, 2019, the Company had indefinite-lived intangible assets of \$31.2 million of purchased IPR&D from the Humabs acquisition. No impairment losses have been recorded as of June 30, 2019.

6. Grant, License and Collaboration Agreements

The Company is a party to various grant and customer contract agreements. Descriptions of the material agreements are included below.

Bill & Melinda Gates Foundation Grants
Campylo/EPEC/EAEC Grant

As part of the Company's acquisition of Humabs in August 2017, the Company acquired a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$4.7 million (the "2017 Grant"). The 2017 Grant supported the Company's discovery, characterization and selection of human monoclonal antibodies with pre-clinical efficacy against three enteric pathogens responsible for life-threatening diarrhea in neonates. The 2017 Grant expired on May 31, 2019.

Payments received in advance that were related to future research activities were deferred and recognized as revenue when the donor-imposed conditions were met, which was as the research and development activities were performed. The Company recognized grant revenue of \$0.7 million and \$0.9 million for the six months ended June 30, 2018 and 2019, respectively.

Human Immunodeficiency Virus ("HIV") Grant

On January 26, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$12.2 million for its HIV program (the "HIV Grant"). The HIV Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of \$2.0 million and \$2.9 million for the six months ended June 30, 2018 and 2019, respectively.

Tuberculosis ("TB") Grant

On March 16, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation pursuant to which it was awarded a grant totaling up to \$14.9 million for its TB program (the "TB Grant"). The TB Grant will remain in effect until June 30, 2020, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements**

Payments received in advance that are related to future research activities are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The Company recognized grant revenue of \$0.5 million and \$1.3 million for the six months ended June 30, 2018 and 2019, respectively.

National Institutes of Health

As part of the Company's acquisition of TomegaVax in September 2016, the Company acquired grant agreements related to TomegaVax's research effort in infectious diseases and cancer that entitled them to several awards under the Small Business Innovation Research Program from the National Institutes of Health ("NIH"). Through June 30, 2019, the Company has acquired or been awarded grants from NIH totaling \$4.1 million. These grants are cost plus fixed fee agreements in which the Company is reimbursed for its direct and indirect costs. Only costs that are allowable under certain government regulations and NIH's supplemental policy and procedure manual may be claimed for reimbursement, subject to government audit.

The Company recognized \$0.7 million and \$0.5 million in grant revenue for the six months ended June 30, 2018 and 2019, respectively, related to the NIH grants.

Brii Biosciences

In May 2018, the Company entered into an option and license agreement (the "Brii Agreement") with Brii Biosciences Limited (previously named BiiG Therapeutics Limited) ("Brii Bio Parent") and Brii Biosciences Offshore Limited ("Brii Bio"), pursuant to which the Company granted to Brii Bio, with respect to up to four of the Company's programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau (collectively, the "China Territory") for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection (the "Field of Use"). The Company's HBV siRNA program being developed under the Alnylam Agreement (described below) is included within the Brii Agreement as a program for which Brii Bio may exercise one of its options. In partial consideration for the options granted by the Company to Brii Bio, Brii Bio Parent and Brii Bio granted the Company, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that the Company may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a Vir program. As of June 30, 2019, no license option had been exercised.

As partial consideration for the Company's entry into the Brii Agreement, upon closing of Brii Bio Parent's Series A preferred stock financing, the Company received ordinary shares equal to 9.9% of the outstanding shares in Brii Bio Parent. As a result of Brii Bio's right to exercise one of its options for the Company's HBV siRNA program, under the terms of the Alnylam Agreement, as amended by a letter agreement with Alnylam, the Company will transfer to Alnylam a specified percentage of such equity consideration allocable to such program. The Company also received an option to purchase additional ordinary shares of Brii Bio Parent at a purchase price of \$0.0001 per share in connection with additional Series A preferred stock issuances by Brii Bio Parent and an option to acquire shares of Brii Bio Parent's Series B preferred stock upon the occurrence of a Series B financing at the same purchase price paid by the other Series B investors.

With respect to programs for which Brii Bio exercises its options, Brii Bio will be required to pay the Company an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to \$20.0 million,

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements**

determined based on the commercial potential of the licensed program. Brie Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to \$30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brie Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of \$175.0 million per licensed program. Brie Bio also will pay royalties to the Company that range from the mid-teens to the high-twenties, as described below.

Upon exercise of each option for a Brie Bio program, the Company will be required to pay to Brie Bio an option exercise fee ranging from the low tens of millions to up to \$50.0 million, determined based on the commercial potential of the licensed program. The Company will be required to make regulatory milestone payments to Brie Bio on a licensed product-by-licensed product basis ranging from the low tens of millions up to \$100.0 million, also determined based on the commercial potential of such program. The Company will also be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products in the United States arising from each licensed program, up to an aggregate of \$175.0 million per licensed program.

In addition, the Company is obligated under the Brie Agreement to pay Brie Bio tiered royalties based on net sales of products arising from the licensed programs in the United States, and Brie Bio is obligated to pay the Company tiered royalties based on net sales of products arising from the licensed programs in the China Territory. The rates of royalties payable by the Company to Brie Bio, and by Brie Bio to the Company, on net sales range from mid-teens to high-twenties. Each party's obligations to pay royalties expires, on a product-by-product and territory-by-territory basis, on the latest of 10 years after the first commercial sale of such licensed product in the United States or China Territory, as applicable; the expiration or abandonment of licensed patent rights that cover such product in the United States or China Territory, as applicable; and the expiration of regulatory exclusivity in the United States or the China Territory, as applicable. Royalty rates are subject to specified reductions and offsets.

The Brie Agreement will remain in force until expiration of all options or, if any option is exercised, expiration of all royalty payment obligations for all licensed products within such licensed program, unless terminated in its entirety or on a program-by-program basis by either party. Each party may terminate for convenience all rights and obligations with respect to any program for which it has an option, with 30 days' written notice (if the terminating party has not exercised an option for such program) or 180 days' notice (following the exercise of an option for such program). The Brie Agreement may also be terminated by either party for insolvency of the other party, and either party may terminate the Brie Agreement in its entirety or on a program-by-program basis for the other party's uncured material breach on 60 days' written notice (or 30 days' notice following failure to make payment).

The Company has determined that Brie Bio Parent and its wholly owned subsidiary Brie Bio are variable interest entities due to their reliance on future financing and having insufficient equity at risk. However, the Company does not have the power to direct activities which most significantly impact the economic success of these entities and is not considered the primary beneficiary of these entities. Therefore, the Company does not consolidate Brie Bio Parent or Brie Bio. The Company also determined that it does not exercise significant influence over Brie Bio Parent or Brie Bio. The investment in Brie Bio Parent was recorded at its initial estimated fair value of \$6.6 million within other assets on the consolidated balance sheet and is subsequently accounted for under the cost method. The Company also recorded a contract liability of \$6.6 million within deferred revenue, noncurrent; which represents the four options that the Company granted to Brie Bio. Revenue will be recognized when Brie Bio exercises its options or the options expire. As of December 31, 2018 and June 30, 2019, the carrying value of the investment in Brie Bio is \$6.6 million, which is included in other assets on the consolidated balance sheets.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

The Company's maximum exposure to loss under the Brie Agreement is represented by options to acquire licenses to develop and commercialize potential products and future milestone payments. The ultimate expense that the Company incurs under the Brie Agreement cannot be quantified at this time as the amount will vary based on the timing and outcome of research activities.

Alnylam

In October 2017, the Company entered into a collaboration and license agreement (the "Alnylam Agreement") with Alnylam Pharmaceuticals, Inc. ("Alnylam") for the development of siRNA products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA therapeutic products directed to up to four other infectious disease targets selected by the Company. The technology licensed under the Alnylam Agreement forms the basis of the Company's siRNA technology platform.

Pursuant to the Alnylam Agreement, the Company obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such as excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to the Company's selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. On a product-by-product basis for each product arising from the HBV and, following the Company's option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

The Company and Alnylam are jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept studies. Prior to the exercise of the Company's option for each siRNA program directed to one of the Company's selected infectious disease targets, Alnylam is responsible for conducting all development activities, at the Company's expense, in accordance with an agreed upon development plan. Following the Company's exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, the Company is solely responsible, at the Company's expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program. If Alnylam exercises a profit-sharing option for a product, the Company will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

Pursuant to the Alnylam Agreement, the Company paid Alnylam an upfront fee of \$10.0 million and issued to Alnylam 1,111,111 shares of the Company's common stock. Both the upfront fee and the estimated fair value of the common stock were recognized as research and development expenses for the year ended December 31, 2017. Additionally, the receipt of consideration from Brie Bio as discussed above triggered a requirement under the Alnylam Agreement to transfer a portion of the consideration, consisting of equity in Brie Bio, to Alnylam. Accordingly, the Company recognized a liability of \$0.8 million as of December 31, 2018, and a corresponding charge to research and development expenses. The liability of \$0.8 million remained outstanding as of June 30, 2019.

Upon the achievement of a certain development milestone, the Company will also issue shares of the Company's common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on the

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Company's stock price at the time such milestone is achieved. The Company will be required to pay Alnylam up to \$190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to \$115.0 million for the achievement of specified development and regulatory milestones by the first product directed to the target of each infectious disease siRNA program for which the Company exercised its option. Following commercialization, the Company will be required to pay to Alnylam up to \$250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to \$100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which the Company exercised its option. The Company may also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. No such liabilities have been recorded as of June 30, 2019.

The term of the Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Alnylam Agreement. If the Company does not exercise its option for an infectious disease program directed to one of its selected targets, the Alnylam Agreement will expire upon the expiration of the applicable option period with respect to such program. However, if Alnylam exercises its profit-sharing option for any product, the term of the Alnylam Agreement will continue until the expiration of the profit-sharing arrangement for such product. The Company may terminate the Alnylam Agreement on a program-by-program basis or in its entirety for any reason on 90 days' written notice. Either party may terminate the agreement for cause for the other party's uncured material breach on 60 days' written notice (or 30 days' notice for payment breach), or if the other party challenges the validity or enforceability of any patent licensed to it under the Alnylam Agreement on 30 days' notice.

The Company incurred \$5.5 million and \$3.1 million of expenses for the joint funding of development activities for the proof of concept study under the Alnylam Agreement during the six months ended June 30, 2018 and 2019, respectively.

Visterra

In August 2017, the Company entered into a collaboration, license and option agreement (the "Visterra Agreement") with Visterra, Inc. ("Visterra") to license Visterra's proprietary technology and to research, develop, and commercialize certain product candidates. Under the Visterra Agreement, the Company paid an upfront fee of \$25.0 million, which was recognized as research and development expenses in the year ended December 31, 2017. The Company incurred \$2.2 million for the research and development activities under the Visterra Agreement during the six months ended June 30, 2018. No expense was incurred under the Visterra Agreement during the six months ended June 30, 2019.

Rockefeller University

In July 2018, the Company entered into an exclusive license agreement with The Rockefeller University ("Rockefeller"), which was amended in May 2019 (the "Rockefeller Agreement"). Pursuant to the Rockefeller Agreement, Rockefeller granted the Company a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The Company uses technology licensed under the Rockefeller Agreement in the Company's antibody platform and in the Company's product candidate VIR-3434.

The Company paid Rockefeller an upfront fee of \$0.3 million for entry into the Rockefeller Agreement, and is required to pay annual license maintenance fees of \$1.0 million, which will be creditable against royalties following commercialization. In addition, for achievement of specified development and regulatory milestone events, the Company will be required to pay up to \$8.5 million with respect to the first infectious disease product for the HIV indication, up to \$7.0 million with respect to each of the first four other infectious disease products with specified projected peak worldwide annual net sales, and up to \$3.6 million with respect to any other infectious disease product. Following regulatory approval, the Company will be required to pay commercial success milestones of up to \$40.0 million in the aggregate for the achievement of specified aggregate worldwide annual net sales of the first infectious disease product for the HIV indication and the first four infectious disease products with specified projected peak worldwide annual net sales. The Company will also be required to pay to Rockefeller a royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. The Company's obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction. The Company recognized the \$1.0 million of annual license maintenance fee as research and development expense during the six months ended June 30, 2019.

The Rockefeller Agreement will remain in force, absent earlier termination, until the expiration of all of the Company's obligations to pay royalties to Rockefeller in all jurisdictions. The Company has the right to terminate the Rockefeller Agreement in its entirety, or in part, for any reason on 60 days' written notice to Rockefeller. Rockefeller may terminate the Rockefeller Agreement on 90 days' written notice for the Company's uncured material breach, or if the Company challenges the validity or enforceability of any of the licensed patents, or immediately in the event of the Company's insolvency. Rockefeller may also terminate the Rockefeller Agreement if the Company ceases to carry on business with respect to the rights granted to the Company under the agreement.

MedImmune

In September 2018, the Company entered into a license agreement ("2018 MedImmune Agreement") with MedImmune, Inc. ("MedImmune"), pursuant to which the Company obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The Company is developing VIR-2482 using technology licensed under the 2018 MedImmune Agreement.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, the Company made an upfront payment to MedImmune of \$10.0 million. The upfront fee was recognized as research and development expenses in the third quarter of 2018.

The Company will be obligated to make development, regulatory, and commercial milestone payments of up to \$343.3 million in the aggregate relating to influenza A and influenza B products. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

The 2018 MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of the Company's obligations to pay royalties to MedImmune. The Company may terminate the 2018 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 2018 MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party. Additionally, MedImmune may terminate the 2018 MedImmune Agreement for cause on 30 days' written notice if the Company challenges the validity or enforceability of the patents to which the Company has obtained a license under the 2018 MedImmune Agreement.

7. Balance Sheet Components
Property and Equipment, net

Property and equipment, net consists of the following:

	December 31, 2018	June 30, 2019
	(in thousands)	
Lab equipment	\$ 7,538	\$10,171
Computer equipment	518	548
Furniture and fixtures	943	1,189
Leasehold improvements	3,114	6,359
Construction in progress	1,893	400
Property and equipment, gross	14,006	18,667
Less accumulated depreciation and amortization	(1,716)	(3,249)
Total property and equipment, net	<u>\$ 12,290</u>	<u>\$15,418</u>

Depreciation and amortization expenses were \$0.6 million and \$1.5 million for the six months ended June 30, 2018 and 2019, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2018	June 30, 2019
	(in thousands)	
Payroll and related expenses	\$ 6,165	\$ 3,834
Research and development expenses	5,016	10,433
Other professional and consulting expenses	694	3,666
Other accrued expenses	2,659	441
Total accrued liabilities	<u>\$ 14,534</u>	<u>\$18,374</u>

8. Commitments and Contingencies
Facility Leases

The Company has various lease arrangements for office and laboratory space located in California, Oregon and Switzerland with contractual lease periods expiring between 2020 and 2028. In April 2019, the Company entered

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

into an amendment to its San Francisco lease to include additional space in the leased facility which will commence in October 2019, and with the contractual lease period expiring in 2024.

Rent expense is recognized on a straight-line basis over the terms of the leases accordingly and the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability.

The following are the aggregate non-cancelable future minimum lease payments under operating leases as of June 30, 2019 (in thousands):

Year Ending December 31:	Amounts
2019 (remaining six months)	\$ 2,046
2020	4,020
2021	3,800
2022	3,885
2023 and thereafter	7,839
Total	<u>\$ 21,590</u>

Rent expense for the six months ended June 30, 2018 and 2019 was \$2.2 million and \$2.0 million, respectively.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with its directors and certain officers that may require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no demands have been made upon the Company to provide indemnification under these agreements, and thus, there are no indemnification claims that the Company is aware of that could have a material effect on the Company's consolidated balance sheets, consolidated statements of operations, or consolidated statements of cash flows.

9. Related Party Transactions

In January 2017, the Company issued a promissory note to an executive officer and a promissory note to a director for an aggregate principal amount of \$3.1 million with an interest rate of 1.97% per annum. Principal and interest under these notes are due the earlier of (i) December 31, 2025 or (ii) in an event of default. The entire principal amount was used to purchase 3,624,355 shares of restricted stock. The outstanding balance of these notes was approximately \$3.2 million as of December 31, 2018 and June 30, 2019. As the promissory notes are non-recourse in nature, they are accounted for as in-substance stock options. See further discussion in Note 12—Stock-Based Awards.

As a result of the Brie Agreement in May 2018, the Company holds a minority equity interest in Brie Bio through its parent company, Brie Bio Parent. Additionally, the Company's Chief Executive Officer and member of the board of directors as well as another member of the Company's board of directors serve on Brie Bio Parent's board of directors.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

In January 2019, the Company issued 18,202,213 shares of Series B convertible preferred stock to existing Series A-1 preferred stockholders. See further discussion in Note 10—Convertible Preferred Stock.

10. Convertible Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of shares: preferred stock and common stock. The preferred stock was issued in a series.

In June 2018, the Company and certain investors entered into an amended Amended and Restated Series A-1 and B Purchase Agreement (as amended, the "Amended A&R Series A-1 and B Purchase Agreement"), pursuant to which the Company sold an aggregate of 3,222,220 shares of Series A-1 convertible preferred stock at \$4.50 per share for gross proceeds of \$14.5 million in three closings (the "Additional Closings"): (i) 2,777,776 shares in two closings in June 2018; and (ii) 444,444 shares in July 2018. Pursuant to the Amended A&R Series A-1 and B Purchase Agreement, after the Additional Closings, the Company was authorized to sell up to 1,111,121 additional shares of Series A-1 convertible preferred stock in one or more additional closings.

In January 2019, pursuant to the Amended A&R Series A-1 and B Purchase Agreement, the Company sold an aggregate of 18,202,213 shares of Series B convertible preferred stock at \$18.00 per share for gross proceeds of \$327.6 million in two closings (the "Series B Closing"). The Company is authorized to sell up to 4,020,009 additional shares of Series B convertible preferred stock in one or more additional closings.

At December 31, 2018, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

	December 31, 2018				
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	310,350,000	67,611,100	\$ 4.50	\$ 303,224	\$ 322,100
Series A-2	11,100,000	2,299,420	\$ 2.57	5,913	10,958
Series B	100,000,000	—	—	—	—
	<u>421,450,000</u>	<u>69,910,520</u>		<u>\$ 309,137</u>	<u>\$ 333,058</u>

At June 30, 2019, convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

	June 30, 2019				
	Shares Authorized	Shares Issued and Outstanding	Issuance Price per Share	Carrying Value	Liquidation Preference
Series A-1	310,350,000	67,611,100	\$ 4.50	\$ 303,224	\$ 322,499
Series A-2	11,100,000	2,299,420	\$ 2.57	5,913	10,968
Series B	100,000,000	18,202,213	\$ 18.00	327,475	337,139
	<u>421,450,000</u>	<u>88,112,733</u>		<u>\$ 636,612</u>	<u>\$ 670,606</u>

The Company recorded its convertible preferred stock at the issuance price on the dates of issuance, net of issuance costs.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Certain purchasers of Series A-1 convertible preferred stock committed to purchase a pre-determined number of shares of Series B convertible preferred stock at a purchase price of \$18.00 per share. In the event that any purchaser of Series A-1 convertible preferred stock did not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Series A-1 convertible preferred stock and Series B convertible preferred stock (collectively, "Senior Preferred Stock") originally purchased by such purchaser would have automatically converted into 5% of the number of shares of common stock that would otherwise have been issuable upon conversion of such shares if the purchaser had elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion would have been canceled by the Company for no consideration. No such conversions have taken place as of June 30, 2019 because the relevant purchasers of Series A-1 convertible preferred stock had purchased the number of Series B convertible preferred stock as committed pursuant to the Amended A&R Series A-1 and B Purchase Agreement.

The convertible preferred stock is an equity instrument with various features, including convertibility and dividends. The Company determined that none of the features required bifurcation from the underlying shares, either because they are clearly and closely related to the underlying shares or because they do not meet the definition of a derivative. The Company did not separately account for the purchase rights of the shares of Series B convertible preferred stock described above as they were not freestanding from the associated shares of Series A-1 convertible preferred stock.

The holders of the convertible preferred stock have the following rights and preferences:

Dividend Rights

The holders of preferred stock are entitled to receive dividends, if and when declared by the Company's board of directors, at the rate of \$0.27 per share per annum for each of Series A-1 convertible preferred stock and Series A-2 convertible preferred stock and \$1.08 per share per annum for Series B convertible preferred stock, from and after the date of issuance of such shares. As of December 31, 2018 and June 30, 2019, no such dividends were declared or accrued.

Conversion Rights

Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock is convertible, at the option of the holder, into one share of common stock, subject to certain adjustments for dilution, if any, resulting from future stock issuances. Each share of Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock shall automatically be converted into shares of common stock at the then-effective conversion rate for such share either: (i) upon the closing of a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in gross proceeds to the Company of not less than \$200.0 million; or (ii) by vote or written consent of the holders of at least 60% of the then outstanding shares of Series A-1 convertible preferred stock and Series B convertible preferred stock. Additionally, in the event that any purchaser of Series A-1 convertible preferred stock does not purchase such number of shares of Series B convertible preferred stock it agreed to purchase pursuant to the Amended A&R Series A-1 and B Purchase Agreement, other than as a result of the nonfulfillment of conditions to such purchaser's obligation to purchase such shares, then (i) each share of Senior Preferred Stock originally purchased

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements**

by such purchaser shall automatically be converted into 5% of the number of shares of common stock that would otherwise be issuable upon conversion of such shares should the purchaser have elected to convert the shares to common stock and (ii) with respect to any shares of common stock outstanding at the time of a Series B Closing that were issued to the purchaser upon its conversion election of Senior Preferred Stock, 95% of the shares of common stock issued upon such conversion shall be canceled by the Company for no consideration.

The conversion price for each series of preferred stock will be subject to an adjustment in the event of stock split, stock dividend, combination or other similar recapitalization with respect to the common stock.

Voting Rights

Each holder of outstanding shares of preferred stock has voting rights equal to the whole number of shares of common stock into which such shares could be converted as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Company's amended and restated certificate of incorporation, the holders of the Series A-1 convertible preferred stock, Series A-2 convertible preferred stock and Series B convertible preferred stock shall vote together with the holders of common stock as a single class. Holders of shares of Series A-1 convertible preferred stock, voting as a separate class, were entitled to elect three directors of the Company prior to the date shares of Series B convertible preferred stock were issued (the "Series B Issuance Date") and are entitled to elect two directors of the Company after the Series B Issuance Date. The holders of shares of Series A-2 convertible preferred stock, voting as a separate class, are entitled to elect one director of the Company. The holders of shares of Series B convertible preferred stock, voting as a separate class, are entitled to elect one director of the Company. Holders of a majority of the outstanding shares of common stock and preferred stock, voting as a single class on an as-converted basis, are entitled to elect any remaining directors.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, as further defined in the Company's amended and restated certificate of incorporation, the holders of shares of Senior Preferred Stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders, on a *pari passu* basis and before any payment shall be made to the holders of Series A-2 convertible preferred stock and common stock, an amount per share equal to the greater of: (i) the original issue price of Senior Preferred Stock held plus any dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid thereon; or (ii) such amount per share as would have been payable if all shares of Senior Preferred Stock had been converted to common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation event. If assets of the Company available are insufficient to pay holders of Senior Preferred Stock the full amount they are entitled to, the holders of Senior Preferred Stock would have shared ratably in any distribution of the assets available for distribution in proportion to the amounts due such holders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock, the remaining assets of the Company will be distributed among the holders of the shares of Series A-2 convertible preferred stock using the same distribution method as the Senior Preferred Stockholders. After the payments of all preferential amounts required to the holders of shares of Senior Preferred Stock and Series A-2 convertible preferred stock, the remaining assets of the Company available for distribution will be distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each such holder.

Redemption

The preferred stock is not redeemable at the option of the holder.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Classification***

The Company has classified the convertible preferred stock as temporary equity on the consolidated balance sheets as the shares can be redeemed upon the occurrence of certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation will occur.

11. Convertible Preferred Stock Warrant Liability

In September 2016, the Company issued a warrant to purchase an aggregate of 244,444 shares of the Company's Series A-1 convertible preferred stock with an exercise price of \$4.50 per share in connection with the termination of a sponsor research agreement. The warrant was fully vested upon the issuance date and expires on September 11, 2026. The initial fair value of the warrant was calculated using the Black-Scholes pricing model and the following assumptions: volatility of 99.32%, expected term of 10 years, risk-free interest rate of 1.68%, exercise price of \$4.50 and dividend rate of 0%. The fair value of the warrant was determined to be \$1.0 million and \$1.8 million as of December 31, 2018 and June 30, 2019, respectively.

12. Stock-Based Awards***2016 Equity Incentive Plan***

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the "2016 Plan") for the issuance of stock options, non-qualified stock options, stock appreciation rights, restricted stock and other stock awards, to employees, non-employee directors, and consultants under terms and provisions established by the Company's board of directors and approved by the stockholders.

Awards granted under the 2016 Plan expire no later than ten years from the date of grant. For incentive stock options and non-statutory stock options, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. For all stock options granted between July 2018 and June 2019, the Company incorporated reassessed fair values using hindsight for calculating stock-based compensation expense.

As of June 30, 2019, there were 2,891,011 shares available for the Company to grant under the 2016 Plan.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
Stock Option Activity

The following table summarizes option award activity under the 2016 Plan:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	5,044,924	\$ 1.50	9.13	
Granted	1,299,534	5.18		
Exercised	(468,073)	1.50		
Forfeited	(331,409)	1.50		
Outstanding at June 30, 2019	5,544,976	2.36	8.92	\$ 44,527
Vested and expected to vest at June 30, 2019	5,544,976	2.36	8.92	44,527
Vested and exercisable at June 30, 2019	1,233,074	\$ 2.38	8.75	\$ 9,887

Aggregate intrinsic value represents the difference between the Company's reassessed fair value of its common stock and the exercise price of outstanding options. During the six months ended June 30, 2018 and 2019, the estimated weighted-average grant date fair value of the options granted was \$1.13 and \$5.62 per share, respectively.

As of June 30, 2019, the Company expects to recognize the remaining unamortized stock-based compensation expense of \$10.1 million related to stock options, over an estimated weighted average period of 2.8 years.

Stock Options Granted to Employees

The fair value of stock options granted to employees was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Six Months Ended June 30,	
	2018	2019
Expected term of options (in years)	6.0	5.9
Expected stock price volatility	88.0% – 88.1%	89.4%
Risk-free interest rate	2.5% – 2.9%	2.5%
Expected dividend yield	—	—

The valuation assumptions were determined as follows:

Expected Term—The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility—The expected volatility was determined by examining the historical volatilities for industry peers and using an average of historical volatilities of Company's industry peers as the Company's stock is not actively traded on any public markets.

Risk-Free Interest Rate—The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Expected Dividend Rate—The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its profit interest units in the foreseeable future.

Restricted Stock Activity

The following table summarizes restricted stock activity:

	Number of Shares	Weighted Average Fair Value at Date of Grant per Share
Unvested as of December 31, 2018	4,814,733	\$ 1.15
Vested	(395,966)	0.95
Unvested as of June 30, 2019	<u>4,418,767</u>	<u>\$ 1.17</u>

The unvested shares of restricted stock have not been included in the shares issued and outstanding.

In January 2017, the Company entered into a restricted stock purchase agreement with an executive officer and a restricted stock purchase agreement with a director whereby the executive officer and the director purchased an aggregate of 3,624,355 shares of restricted stock. The consideration for the restricted stock was the issuance of promissory notes which are non-recourse in nature and are accounted for as in-substance stock options. The Company measured compensation cost for these in-substance options based on their estimated fair value on the grant date using the Black-Scholes pricing model. The Company is recognizing compensation cost over the requisite service period with an offsetting credit to additional paid-in capital.

As of June 30, 2019, there was \$2.1 million of total unrecognized compensation cost related to unvested restricted stock, all of which is expected to be recognized over a remaining weighted-average period of 1.3 years.

Stock-Based Compensation Expense

The following table sets forth the total stock-based compensation expense for all awards granted to employees and non-employees, including shares sold through the issuance of non-recourse promissory notes of which all the shares are considered to be options for accounting purposes in the Company's statements of operations:

	Six Months Ended June 30,	
	2018	2019
	(in thousands)	
Research and development	\$ 457	\$ 1,001
General and administrative	2,195	2,851
Total stock-based compensation	<u>\$ 2,652</u>	<u>\$ 3,852</u>

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
13. Net Loss and Unaudited Pro Forma Net Loss Per Share

As the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common securities outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of June 30,	
	2018	2019
Convertible preferred stock	69,466,076	88,112,733
Options issued and outstanding	4,161,343	5,544,976
Restricted shares subject to future vesting	5,767,070	4,418,767
Warrants to purchase convertible preferred stock	244,444	244,444
Total	<u>79,638,933</u>	<u>98,320,920</u>

Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share of common stock:

	Six Months Ended June 30, 2019 (in thousands, except share and per share data)
Numerator:	
Net loss	\$ (62,598)
Add: change in fair value of convertible preferred stock warrant liability	784
Net loss used in calculating pro forma earnings per share, basic and diluted	<u>\$ (61,814)</u>
Denominator:	
Weighted-average shares outstanding	9,165,311
Weighted-average convertible preferred stock	87,747,196
Pro forma weighted-average shares outstanding, basic and diluted	<u>96,912,507</u>
Pro forma net loss per share, basic and diluted	<u>\$ (0.64)</u>

14. Defined Benefit Pension and Other Postretirement Plans
Postretirement Benefits (Pension Plans) for Humabs

The Company's subsidiary, Humabs, provides its Swiss employees with mandatory cash balance pension benefits whereby employer and employee contributions are accumulated in individual accounts with interest to retirement or withdrawal, if earlier. The benefits are financed through the Swiss Life Collective BVG Foundation with Swiss Life Asset Management through two separate plans. The plans insured base salary and annual incentives up to an aggregate maximum of CHF 0.9 million (\$0.9 million as of June 30, 2019). In addition to retirement benefits, the plans provide benefits on death or long-term disability of its employees.

The first plan is a defined normal benefit plan which is funded 65% by the Company and 35% by employee contribution to a collective foundation with Swiss Life Asset Management. On retirement, the plan participant

[Table of Contents](#)
VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

will receive his/her accumulated savings, which consist of all contributions paid by the employer and the employees, net of any withdrawals, and the interest granted on those savings at the discretion of the pension foundation. At that time, the plan participant has the right to choose between a lump-sum payment and an annuity, or a combination thereof. The annuity is calculated using a fixed conversion rate determined by the pension foundation. The pension fund's plan assets are pooled and the Company's share is calculated based on its share of retirement savings. Additional funding requirements may be determined by the pension foundation in case of a severe underfunding. Should the Company withdraw from the plan, the withdrawal may qualify as a partial liquidation/settlement under Swiss law, which may trigger an obligation to fund any proportionate deficit or a right to any overfunding in existence at that time.

The second plan is a defined management plan. This plan is set up as a collective foundation with Swiss Life Asset Management, for which contributions are split up as 40% paid by the employees and 60% paid by the Company. The purpose of this plan is to allow higher saving opportunity (in a tax effective manner) and risk benefits for management.

The expected rate of return on assets corresponds to the return on benefits expected to be provided under the insurance contract. Net periodic pension cost includes the following components (in thousands):

	Six Months Ended June 30,	
	2018	2019
Service cost	\$ 131	\$ 131
Interest cost	12	16
Expected return on plan assets	(10)	(11)
Net funded status	<u>\$ 133</u>	<u>\$ 136</u>

15. Income Taxes

The Company's income tax provision for interim periods is determined using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in the quarter. The Company's effective tax rate differs from the U.S. statutory tax rate primarily due to valuation allowances on our deferred tax assets in all jurisdictions as it is more likely than not that the Company's deferred tax assets will not be realized.

During the six months ended June 30, 2019, the Company recorded an immaterial tax provision related to state income taxes.

During the six months ended June 30, 2018, the Company recorded a tax benefit of \$0.5 million related to the reversal of deferred tax liability associated with the developed technology acquired from Statera.

16. Subsequent Events
Notes Receivable

In August 2019, in accordance with the terms of the notes, the Company received \$3.3 million as repayment of the outstanding promissory notes issued to an executive officer and a director.

MedImmune

In August 2019, the Company achieved one of the specified development milestones relating to influenza A pursuant to the 2018 MedImmune Agreement. As such, the Company is obligated to pay \$5.0 million related to this milestone event within thirty days.

[Table of Contents](#)**VIR BIOTECHNOLOGY, INC.****Notes to Unaudited Condensed Consolidated Financial Statements*****Sale and Leaseback***

In August 2019, the Company entered into a lease agreement whereby the Company sold various laboratory instruments, furniture, and other equipment for gross proceeds of \$1.2 million to a bank and leased them back for a five-year term, collateralized by the underlying equipment.

Patent License Agreement with Xencor

In August 2019, the Company entered into a patent license agreement (the “Xencor Agreement”) with Xencor, Inc., (“Xencor”). Pursuant to the Xencor Agreement, the Company obtained a non-exclusive, sublicensable (only to its affiliates and subcontractors) license to incorporate Xencor’s half-life extension Fc region-related technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. The Company is obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor’s half-life extension Fc-related technologies, for each of the influenza A and HBV research programs. These technologies are used in the Company’s VIR-2482 and VIR-3434 product candidates.

In consideration for the grant of the license, the Company paid Xencor an upfront fee. For each of the influenza A and HBV research programs, the Company will be required to pay Xencor development and regulatory milestone payments of up to \$17.8 million in the aggregate, and commercial sales milestone payments of up to \$60.0 million in the aggregate, for a total of up to \$77.8 million in aggregate milestones for each program and \$155.5 million in aggregate milestones for both programs. On a product-by-product basis, the Company will also be obligated to pay tiered royalties based on net sales of licensed products in the low single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the expiration of the last to expire valid claim in the licensed patents covering such product in such country.

The Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Xencor Agreement. The Company may terminate the Xencor Agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days’ written notice. Either party may terminate the Xencor Agreement for the other party’s uncured material breach upon 60 days’ written notice (or 30 days in the case of non-payment) or in the event of bankruptcy of the other party immediately upon written notice. Xencor may terminate the Xencor Agreement immediately upon written notice if the Company challenges, or upon 30 days’ written notice if any of the Company’s sublicensees challenge, the validity or enforceability of any patent licensed to the Company under the Xencor Agreement.

Stock Option Grants

In July 2019, the Company’s board of directors granted stock options to purchase an aggregate of 1,031,758 shares of common stock with an exercise price of \$10.40 per share.

[Table of Contents](#)

7,142,858 Shares



Common Stock

PROSPECTUS

Goldman Sachs & Co. LLC

J.P. Morgan

Cowen

Barclays

October 10, 2019

Through and including November 4, 2019 (the 25th day after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.
