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Filed Pursuant to Rule 424(b)(4) Registration No. 333-227387

**PROSPECTUS** 

# 4,670,000 Shares



# **Common Stock**

This is the initial public offering of Equillium, Inc. We are offering 4,670,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price of our common stock is \$14.00 per share.

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "EQ."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11.

	PER SHARE	TOTAL
Initial Public Offering Price	\$ 14.00	\$65,380,000
Underwriting Discounts and Commissions (1)	\$ 0.98	\$ 4,576,600
Proceeds to Equillium (before expenses)	\$ 13.02	\$60,803,400

<sup>(1)</sup> We have agreed to reimburse the underwriters for certain expenses. See "Underwriting."

We have granted the underwriters a 30-day option to purchase up to a total of 700,500 additional shares of common stock from us at the initial public offering price less the underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock to purchasers on or about October 16, 2018 through the book-entry facilities of The Depository Trust Company.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Joint Book-Running Managers

Jefferies Leerink Partners Stifel

The date of this prospectus is October 11, 2018

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We have not, and the underwriters have not, 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.

Through and including November 5, 2018 (25 days 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.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

For investors outside the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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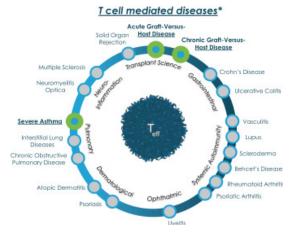
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# PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially "Risk Factors" and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to "Equillium," "the Company," "we," "us" and "our" refer to Equillium, Inc.

#### **OVERVIEW**

We are a biotechnology company leveraging deep understanding of immunobiology to develop products for severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our initial product candidate, EQ001 (itolizumab), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of effector T cells, or Teff cells. Activated Teff cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe EQ001 may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.



\* We are focusing our initial development efforts on EQ001 for the treatment of the diseases underlined in bold and are evaluating additional T cell driven indications for future development.

Our pipeline is focused on developing EQ001 as a potentially best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. We plan to initiate a Phase 1b/2 clinical trial of EQ001 for the treatment of acute graft-versus-host disease, or aGVHD, in early 2019, and expect top-line data from the Phase 1b part of this trial within 12 months of initiation. Our Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for aGVHD was accepted in July 2018. Additionally, in the first half of 2019, we plan to commence a Phase 2 clinical trial of EQ001 for the treatment of chronic graft-versus-host disease, or cGVHD, initiate a proof-of-concept clinical trial for the treatment of severe asthma and select one or more additional indications for future development. The following chart summarizes our initial development plans for EQ001.

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equillium Eq001					
Therapeutic Area	Indication	Phase 1*	Phase 1b / 2	Phase 3	Expected Milestones
Transplant Science	aGVHD		IND open		Phase 1b/2 aGVHD trial to initiate early 2019
	cGVHD				Phase 2 cGVHD trial to initiate H1 2019
Pulmonary	severe asthma				severe asthma proof-of-concept trial to initiate H1 2019

\* The Phase 1 clinical trial was conducted by Biocon, our collaboration partner, in Australia.

We have an ongoing translational biology program to assess the therapeutic utility of EQ001 in additional indications where the CD6 pathway and activated T<sub>eff</sub> cells play an important role in the pathogenesis of T cell mediated diseases. Our selection of additional indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing EQ001 into further development.

We acquired U.S. and Canadian rights to itolizumab in May 2017, pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon). Following completion of a Phase 3 clinical trial conducted outside of North America, itolizumab was approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon as ALZUMAb. Today, India is the only jurisdiction where ALZUMAb is approved or marketed. EQ001 has been evaluated in one Phase 1 clinical trial to date, conducted by Biocon, and is not approved for commercial sale in the United States or Canada. Our partnership with Biocon includes an exclusive supply agreement for clinical and commercial drug product of EQ001. Biocon currently manufactures EQ001 at commercial scale in a facility regulated by the FDA.

We have assembled an accomplished team that includes veterans in drug discovery, development and commercialization. Notably, our Chief Executive Officer is Daniel Bradbury, who has over 30 years of experience bringing novel medicines to market. Mr. Bradbury was the President, Chief Executive Officer and Director of Amylin Pharmaceuticals, Inc., where during his 18 year tenure he oversaw the development and launch of three first-in-class medicines, which ultimately led to the acquisition of Amylin Pharmaceuticals, Inc. by Bristol-Myers Squibb.

# Understanding the Basis of Our Approach: The Role of CD6 in Autoimmunity

The role of the immune system is to defend the body against foreign organisms and cells, including cancerous cells, and in doing so must distinguish accurately between self- and non-self entities, a process called tolerance. Autoimmunity is an immune response directed against the body's own healthy cells and tissues, and is the underlying process in many inflammatory diseases. Autoimmunity results from a loss of tolerance caused in part by an imbalance in the relationship between regulatory T cells, or T<sub>reg</sub> cells, and T<sub>eff</sub> cells.

CD6 is a novel, tightly-regulated, co-stimulatory receptor that plays an integral role in modulating T cell activation, proliferation, differentiation and trafficking. CD6 serves as a key checkpoint in regulating  $T_{eff}$  cells that are central to autoimmune responses. Preclinical and clinical studies have shown that blockade of CD6 co-stimulation leads to selective inhibition of pathogenic  $T_{eff}$  cell activity and trafficking, while preserving the important regulatory function of  $T_{reg}$  cells. Such studies and new insights into the underlying biology highlight CD6 as a resurgent target for the treatment of multiple immuno-inflammatory diseases.

# Modulation of Teff Cell Activity with EQ001

EQ001 is a humanized antibody that selectively binds to human CD6 and inhibits the interaction of CD6 with its ligand ALCAM, preventing co-stimulation, and thereby reducing T<sub>eff</sub> cell activity and trafficking. Preclinical

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studies of EQ001 have shown that blockade of CD6 leads to a reduction in  $T_{eff}$  cell proliferation and downregulation of several important intracellular pathways that contribute to  $T_{eff}$  cell development. Critically, CD6 blockade leads to the downregulation of important cellular pathways that control inflammation, including STAT3 and ROR $\gamma$ t. The downregulation of these pathways is accompanied by decreased secretion of the pro-inflammatory  $T_{eff}$  cytokines IFN- $\gamma$ , TNF- $\alpha$ , IL-6 and IL-17. Additionally, inhibiting the binding of ALCAM to CD6, either by anti-CD6 monoclonal antibodies or by deletion of the gene expressing CD6, modulates lymphocyte trafficking and results in reduced  $T_{eff}$  cell infiltration into inflamed tissues. Based on its broad multi-modal mechanism, we believe EQ001 has the potential to treat multiple immuno-inflammatory diseases including those that are resistant or refractory to existing therapies.

#### **Our Planned Initial Clinical Indications**

We plan to initially develop EQ001 for the treatment of aGVHD, cGVHD, severe asthma and at least one additional indication. We expect to initiate a Phase 1b/2 clinical trial of EQ001 in patients with aGVHD in early 2019 and a Phase 2 clinical trial of EQ001 in patients with cGVHD in the first half of 2019. We also plan to initiate a proof-of-concept clinical trial in severe asthma in the first half of 2019. We continue to evaluate additional indications for future development and plan to select a fourth indication in the first half of 2019.

# **Recent Developments**

In July 2018, we received a "study may proceed" letter from the FDA in response to our initial IND submission related to the conduct of clinical trials of EQ001 in the indication of aGVHD.

In August 2018, we hired Dr. Krishna Polu to serve as our Chief Medical Officer and, in September 2018, we added three experienced independent members to our board of directors.

In September 2018, we submitted a request to the U.S. Department of the Treasury's Office of Foreign Assets Control, or OFAC, seeking guidance on the application of a general license permitting the import, development and commercialization of EQ001, a product that is derived from intellectual property of Cuban origin (see "Business—Government Regulation and Product Approval—Governmental Regulations Related to Economic Sanctions" for additional background).

# Strategy

Our goal is to become a leading, fully-integrated biotechnology company focused on therapies for severe immuno-inflammatory disorders. To achieve our goal, we intend to:

- Advance EQ001 through clinical development for aGVHD and cGVHD. Based on our deep and proprietary understanding of the CD6 pathway, our translational research and prior clinical studies targeting CD6, we are initially focused on aGVHD and cGVHD as our initial indications for the clinical development of EQ001. We plan to initiate a Phase 1b/2 clinical trial of EQ001 as a front-line therapy concomitant with steroids in patients with aGVHD in early 2019 and expect top-line data from the Phase 1b part of this trial within 12 months of initiation. In this trial we will assess safety, overall response rate, survival, steroid taper and incidence of cGVHD. In addition, we plan to initiate a Phase 2 clinical trial of EQ001 in patients with cGVHD in the first half of 2019.
- **Develop EQ001 for the treatment of severe asthma.** We believe that the unique mechanism of action of EQ001 has the potential to treat severe asthma patients characterized by an immunophenotype of low T<sub>n</sub>2 and high T<sub>n</sub>17 and who consequently have a poor response to high dose inhaled and/or oral steroids. There are a sizeable number of these patients who are underserved by currently available therapies and for which there are no FDA-approved biologic or other targeted treatments. We plan to initiate a proof-of-concept clinical trial of EQ001 in patients with severe asthma in the first half of 2019.
- Expand clinical development of EQ001 into additional indications based on our translational biology program. We will
  continue to conduct studies in animal models and human tissue, as well as EQ001

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clinical trials, to help inform the selection of additional indications for further development. In the first half of 2019, we intend to select a fourth indication for future EQ001 development.

- Opportunistically expand our pipeline of product candidates. We will leverage the collective talent within our organization to
  opportunistically acquire or in-license other high-value therapeutic programs that may complement our core strategy or have the
  potential for synergistic therapeutic benefit in combination with EQ001.
- Build a commercial infrastructure. If approved, we intend to commercialize EQ001 ourselves in indications that can be efficiently
  targeted using a specialty sales force, such as aGVHD and cGVHD. For other indications, we intend to commercialize EQ001
  either independently or through collaborations with other parties.

# **RISKS ASSOCIATED WITH OUR BUSINESS**

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

- We have a very limited operating history and have never generated any revenues. We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We are highly dependent on the success of our product candidate, EQ001, which is in early stage clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate in any of the indications for which we plan to develop it.
- If we fail to comply with U.S. export control and economic sanctions, our business, financial condition and prospects may be materially and adversely affected.
- EQ001 is a monoclonal antibody that selectively targets CD6, a target for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for EQ001. We do not know whether our approach in targeting CD6 will allow us to develop any products of commercial value.
- Even if this offering is successful, we will need to obtain substantial additional funding to complete the development and any commercialization of EQ001. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.
- We are very early in our development efforts. We have not yet begun our first clinical trial to evaluate EQ001 in patients and, as a company, we have limited experience in this area.
- We have licensed EQ001 from Biocon pursuant to an exclusive license agreement which rights are conditioned upon us meeting certain development and commercialization milestones and on making significant milestone payments in connection with regulatory approval and commercial milestones as well as royalty payments.
- The development and commercialization of biopharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for EQ001 in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all.
- Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Adverse side effects or other safety risks associated with EQ001 could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

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The manufacture of biologics is complex and Biocon, our third-party manufacturer, may encounter difficulties in production. If Biocon encounters such difficulties, our ability to provide supply of EQ001 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped.

- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies, and these third
  parties may not perform satisfactorily.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.
- If we are unable to obtain or protect intellectual property rights covering our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market.
- There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares at or above the initial public offering price.

#### CORPORATE AND OTHER INFORMATION

We were originally incorporated as Attenuate Biopharmaceuticals, Inc. in Delaware in March 2017 and subsequently changed our name to Equillium, Inc. in May 2017. Our principal executive offices are located at 2223 Avenida de la Playa, Suite 108, La Jolla, CA 92037, and our telephone number is 858-412-5302. Our corporate website address is www.equilliumbio.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

#### IMPLICATIONS OF BEING AN EMERGING GROWTH COMPANY

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, as amended, or JOBS Act, enacted in April 2012. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least

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\$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with the adoption of new or revised accounting standards. We have elected to avail ourselves of this exemption. Therefore, we may not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

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# THE OFFERING

Common stock offered by us 4,670,000 shares

Common stock to be outstanding after this offering 16,752,658 shares

Option to purchase additional shares

The underwriters have a 30-day option to purchase up to a total of 700,500 additional

shares of common stock.

Use of proceeds We intend to use the net proceeds from this offering to fund research and development

of EQ001 and for working capital and other general corporate purposes, including costs and expenses associated with being a public company. See "Use of Proceeds."

Risk factors You should read the "Risk Factors" section of this prospectus for a discussion of

certain of the factors to consider carefully before deciding to purchase any shares of

our common stock.

Nasdaq Global Market symbol "EQ"

The number of shares of our common stock to be outstanding after this offering is based on 12,082,658 shares of common stock outstanding as of June 30, 2018, including 267,690 shares of restricted common stock which are subject to a right of repurchase by us as of June 30, 2018 and after giving effect to (i) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018 and (ii) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon, pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share, and excludes:

- 107,084 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2018, each at an exercise price of \$0.05 per share:
- 2,229,773 shares of common stock reserved for future issuance under our 2018 equity incentive plan, or the 2018 Plan, which became effective in connection with the execution and delivery of the underwriting agreement for this offering (including 1,040,000 new shares plus the number of shares (not to exceed 1,189,773 shares) (i) that remain available for grant of future awards under our 2017 equity incentive plan, or the 2017 Plan, which shares were added to the shares reserved under the 2018 Plan upon its effectiveness and (ii) any shares underlying outstanding stock awards granted under our 2017 Plan that expire, or are forfeited, cancelled, withheld or reacquired, as more fully described under the terms of the 2018 Plan described in the section titled "Executive Compensation—Equity Benefit Plans"); and
- 343,275 shares of common stock reserved for future issuance under our 2018 employee stock purchase plan, or the ESPP, which became effective in connection with the execution and delivery of the underwriting agreement for this offering.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018;

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the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share;

- no exercise by the underwriters of their option to purchase up to a total of 700,500 additional shares of our common stock;
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the completion of this offering; and
- a one-for-8.62 stock split of our common stock effected on October 1, 2018.

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# **SUMMARY FINANCIAL DATA**

The following summary statement of operations data for the period March 16, 2017 (inception) through December 31, 2017 is derived from our audited financial statements appearing elsewhere in this prospectus. The summary statements of operations data for the period March 16, 2017 (inception) through June 30, 2017 and the six months ended June 30, 2018 and the balance sheet data as of June 30, 2018 are derived from our unaudited interim financial statements included elsewhere in this prospectus. In our opinion, these unaudited financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read these data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the interim periods are not necessarily indicative of the results that may be expected for any other interim periods or any future year.

	PERIOD MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017	PERIOD MARCH 16, 2017 (INCEPTION) THROUGH JUNE 30, 2017	SIX MONTHS ENDED JUNE 30, 2018
Statement of Operations Data:		(unau	iuiteu)
Operating expenses:			
Research and development	\$ 1,333,721	\$ 801,364	\$ 1,202,917
General and administrative	378,328	187,173	958,691
Total operating expenses	1,712,049	988,537	2,161,608
Loss from operations	(1,712,049)	(988,537)	(2,161,608)
Interest expense	379,385	7,069	1,108,197
Interest income	_	_	(29,926)
Change in fair value of Biocon anti-dilution right	170,440	18,887	102,280
Net loss and comprehensive loss	<u>\$ (2,261,874)</u>	<u>\$(1,014,493</u> )	<u>\$ (3,342,159</u> )
Net loss per share, basic and diluted (1)	\$ (0.28)	\$ (0.19)	\$ (0.31)
Weighted average shares of common stock outstanding, basic and diluted (1)	8,030,029	5,307,596	10,711,788
Pro forma net loss per share, basic and diluted (unaudited) (1)	\$ (0.21)		\$ (0.18)
Pro forma weighted average shares of common stock outstanding, basic and diluted (unaudited) (1)	8,300,869		11,679,293

<sup>(1)</sup> See Note 2 to our financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share, unaudited pro forma basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

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	AS OF JUNE 30, 2018		
	ACTUAL	PRO FORMA (1) (unaudited)	PRO FORMA AS ADJUSTED (2)
Balance Sheet Data:		, ,	
Cash and cash equivalents	\$ 6,626,443	\$ 6,626,443	\$ 65,329,843
Working capital	5,788,958	6,125,507	64,828,907
Total assets	6,728,134	6,728,134	65,431,534
Convertible promissory notes, including related party	10,517,896	_	_
Accumulated deficit	(5,604,033)	(5,604,033)	(5,604,033)
Total stockholders' (deficit) equity	(5,593,501)	6,139,067	64,842,467

<sup>(1)</sup> Pro forma amounts reflect (i) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018 and (ii) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share.

<sup>(2)</sup> Pro forma as adjusted amounts reflect the pro forma adjustments described in footnote (1) above, as well as the sale of 4,670,000 shares of our common stock in this offering based on the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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#### **RISK FACTORS**

Investing in our common stock is speculative and involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Information Regarding Forward-Looking Statements."

#### Risks Related to Our Business and to the Development and Regulatory Approval of EQ001

#### We have a very limited operating history and have never generated any revenues.

We are an early-stage biotechnology company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We were incorporated in March 2017 and our operations, to date, have been limited to organizing and staffing our company, business planning, raising capital, in-licensing rights to EQ001, conducting preclinical research, filing our initial IND and preparing to commence clinical development of EQ001. We have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, and we have never generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

# We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and we cannot estimate with precision the extent of our future losses. For the period March 16, 2017 (inception) through December 31, 2017 and six months ended June 30, 2018, our net losses were \$2.3 million and \$3.3 million, respectively. As of December 31, 2017, and June 30, 2018, we had an accumulated deficit of \$2.3 million and \$5.6 million, respectively. We expect to incur increasing levels of operating losses for the foreseeable future as we execute our plan to continue our research and development activities, including the planned clinical development of EQ001, and as we incur the additional costs of operating as a public company. In addition, if we obtain regulatory approval for EQ001, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of EQ001, obtaining marketing approval for EQ001, manufacturing, marketing and selling EQ001 if we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing EQ001, we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our auditors have issued a going concern opinion on our financial statements as of December 31, 2017 and for the period from March 16, 2017 (inception) to December 31, 2017, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to successfully complete this offering, we will need to create and implement alternate financing or operational plans to continue as a going concern, and investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We are highly dependent on the success of our product candidate, EQ001, which is in early stage clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate in any of the indications for which we plan to develop it.

Our future success will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize EQ001, in any of the indications for which we initially plan to develop it, including aGVHD, cGVHD and severe asthma, which may never occur. We have no product candidates in our pipeline other than EQ001. We currently generate no revenues from sales of any biopharmaceutical products or otherwise, and we may never be able to develop or commercialize a marketable biopharmaceutical product.

Before we can market and sell EQ001 in the United States, we will need to manage research and development activities, commence and complete clinical trials, obtain necessary regulatory approvals from the FDA and build a commercial organization or enter into a marketing collaboration with a third party, among other things. We cannot assure you that we will be able to successfully complete the necessary clinical trials and/or obtain regulatory approval and develop sufficient commercial capabilities for EQ001. We have not submitted a Biologics License Application, or BLA, to the FDA for any product candidate. Further, EQ001 may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain regulatory approval, we may never generate significant revenues from any commercial sales of EQ001. If EQ001 is approved and we fail to successfully commercialize it, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, prospects, financial condition and results of operations will be adversely affected.

If we fail to comply with U.S. export control and economic sanctions, our business, financial condition and prospects may be materially and adversely affected.

Our business and our products are subject to U.S. export control laws and regulations, including the U.S. Export Administration Regulations and economic and trade sanctions regulations administered by OFAC. See "Business—Government Regulation and Product Approval—Governmental Regulations Related to Economic Sanctions." Our company must comply with these laws and regulations. The antibody sequence for both EQ001 and ALZUMAb is derived from Cuban-origin intellectual property and thus we believe this to be a pharmaceutical of Cuban origin which would make the import, development and commercialization of EQ001 subject to these laws, sanctions and regulations. We currently rely on a general license issued by OFAC under the Cuban Assets Control Regulations, or CACR, relating to Cuban-origin pharmaceuticals to import and conduct clinical trials relating to EQ001. Although we believe our activities for EQ001 qualify for, and are authorized under, the OFAC general license and we have maintained compliance with the general license requirements, there is some question regarding such applicability given that we have licensed EQ001 from Biocon and OFAC has not confirmed the applicability of the general license to EQ001 or products not wholly developed in or exported from Cuba. In the absence of the OFAC general license, all of our development and potential commercialization activities for EQ001 would be prohibited under the CACR, and we would be required to request a specific license from OFAC authorizing such activities, which OFAC could deny. We have submitted to OFAC a request for interpretive guidance confirming the applicability of the general license to EQ001, or in its absence, a specific license authorization from OFAC. We have simultaneously requested that OFAC treat our submission as a voluntary disclosure if OFAC concludes that our determination that the general license applies to EQ001 was in error. Even if OFAC concludes that the general license applies to EQ001, there can be no assurance that the general license will not be revoked or modified by OFAC in the future, or that we will remain in compliance with these or other export laws and regulations. If OFAC determines that the general license

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does not apply, and OFAC then denies our request for a specific license, we will be unable to deal in, or otherwise commercialize, EQ001. In that case, we would be required to cease operations related to EQ001 which would materially and adversely affect our financial condition and business prospects. In addition, in the absence of the general or specific license, the transfer, sale and/or purchase of our securities could be prohibited, and the ownership or possession of our securities could be subject to an affirmative OFAC reporting requirement relating to blocked property. We and certain of our employees could also be subject to substantial civil or criminal penalties.

EQ001 is a monoclonal antibody that selectively targets CD6, a target for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for EQ001. We do not know whether our approach in targeting CD6 will allow us to develop any products of commercial value.

We have concentrated our research and development approach on targeting CD6, and our future success depends on the successful development of this therapeutic approach to the diseases we are targeting for treatment. To date, there are no FDA-approved drugs that target CD6, and while there are a number of independent studies clinically validating CD6 as a target, other than our partner Biocon, CD6 has not traditionally been a pathway targeted by other biopharmaceutical companies. The regulatory approval process for novel product candidates such as EQ001 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring EQ001 to market could decrease our ability to generate sufficient revenue to maintain our business.

Even if this offering is successful, we will need to obtain substantial additional funding to complete the development and any commercialization of EQ001. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.

We expect our expenses to increase substantially during the next few years. The development of biotechnology product candidates is capital intensive. As EQ001 enters and advances through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for EQ001, we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution. Furthermore, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2018, we had \$6.6 million in cash and cash equivalents. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operations for at least the next 24 months. In particular, we expect that the net proceeds from this offering will allow us to fund a Phase 1b/2 clinical trial of EQ001 for aGVHD, a Phase 2 clinical trial of EQ001 for cGVHD and a proof-of-concept clinical trial of EQ001 for severe asthma. However, changing circumstances or inaccurate estimates by us may cause us to use capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our planned clinical trials for EQ001 may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect. Even with the expected net proceeds from this offering, we will not have sufficient funds to complete the clinical development of EQ001 through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of EQ001.

Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our planned clinical trials for EQ001;
- the number and scope of indications we decide to pursue for EQ001 development;
- the cost, timing and outcome of regulatory review of any BLA we may submit for EQ001;
- the costs and timing of manufacturing for EQOO1, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of EQ001;
- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;

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- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing EQ001, if approved for commercial sale.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for sale for at least the next several years, if ever. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. 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. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations.

We are very early in our development efforts. We have not yet begun our first clinical trial to evaluate EQ001 in patients and, as a company, we have limited experience in this area.

While Biocon has evaluated EQ001 in a Phase 1 clinical trial, we expect to initiate our first clinical trial of EQ001 in patients with aGVHD in early 2019. We have one active IND with the FDA for EQ001 in the aGVHD indication. Because of our limited interaction with the FDA, we may not learn of certain information or data that the FDA may request until future interactions. In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be initiated on time, that our planned clinical trials will be completed on time, if at all, or that our planned development programs would be acceptable to the FDA.

Adverse safety and toxicology findings may emerge as we conduct clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. For example, although EQ001 and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, results seen in clinical trials of ALZUMAb conducted by Biocon may not be predictive of the results of our clinical trials of EQ001. Furthermore, our future clinical trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by the FDA. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results, and we cannot be certain that we will not face similar setbacks. 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. In addition, only a small percentage of biologics under development result in the submission of a BLA to the FDA and even fewer are approved for commercialization.

Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our ability to successfully complete the above activities and any other activities required for the successful development and eventual commercialization of EQ001. The success of EQ001 will further depend on factors such as:

- completion of our planned clinical trials and preclinical studies with favorable results;
- acceptance of INDs by the FDA for our future clinical trials in additional indications such as cGVHD and asthma, as applicable;
- timely and successful enrollment in, and completion of, clinical trials with favorable results;
- demonstrating safety, efficacy and acceptable risk-benefit profile of EQ001 to the satisfaction of the FDA;
- receipt of marketing approvals from the FDA;
- maintaining arrangements with Biocon, our third-party manufacturer, for cell lines and drug product clinical supply and, if and when approved, for commercial supply of EQ001;
- establishing sales, marketing and distribution capabilities and launching commercial sale of EQ001, if and when approved in one or more indications;
- acceptance of EQ001, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;

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obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for EQ001; and

maintaining a continued acceptable safety profile of EQ001, following approval.

If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to successfully obtain marketing approval and commercialize EQ001, which would materially harm our business.

We have licensed EQ001 from Biocon pursuant to an exclusive license agreement, which rights are conditioned upon us meeting certain development and commercialization milestones and on making significant milestone payments in connection with regulatory approval and commercial milestones as well as royalty payments.

We are party to an exclusive license agreement with Biocon, pursuant to which we acquired an exclusive license in the United States and Canada to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit EQ001 and any pharmaceutical composition or preparation containing or comprising EQ001. We are obligated, under this agreement, to use commercially reasonable efforts to achieve certain development, regulatory, commercialization and funding milestones within specified timeframes in order to retain all of the licensed rights. Certain of such milestones are largely outside of our control. Further, we are obligated to make certain cash milestone payments to Biocon upon completion of certain development and commercial milestones and are required to make certain cash royalty payments upon our achievement of target levels of revenue from sales of EQ001, if approved. Though we believe that the royalty rates and milestone payments are reasonable in light of our business plan, we will require large amounts of capital to satisfy these obligations. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization and marketing efforts or seek funds to meet these obligations on terms unfavorable to us. In addition, if we are unable to make any payment when due or, if we fail to use commercially reasonable efforts to achieve the development, regulatory, commercial and funding milestones within the timeframes required by the license agreement, Biocon may have the right to limit the scope of our license or terminate the agreement and all of our rights to develop and commercialize EQ001.

We have only licensed the rights to EQ001 in the United States and Canada. Any adverse developments that occur during any clinical trials conducted by third parties in other jurisdictions may affect our ability to obtain regulatory approval or commercialize EQ001.

Biocon and its partner, over which we have no control, have the rights to develop and commercialize itolizumab in geographies outside of the United States and Canada. Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon as ALZUMAb. In addition, a conditional approval for itolizumab was granted to Centro de Immunologia Molecular, Cuba in May 2014. This approval is subject to completion of a Phase 3 clinical trial in Cuban patients. Two clinical trials are currently open in Cuba. If serious adverse events occur with patients using ALZUMAb or during any clinical trials of itolizumab conducted by third parties, the FDA may delay, limit or deny approval of EQ001 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for EQ001 and a new and serious safety issue is identified in connection with use of ALZUMAb or in clinical trials of itolizumab conducted by third parties, the FDA may withdraw their approval of the product or otherwise restrict our ability to market and sell EQ001. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize EQ001.

The development and commercialization of biopharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for EQ001 in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to EQ001, currently our only product candidate, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA and we

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are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of EQ001 or any future product candidates may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be adequately safe and effective;
- may not agree that the data collected from clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for EQ001.

If we experience delays in obtaining approval or if we fail to obtain approval of EQ001, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials of EQ001 in any distinct indication, we must submit the

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results of preclinical studies to the FDA along with other information, including information about EQ001 chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of EQ001 in any indication, we must conduct extensive clinical studies to demonstrate the safety and efficacy of EQ001. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our partner, Biocon, as well as contract research organizations, or CROs, and other third parties for regulatory submissions for EQ001. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. To date, we have only submitted an IND for clinical trials of EQ001 for the treatment of aGVHD, and we will need to submit an IND for acceptance by the FDA prior to initiating any clinical trials in the United States in other indications.

The FDA may require us to conduct additional preclinical studies for EQ001 or any future product candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs. Any such delays in the commencement or completion of our planned or future clinical trials could significantly affect our product development costs. We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA disagreeing as to the design or implementation of our clinical studies;
- obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- us, or our third-party contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; or

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third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Certain of our scientific advisors or consultants who receive compensation from us are likely to be investigators for our future clinical trials. 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 study. 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 EQ001 in one or more indications. If we experience delays in the completion of, or termination of, any clinical trial of EQ001, the commercial prospects of EQ001 will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in enrolling patients in our planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our planned clinical trials for EQ001 if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. The first indication that we are pursuing, aGVHD, is an acute and life threatening condition which may make it difficult to enroll patients in clinical trials. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as EQ001, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. This is acutely relevant for our development of EQ001 for the treatment of patients with severe asthma, a disease for which there is significant competition for clinical trial subjects. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- invasive procedures required to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

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Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with EQ001 could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with EQ001 in our planned clinical trials. In the Phase 1 clinical trial of EQ001 conducted by Biocon in healthy subjects, there were no serious adverse events, dose limiting toxicities, or study drug discontinuations reported.

Biocon has completed three clinical studies of ALZUMAb in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb to date at dose levels ranging from 0.2 mg/kg to 1.6 mg/kg. An additional 35 patients have received itolizumab in clinical trials conducted in Cuba. In Biocon's Phase 3 clinical trial, infusion-related reactions and related events were the main adverse events attributed to itolizumab. There were five serious adverse events reported including exfoliative dermatitis (widespread redness and peeling of the skin), erythrodermic (severe) psoriasis, infusion-related reaction, adjustment disorder with anxiety, and bacterial arthritis. There has been limited market experience of ALZUMAb in patients since the date of market authorization in India in December 2012. Since the date of market authorization and as of the current cut-off date of August 10, 2017 for the most recent Periodic Safety Update Report, ALZUMAb has accrued approximately 275 patient-years of use. Post-market safety surveillance has demonstrated 27 adverse event reports in that time period, of which four have been noted as serious, including infusion reaction, type 1 hypersensitivity, diarrhea and urticaria (hives). The majority of reactions have involved the dermatologic standard of care and include rash, acne, urticaria, increased pruritus (itching) and increased psoriasis. Although EQ001 and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, clinical results seen with ALZUMAb may have no bearing on results, including adverse events, that may be seen with EQ001.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by EQ001 could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons. Additionally, a material percentage of patients in our GVHD clinical trials will die from GVHD, possibly as a result of EQ001, which could impact development of EQ001. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of EQ001 will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of EQ001. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if EQ001 is associated with undesirable side effects in clinical trials or has characteristics that are unexpected, we may elect to abandon or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for EQ001, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test EQ001 in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of EQ001 becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

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In addition, if EQ001 receives marketing approval, and we or others later identify undesirable side effects caused by EQ001, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of EQ001;
- we may be required to recall a product or change the way EQ001 is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product:
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- EQ001 could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of EQ001, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Interim, topline or 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 publicly disclose preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering. See the description of risks under the heading "Risks Related to our Common Stock and this Offering" for more disclosure related to the risks of volatility in our stock price.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular biopharmaceutical product, biopharmaceutical product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, EQ001 or any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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A Phase 1 clinical trial for EQ001 was recently conducted by Biocon in Australia, and we may conduct additional clinical trials of EQ001 outside of the United States. However, the FDA may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

In the fourth quarter of 2017, Biocon completed a Phase 1 clinical trial of EQ001 in healthy subjects in Australia to assess the safety and tolerability of the subcutaneous version of EQ001. The trial also included a separate stage to compare the pharmacokinetics of the intravenous administration of EQ001 to ALZUMAb and determine the absolute bioavailability of subcutaneous EQ001 SC, but this stage was terminated early due to the occurrence of an initial decrease in lymphocyte counts and the occurrence of transient lymphopenia in the healthy subjects. We submitted this data to the FDA as part of our IND submission for the conduct of clinical trials for the treatment of aGVHD. However, it is possible that the FDA will not authorize us to proceed with clinical studies in connection with any future IND submissions in other indications that have different patient populations, and we may be required to conduct additional Phase 1 clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Although the FDA may accept data from clinical trials conducted entirely outside the United States and not under an IND, acceptance of such study data is generally subject to certain conditions. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to test EQ001 in the future. We may expend our limited resources to pursue a particular indication for EQ001 and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Our translational biology program may initially show promise in identifying additional indications for which EQ001 may have therapeutic benefit, yet this may fail to yield additional clinical development opportunities for EQ001 for a number of reasons, including, EQ001 may, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that indicate that it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. Research programs to identify additional indications for EQ001 require substantial technical, financial and human resources.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus EQ001 development on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other indications or for any future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on EQ001 for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for EQ001 or any future product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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Even if we receive regulatory approval for EQ001 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, EQ001 and any future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for EQ001 or any future product candidates may be subject to 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 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves any product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, undesirable side effects caused by the product, problems encountered by our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, either before or after product approval, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- requirements to include additional warnings on the label;
- requirements to create a medication guide outlining the risks to patients;
- withdrawal of the product from the market;
- voluntary or mandatory product recalls;
- requirements to change the way the product is administered or for us to conduct additional clinical trials;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- harm to our reputation.

Additionally if any product candidate receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the therapy outweigh its risks, which may include, among other things, a medication guide outlining the risks for distribution to patients and a communication plan to health care practitioners. Any of these events could prevent us from achieving or maintaining market acceptance of the product or the particular product candidate at issue and could significantly harm our business, prospects, financial condition and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical 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. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of EQ001 or any future product candidates. We cannot predict the likelihood, nature or

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extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Even if EQ001 receives marketing approval in any indication, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial

If EQ001 receives marketing approval in any one or more indication, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If EQ001 does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of EQ001, if approved for commercial sale in any indication, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer EQ001 for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- potential product liability claims;
- the timing of market introduction of EQ001 as well as competitive biopharmaceutical products;
- the effectiveness of our or any of our potential future sales and marketing strategies;
- unfavorable publicity relating to EQ001;
- sufficient third-party payor coverage and adequate reimbursement;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient thirdparty coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell EQ001, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If EQ001 ultimately receives regulatory approval, we may not be able to effectively market and distribute it. We may have to seek collaborators or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that EQ001 will be approved, if at all. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute EQ001 ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market EQ001 effectively. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by EQ001; and
- our direct sales and marketing efforts may not be successful.

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We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop drugs and biologics for the treatment of immuno-inflammatory diseases. Our commercial opportunity 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 expensive than any products that we may develop, or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing 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.

Other products in the same class as EQ001 have already been approved or are further along in development. Currently-marketed treatments for cGVHD include AbbVie Inc.'s Imbruvica (ibrutinib), a BTK inhibitor previously approved for the treatment of chronic lymphocytic leukemia and other cancers. Further, we are aware of both private and public companies with development programs in GVHD, including AbbVie Inc., Amgen Inc., Biogen Inc., Bristol-Myers Squibb Company, CSL Behring LLC, Incyte Corporation, Jazz Pharmaceuticals plc, Kadmon Holdings, Inc., Kalytera Therapeutics, Inc., Kamada Ltd., Mesoblast Limited, Novartis AG, Prometheus Laboratories Inc. and Xenikos B.V. Major, currently marketed asthma therapies include several biologic therapies that specifically target IgE or Th2-associated cytokines including products developed by AbbVie Inc., Amgen Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Regeneron Pharmaceutical Industries Limited, and we are aware of several companies with development programs in this indication including, AbbVie Inc., Amgen Inc., AnaptysBio, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Sanofi-Aventis U.S. LLC.

Many of our competitors, such as large pharmaceutical and biotechnology companies like Amgen Inc. and Bristol-Myers Squibb Company have longer operating histories and significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. In addition, these larger companies may be able to use their greater market power to obtain more favorable distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

Further, as more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenues and financial condition would be materially and adversely affected.

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 other 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 and management personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, EQ001 or any future programs.

The key competitive factors affecting the success of EQ001 are likely to be its efficacy, safety, convenience and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

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# EQ001 and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 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. 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 the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

# If the U.S. market opportunities for EQ001 are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We only have the rights to EQ001 for the United States and Canada and we are focused on the development of EQ001 for immuno-inflammatory diseases, with an initial intention to develop it for the treatment of aGVHD, cGVHD and severe asthma. Our projections of addressable patient populations in the United States and Canada that have the potential to benefit from treatment with EQ001 are based on estimates and may prove to be incorrect. If any of our estimates are inaccurate, the market opportunities for EQ001 could be significantly diminished and have an adverse material impact on our business.

# We may be unsuccessful in our efforts to obtain orphan drug designations from the FDA for EQ001 or may not ultimately realize the potential benefits of orphan drug designation.

We intend to seek orphan drug designation for EQ001 in eligible indications. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years (with certain exceptions). However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process. If we are unable to secure orphan drug designation in eligible indications, our regulatory and commercial prospects may be negatively impacted.

Even if we obtain orphan drug designations and are awarded marketing exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity

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does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to biosimilar competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as EQ001, we may face increased competition and lose market share regardless of orphan drug exclusivity.

#### Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of biologics is complex and Biocon, our third-party manufacturer, may encounter difficulties in production. If Biocon encounters such difficulties, our ability to provide supply of EQ001 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on Biocon to fulfill our clinical and commercial supply of EQ001. In May 2017, we entered into an exclusive clinical supply agreement with Biocon and have agreed to enter into an exclusive commercial supply agreement with Biocon in the future. Biocon manufactures EQ001 at its FDA regulated facility in Bangalore, India. However the process of manufacturing biologics is complex, highly-regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for EQ001 or any future product candidates, there is no assurance that Biocon or other potential manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business. financial condition, results of operations and growth prospects.

Scaling up a biologic manufacturing process is a difficult and uncertain task, and Biocon may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand. If Biocon is unable to meet our manufacturing requirements, it has the discretion to outsource manufacturing to a third party and the joint steering committee may determine to shift manufacturing to a third party. However, transfer of the manufacturing of biologic products to a new contract manufacturer can be lengthy and involve significant additional costs. Even if we are able to adequately validate and scale-up the manufacturing process for EQ001 with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us, if at all. In addition, Biocon has certain rights to reacquire exclusive manufacturing rights for EQ001, even after a third party has been engaged following shortfalls by Biocon, which will may make it difficult and expensive to engage any third party manufacturer for EQ001 other than Biocon.

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We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we will be dependent on third parties to conduct our planned clinical trials of EQ001 and preclinical studies, and any future preclinical studies and clinical trials of any other product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trial may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing EQ001 or any future product candidates

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other biopharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for EQ001 or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Even if we receive marketing approval, we may not be able to successfully commercialize EQ001 due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell EQ001 or any future product candidates profitably.

Obtaining coverage and adequate reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of EQ001 or other future products to the payor. There may be significant delays in

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obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting pharmaceutical prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. 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. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Similarly, because our product candidates are physician-administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may be reimbursed for providing the treatment or procedure in which our product is used. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. 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 list of covered drugs, or formulary, it will be placed. The position on a payor's 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 medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and

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economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of EQ001 or any future product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture EQ001, we must share trade secrets with them. 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 the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, 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. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to future product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of EQ001 and any future product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with biotechnology companies for the development and potential commercialization of product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;

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- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our future product candidates or bring them to market and generate product revenue. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

#### Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights covering our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market.

Our success depends in significant part on our and Biocon's ability to establish, maintain and protect patents and other intellectual property rights with respect to our proprietary technologies, research programs, and product candidates, including EQ001 and operate without infringing the intellectual property rights of others. The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current and future licensors, licensees or partners will fail to identify patentable aspects of our research or inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Although we enter into confidentiality agreements with parties who have access to patentable aspects of our research and development programs, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection on technology relating to our research programs. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensess or partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent

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protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, allowing foreign competitors a better opportunity to create, develop and market competing product candidates, or vice versa. We cannot be certain that the claims in our pending patent applications directed to our product candidates such as EQ001 and others, as well as technologies relating to our research programs, will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or partners' patent rights are highly uncertain. Our and our licensors', licensees' or partners' pending and future patent applications may not result in patents being issued, which protect our technology or products, in whole or in part, or their intended uses, methods of manufacture or formulations, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or partners to narrow the scope of the claims of our or our licensors', licensees' or partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. In the past, we have not always been able to obtain the full scope of patent protection we have initially sought in our patent applications, and as described above and as is typical for most biotechnology patent prosecution, we have been required to narrow or eliminate patent claims as part of the patent prosecution process. In addition, some patent applications that we or our licensors have filed have not resulted in issued patents because we or our licensors have abandoned those patent applications as changes in business and/or legal strategies dictated.

We cannot assure you that all of the potentially relevant prior art—information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention—relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application, and we may be subject to a third party pre-issuance submission of prior art to the USPTO. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may an initiate litigation or opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated, may allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or limit the duration of the patent protection of our technology and products. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our and our licensors', licensees' or partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because 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 any patent application related to our research programs and product candidates such as EQ001. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications.

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If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for EQ001 or any other product candidates that we may identify, our business may be materially harmed.

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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the expiration of the patent. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However the applicable authorities, including the FDA and USPTO, in the United States, and any equivalent foreign regulatory authority, 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 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

The degree of future protection for our proprietary rights is uncertain, and we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether any of the patents we own or license will be found to ultimately be valid and enforceable;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether the patents of others will not have an adverse effect on our business;
- whether we will develop additional proprietary technologies or products that are separately patentable
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We depend on intellectual property licensed from Biocon and termination of our license could result in the loss of significant rights, which would harm our business.

We currently in-license certain intellectual property that is important to our business from Biocon and, in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. We rely to some extent on Biocon to file patent applications and to otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by Biocon have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which Biocon initiates an infringement proceeding against a third-party infringer of the intellectual property that is licensed to us. It is possible that our licensor's infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

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Furthermore, in-licensed patents may be subject to a reservation of rights by one or more third parties. Further, our existing license with Biocon imposes, and future agreements may also impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, we may be required to pay damages and our licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property and our competitors or other third parties might be able to gain access to technologies and products that are identical to ours. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the licenses, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. Disputes may also arise between us and our licensor regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues:
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

In addition, intellectual property or technology license agreements, including our existing agreements, are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensor fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash 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. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

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In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our product candidates such as EQ001 and/or others. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development
  or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive
  products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing
  priorities:
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources:
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent, which might adversely affect our ability to develop and market our products.

We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to our therapeutic research programs or necessary for the commercialization of our product candidates such as EQ001 and/or others in any jurisdiction.

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Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of EQ001 that we may identify. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware, potentially relating to our research programs and product candidates such as EQ001 and others, or their intended uses. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, which include EQ001 and others, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell EQ001 and other potential future product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting 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 and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents.

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There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our current and future product candidates, including EQ001 and others, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we or our licensor may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we or our licensor assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and the outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own or have licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products.

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Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. For example, an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring EQ001 or other product candidates that we may identify to market. Any of these occurrences could adversely affect our competitive business position, results of operations business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 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 a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent relating to our research programs and product candidates, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, including EQ001, if such technologies or features are found to

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incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or USPTO rules and regulations could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued paten

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. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

### We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our

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patents at risk of being invalidated or interpreted narrowly and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations 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. Non-compliance 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, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our research programs and product candidates such as EQ001 and others as well as their respective methods of use, manufacture and formulations thereof, our competitive position would be adversely affected, as, for example, competitors might be able to enter the market earlier than would otherwise have been the case.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. Unauthorized parties may also attempt to copy or reverse engineer certain

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aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

### We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensor may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently do not own any registered trademarks. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

### Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending
  patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators 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 have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors:
- our competitors might conduct research and development activities 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.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

### Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

### We are highly dependent on the services of our key personnel.

We are highly dependent on the services of our key personnel, Daniel M. Bradbury, who serves as our Chief Executive Officer, Bruce D. Steel, who serves as our President and Chief Business Officer, Krishna R. Polu, M.D., who serves as our Chief Medical Officer, and Stephen Connelly, Ph.D., who serves as our Chief Scientific Officer. Although we have entered into agreements with them regarding their employment, they are not for a specific term and each of them may terminate their employment with us at any time, though we are not aware of any present intention of either of these individuals to leave us.

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We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2018, we had seven full-time employees. As we advance EQ001 into clinical development, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if EQ001 or any future product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- identify and lease additional facilities;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for EQ001 and any future product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize EQ001 and any future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our planned clinical trials and the manufacture of EQ001 and any future product candidates. We cannot assure you that the services of such third party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by leasing additional facilities, hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize EQ001 and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the Greater San Diego Area and the San Francisco Bay Area, regions that are home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize EQ001 or any future product candidates and to grow our business and operations as currently contemplated.

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Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt a code of conduct applicable to all of our employees prior to completion of this offering, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, 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.

Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of EQ001 or any future product candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause

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interruptions in our operations, it could result in a material disruption of our programs and the development of EQ001 or any future product candidates could be delayed. In addition, the loss of clinical trial data for EQ001 or any future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

As of May 25, 2018, the General Data Protection Regulation, or GDPR, has replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third party processors in connection with the processing of the personal data. The GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the European Union member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. To comply with the new data protection rules imposed by GDPR we may be required to put in place additional prospects.

European data protection law also imposes strict rules on the transfer of personal data out of the European Union, including to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently

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litigation challenging other E.U. mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our E.U. business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Further, the United Kingdom's vote in favor of exiting the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and main research facility are located in the Greater San Diego Area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

### U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. We do not expect this tax legislation to have a material impact to our current projection of minimal cash taxes for the near future. However, we continue to examine the impact that this tax legislation may have on our business in the longer term. Accordingly, notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this

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tax legislation on holders of our common stock is also uncertain and could be adverse. We urge prospective investors to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We face an inherent risk of product liability exposure related to the testing of EQ001 and any future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that EQ001 or any future product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, or marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We do not currently have product liability insurance but intend to obtain it before we initiate our first clinical trials. However, the amount of insurance that we obtain may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as EQ001 and any future product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may have a significant adverse effect on our business and results of operations.

There have been, and 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. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (which

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through subsequent legislative amendments, will be increased to 70% from 50% starting in 2019) 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; (vi) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (vii) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (viii) created a licensure framework for follow-on biologic products; and (ix) established a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act 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." Since the enactment of the Tax Cuts and Jobs Act of 2017, there have been additional amendments to certain provisions of the Affordable Care Act, and we expect the current Trump administration and Congress will likely continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition. Congress may consider other legislation to repeal and replace elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted since the Affordable Care Act 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 and subsequent laws, which began in 2013 and will remain in effect through 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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 Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Most recently, the Trump administration released a "Blueprint," or plan, to reduce the cost of drugs. The Trump administration's Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing,

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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.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded 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 drugs, once marketing approval is obtained.

We will be subject to applicable foreign, federal and state fraud and abuse, transparency, government price reporting, 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 will play a primary role in the recommendation and prescription of any future product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that

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the customers would bill federal programs for the product, providing consulting fees and other benefits to physicians to induce them to prescribe products, engaging in promotion for "off-label" uses, and submitting inflated best price information to the Medicaid Rebate Program:

- HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH and its implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices:
- the Public Health Service Act, which prohibits, among other things, the introduction of a biological product into interstate commerce without an approved BLA;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to HHS information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; track and report gifts, compensation and other remuneration provided to physicians, other health care providers, and certain health care entities; and/or ensure the registration and compliance of sales and medical personnel. In addition, we may be subject to federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of EQ001 and any future product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with

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providers who may influence the ordering of and use of EQ001 or any future product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, collectively, Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

After the completion of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the Securities and Exchange Commission, or the SEC, or any securities exchange relating to public companies. Sarbanes-Oxley, as well as rules subsequently adopted by the SEC, and The Nasdaq Global Market to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and

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regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

### Risks Related to our Common Stock and this Offering

There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares at or above the initial public offering price.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock following this offering. If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the initial public offering price. An active or liquid market in our common stock may not develop upon the completion of this offering or, if it does develop, it may not be sustainable. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

our operating performance and the performance of other similar companies;

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- our ability to enroll subjects in our ongoing and planned clinical trials;
- results from our planned clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our ability to achieve product development goals in the timeframe we announce;
- announcements of clinical trial results, regulatory developments, acquisitions, strategic alliances or significant agreements by us or by our competitors;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock:
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and
- any other factors discussed in this prospectus.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many life sciences companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration and license agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt 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 collaboration and license agreements 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. If we are unable to raise additional funds through equity or debt financings 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 prefer to develop and market ourselves.

Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. After this offering, we will have 16,752,658 outstanding shares of our common stock, based on the number of shares outstanding as of June 30, 2018. All of the shares of common stock sold in this offering will be available for sale in the public market. All of our outstanding shares of common stock are currently restricted from resale as a result of market standoff and

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"lock-up" agreements, as more fully described in "Shares Eligible for Future Sale." These shares will become available to be sold 181 days after the date of this prospectus. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and various vesting agreements.

After our initial public offering, certain of our stockholders 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 our stockholders, subject to market standoff and lockup agreements. We also intend to register shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements. Jefferies LLC and Leerink Partners LLC may, in their discretion, permit our stockholders to sell shares prior to the expiration of the restrictive provisions contained in those lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

### If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution.

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share of \$10.12 per share as of June 30, 2018, based on the initial public offering price of our common stock of \$14.00 per share because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution upon exercise of options to purchase common stock under our equity incentive plans, upon vesting of options to purchase common stock under our equity incentive plans, if we issue restricted stock to our employees under our equity incentive plans or if we otherwise issue additional shares of our common stock.

We will have broad discretion in the use of the net proceeds of this offering and may not use them effectively or in ways that increase the value of our share price.

We cannot specify with any certainty the particular uses of the net proceeds that we will receive from this offering, but we currently expect such uses will include funding research and development of EQ001 and working capital and other general corporate purposes, including the additional costs associated with being a public company. We will have broad discretion in the application of the net proceeds, including working capital and other general corporate purposes, and you and other stockholders may disagree with how we spend or invest these proceeds. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest the net proceeds from our initial public offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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### Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, 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:
- 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 non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act.

We cannot predict if 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 stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

# We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any

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dividends in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Based upon shares outstanding as of June 30, 2018, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 98.2% of our common stock, and upon the completion of this offering, that same group, in the aggregate, will beneficially own approximately 66.5% of our common stock, assuming that these holders do not purchase any shares in this offering, no exercise by the underwriters of their option to purchase additional shares, no exercise of outstanding options or warrants and after giving effect to the issuance of shares in this offering. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders, including those who purchase shares in this offering, oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect at the completion of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the completion of this offering, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- 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 our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- 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;
- divide our board of directors into three classes;
- 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;
- 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 notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice:
- do 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);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or
  proceeding brought on our behalf, (ii) any action asserting a claim of breach of a

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fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

For information regarding these and other provisions, see "Description of Capital Stock."

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is 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 will provide that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of 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 and 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. If a court were to find the choice of forum provisions 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.

# We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop and commercialize EQ001 and any future product candidates;
- our ability to obtain and maintain regulatory approval of EQ001 in any of the indications for which we plan to develop it;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical trials of EQ001;
- the success, cost, and timing of our product development activities, including our planned clinical trials of EQ001;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize EQ001;
- the rate and degree of market acceptance of EQ001;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States;
- the performance of our third-party service providers, including Biocon and other suppliers and manufacturers;
- the safety, efficacy and market success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- our use of the proceeds from this offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for EQ001 and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this prospectus in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, 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 any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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You should carefully 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.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

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#### **USE OF PROCEEDS**

We estimate that we will receive net proceeds of approximately \$58.7 million (or approximately \$67.8 million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We anticipate that we will use the net proceeds of this offering as follows:

- approximately \$50.0 million to fund research and development of EQ001; and
- the remainder for working capital and other general corporate purposes, including the additional costs associated with being a public company.

We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current plans, commitments or obligations to do so.

We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our currently planned operations for at least the next 24 months, although there can be no assurance in that regard. In particular, we expect that the net proceeds from this offering will allow us to fund a Phase 1b/2 clinical trial of EQ001 for aGVHD, a Phase 2 clinical trial of EQ001 for cGVHD and a proof-of-concept clinical trial of EQ001 for severe asthma.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the progress, cost and results of our preclinical and clinical development programs, our ability to obtain additional financing, and other factors described under "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant, and subject to the restrictions contained in any future financing instruments.

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### **CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2018 as follows:

- on an actual basis;
- on a pro forma basis to reflect (1) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018, (2) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share, and (3) the filing of our amended and restated certificate of incorporation immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 4,670,000 shares of common stock in this offering based on the initial public offering price of \$14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes included in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

	AS OF JUNE 30, 2018 (unaudited)			
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED	
Cash and cash equivalents	\$ 6,626,443	6,626,443	65,329,843	
Convertible promissory notes, including related party	10,517,896	_	_	
Stockholders' (deficit) equity:				
Common stock, \$0.0001 par value; 43,100,000 shares authorized at June 30, 2018 (unaudited);				
10,975,764 shares issued and outstanding as of June 30, 2018, which includes 267,690				
shares of restricted common stock subject to a right of repurchase	127	236	703	
Additional paid-in capital	10,405	11,742,864	70,445,797	
Accumulated deficit	(5,604,033)	(5,604,033)	(5,604,033)	
Total stockholders' (deficit) equity	(5,593,501)	6,139,067	64,842,467	
Total capitalization	\$ 4,924,395	6,139,067	64,842,467	

The number of shares in the table above excludes, as of June 30, 2018:

- 107,084 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2018, each at an exercise price of \$0.05 per share;
- 2,229,773 shares of common stock reserved for future issuance under our 2018 Plan which became effective in connection with the execution and delivery of the underwriting agreement for this offering (including 1,040,000 new shares plus the number of shares (not to exceed 1,189,773 shares) (i) that remain available for grant of future awards under our 2017 Plan which shares were added to the shares reserved under the 2018 Plan upon its effectiveness and (ii) any shares underlying outstanding stock awards granted under our 2017 Plan that expire, or are forfeited, cancelled, withheld or reacquired, as more fully described under the terms of the 2018 Plan described in the section titled "Executive Compensation—Equity Benefit Plans"); and
- 343,275 shares of common stock reserved for issuance under the ESPP, which became effective in connection with the execution and delivery of the underwriting agreement for this offering.

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#### DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately 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.

As of June 30, 2018, we had a historical net tangible book deficit of \$(5.6) million, or \$(0.51) per share of common stock. Our historical net tangible book deficit per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding (including 267,690 shares of restricted common stock which are subject to a right of repurchase by us as of June 30, 2018) at June 30, 2018.

After giving effect to the (i) conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018, and (ii) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share, our pro forma net tangible book value as of June 30, 2018 is \$6.14 million, or \$0.51 per share of our common stock.

After giving further effect to the sale of 4,670,000 shares of common stock that we are offering at the initial public offering price of \$14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2018 is \$64.8 million, or approximately \$3.88 per share. This amount represents an immediate increase in pro forma net tangible book value of \$3.37 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$10.12 per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Initial public offering price per share		\$14.00
Historical net tangible book deficit per share at June 30, 2018, before giving effect to this offering	\$(0.51)	
Pro forma increase in historical net tangible book value per share attributable to conversion of convertible promissory	4.00	
notes and issuance of shares of common stock pursuant to anti-dilution rights	1.02	
Pro forma net tangible book value per share at June 30, 2018, before giving effect to this offering	0.51	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering	3.37	
Pro forma as adjusted net tangible book value per share after this offering		3.88
Dilution per share to new investors participating in this offering		\$10.12

If the underwriters exercise their option to purchase 700,500 additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be \$4.25 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$0.37 per share and the dilution per share to new investors would be \$(0.37) per share.

The following table summarizes on a pro forma as adjusted basis as of June 30, 2018, the number of shares of common stock purchased or to be purchased from us, the total consideration paid or to be paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid

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by new investors in this offering. The calculation below is based on the initial public offering price of \$14.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PU	RCHASED	TOTAL CONSIDERATION			AVERAGE PRICE PER	
	NUMBER	PERCENT	AMOUNT	PERCENT		HARE	
Existing stockholders	12,082,658	72.1%	\$ 9,922,008	13.2%	\$	0.82	
Investors participating in this offering	4,670,000	27.9	65,380,000	86.8		14.00	
Total	16,752,658	100.0%	\$75,302,008	100.0%	\$	4.49	

The foregoing tables and calculations exclude:

- 107,084 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2018, each at an exercise price of \$0.05 per share;
- 2,229,773 shares of common stock reserved for future issuance under our 2018 Plan which became effective in connection with the execution and delivery of the underwriting agreement for this offering (including 1,040,000 new shares plus the number of shares (not to exceed 1,189,773 shares) (i) that remain available for grant of future awards under our 2017 Plan which shares were added to the shares reserved under the 2018 Plan upon its effectiveness and (ii) any shares that underlying outstanding stock awards granted under our 2017 Plan that expire, or are forfeited, cancelled, withheld or reacquired, as more fully described under the terms of the 2018 Plan described in the section titled "Executive Compensation—Equity Benefit Plans"); and
- 343,275 shares of common stock reserved for issuance under the ESPP, which became effective in connection with the execution and delivery of the underwriting agreement for this offering.

We may choose to raise additional capital through the sale of equity or convertible debt securities due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

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### **SELECTED FINANCIAL DATA**

The following selected statement of operations data for the period March 16, 2017 (inception) through December 31, 2017 and the balance sheet data as of December 31, 2017 are derived from our audited financial statements appearing elsewhere in this prospectus. The selected statement of operations data for the period March 16, 2017 (inception) through June 30, 2017 and the six months ended June 30, 2018 and the balance sheet data as of June 30, 2018 have been derived from our unaudited financial statements included elsewhere in this prospectus. In our opinion, these unaudited financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read these data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the interim periods are not necessarily indicative of the results that may be expected for any other interim periods or any future year.

	PERIOD MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017	PERIOD MARCH 16, 2017 (INCEPTION) THROUGH JUNE 30, 2017	SIX MONTHS ENDED JUNE 30, 2018	
Statement of Operations Data:		(unau	dited)	
Operating expenses:				
Research and development	\$ 1,333,721	\$ 801,364	\$ 1,202,917	
General and administrative	378,328	187,173	958,691	
Total operating expenses	1,712,049	988,537	2,161,608	
Loss from operations	(1,712,049)	(988,537)	(2,161,608)	
Interest expense	379,385	7,069	1,108,197	
Interest income			(29,926)	
Change in fair value of Biocon anti-dilution right	170,440	18,887	102,280	
Net loss and comprehensive loss	<u>\$ (2,261,874)</u>	<u>\$(1,014,493</u> )	<u>\$ (3,342,159</u> )	
Net loss per share, basic and diluted (1)	<u>\$ (0.28)</u>	<u>\$ (0.19)</u>	<u>\$ (0.31)</u>	
Weighted average shares of common stock outstanding, basic and diluted (1)	8,030,029	5,307,596	10,711,788	
Pro forma net loss per share, basic and diluted (unaudited) (1)	<u>\$ (0.21)</u>		<u>\$ (0.18)</u>	
Pro forma weighted average shares of common stock outstanding, basic and diluted				
(unaudited) (1)	8,300,869		11,679,293	

<sup>(1)</sup> See Note 2 to our financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share, unaudited proforma basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

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	AS OF DECEMBER 31, 2017	AS OF JUNE 30, 2018 (unaudited)	
Balance Sheet Data:		(4114441104)	
Cash and cash equivalents	\$ 7,103,553	\$ 6,626,443	
Working capital	6,580,546	5,788,958	
Total assets	7,151,443	6,728,134	
Convertible promissory notes, including related party	8,058,866	10,517,896	
Accumulated deficit	(2,261,874)	(5,604,033)	
Total stockholders' deficit	\$ (2,252,085)	. , , ,	

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#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and 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 that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

#### Overview

We are a biotechnology company leveraging deep understanding of immunobiology to develop products for severe immuno-inflammatory disorders with high unmet medical need. Our initial product candidate, EQ001, is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of Teff cells. Activated Teff cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe EQ001 may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

Our pipeline is focused on developing EQ001 as a potentially best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. We plan to initiate a Phase 1b/2 clinical trial of EQ001 for the treatment of aGVHD in early 2019, and expect top-line data from the Phase 1b part of this trial within 12 months of initiation. Our IND with the FDA for aGVHD was accepted in July 2018. Additionally, in the first half of 2019, we plan to commence a Phase 2 clinical trial of EQ001 for the treatment of cGVHD, initiate a proof-of-concept clinical trial for the treatment of severe asthma and select one or more additional indications for future development. In May 2017, we acquired U.S. and Canadian rights to itolizumab from Biocon. Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon as ALZUMAb.

Since our inception, substantially all of our efforts have been focused on organizing and staffing our company, business planning, raising capital, in-licensing rights to EQ001, conducting preclinical research, filing our initial IND and preparing to commence clinical development of EQ001. We have not generated any revenue from product sales or otherwise. From inception through June 30, 2018, we have raised gross proceeds of \$9.4 million from the issuance of convertible promissory notes to fund our operations. We have incurred losses since our inception. Our net losses were \$2.3 million for the period March 16, 2017 (inception) through December 31, 2017, and \$1.0 million and \$3.3 million for the period March 16, 2017 (inception) through June 30, 2018 months ended June 30, 2018, respectively. As of December 31, 2017 and June 30, 2018, we had an accumulated deficit of \$2.3 million and \$5.6 million, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with our research and preclinical activities and general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing losses into the foreseeable future. We anticipate our expenses will increase substantially as we continue our research and development activities, including the planned clinical development of EQ001, seek regulatory approval for and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur additional costs associated with being a public company.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for EQ001 or any future product candidate, which will not be for at least the next several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. Our failure to raise capital or

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enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### **Financial Overview**

#### Revenue

We currently have no products approved for sale, and we have not generated any revenues to date. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidates, as well as product sales from any approved product, which approval we do not expect to occur for at least the next several years, if ever. Our ability to generate product revenues will depend on the successful development and eventual commercialization of EQ001 and any future product candidates. If we fail to complete the development of EQ001 or any future product candidates in a timely manner, or to obtain regulatory approval for our product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

### Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research and preclinical activities, and clinical development of EQ001. Our research and development expenses include:

- salaries and related overhead expenses, which include stock-based compensation and benefits, for personnel in research and development functions;
- external research and development expenses incurred under arrangements with third parties, such as consultants and advisors for research and development;
- costs related to in-licensing rights to EQ001 from Biocon;
- costs of services performed by third parties, such as contract research organizations, or CROs, that conduct research and development and preclinical activities on our behalf; and
- costs related to preparing and filing an IND with the FDA.

We expense research and development costs as incurred. From our inception through June 30, 2018, we have incurred \$2.5 million in research and development expenses. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs and consultants in connection with our preclinical and clinical development.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of EQ001 and potentially expand the number of indications for which we are developing EQ001. The successful development of EQ001 is highly uncertain. At this time, due to the inherently unpredictable nature of preclinical and clinical development, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of EQ001 or the period, if any, in which material net cash inflows from EQ001 may commence. Clinical development timelines, the probability of success, and development costs can differ materially from expectations.

Completion of clinical trials may take several years or more, and the length of time generally varies according to the type, complexity, novelty, and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites included in our clinical trials;
- the length of time required to enroll suitable patients;

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- the number of doses that patients receive;
- the number of patients that participate in our clinical trials;
- the drop-out or discontinuation rates of patients in our clinical trials;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of procedures, analyses and tests performed during our clinical trials;
- the costs of procuring drug product for our clinical trials;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation and benefits, and consulting fees for executive, finance, and accounting functions. Other significant costs include legal fees relating to patent and corporate matters, insurance, travel and facility costs.

We anticipate that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure and increased professional fees associated with being a public company. In addition, if we obtain regulatory approval for any product candidate, we expect to incur expenses associated with building the infrastructure to commercialize such product. However, we do not expect to receive any such regulatory approval for at least the next several years, if ever.

### Interest Expense

Interest expense consists of interest on our convertible promissory notes.

### Change in Fair Value of Biocon Anti-Dilution Right

We have committed to issue to Biocon additional shares of common stock to maintain Biocon's ownership interest of our fully-diluted capitalization until we have received aggregate cumulative gross proceeds from sales of equity securities of \$15 million, or the Biocon Anti-Dilution Right. The Biocon Anti-Dilution Right has been classified as a liability in the accompanying balance sheet. The Biocon Anti-Dilution Right is recorded at fair value using the Precedent Transaction Method. The fair value of the Biocon Anti-Dilution Right is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense). The Biocon Anti-Dilution Right will be satisfied in full upon the issuance of additional shares of common stock to Biocon in connection with the completion of this initial public offering.

#### **Results of Operations**

# Comparison of the Period March 16, 2017 (Inception) Through June 30, 2017 and the Six Months Ended June 30, 2018

The following table sets forth our results of operations for the period March 16, 2017 (inception) through June 30, 2017 and the six months ended June 30, 2018:

	MAF (IN T	FOR THE PERIOD  MARCH 16, 2017 (INCEPTION)  THROUGH  JUNE 30,  2017		PERIOD-TO-PERIOD CHANGE	
Research and development	\$	(unaudit 801.364	ed) \$1.202.917	¢	401.553
General and administrative	Ψ	187,173	958,691	φ	771,518
Interest expense		7,069	1,108,197		1,101,128
Change in fair value of Biocon anti-dilution right		18,887	102,280		83,393

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### Research and Development Expenses

Research and development expenses were \$0.8 million and \$1.2 million for the period ended June 30, 2017 and the six months ended June 30, 2018, respectively. The \$0.4 million increase in research and development expenses during this period was primarily due to an increase in costs related to our translational research and the filing of our IND. The increase in research and development expense included consulting expenses of \$0.5 million, \$0.4 million of expenses related to preclinical research, salary expenses of \$0.3 million, and other expenses of \$0.1 million, offset by a decrease in license expense of \$0.9 million under our collaboration and license agreement with Biocon, or the Biocon License.

#### General and Administrative Expenses

General and administrative expenses were \$0.2 million and \$1.0 million for the period ended June 30, 2017 and the six months ended June 30, 2018, respectively. The \$0.8 million increase in general and administrative expenses during this period was related to a \$0.4 million increase in salary expenses, a \$0.3 million increase in consulting expenses, and a \$0.1 million increase in other general and administrative expenses.

#### Interest Expense

Interest expense was \$7,069 for the period ended June 30, 2017 compared to \$1.1 million for the six months ended June 30, 2018. Interest expense consisted of non-cash interest expense, including accretion of debt premium and issuance costs in relation to our outstanding convertible promissory notes.

# Change in Fair Value of Biocon Anti-Dilution Right

Change in fair value of the Biocon Anti-Dilution Right was \$18,887 and \$0.1 million for the period ended June 30, 2017 and the six months ended June 30, 2018, respectively. The increase in change in fair value of the Biocon Anti-Dilution Right primarily reflects the increase in the likelihood that the right will be settled.

# Period March 16, 2017 (Inception) Through December 31, 2017

The following table sets forth our results of operations for the period March 16, 2017 (inception) through December 31, 2017:

MARCH 16, 201 (INCEPTION) THROUGH DECEMBER 31 2017		
\$	1,333,721	
	378,328	
	379,385	
	170,440	
	DE	

FOR THE PERIOD

# Research and Development Expenses

Research and development expenses were \$1.3 million for the period ended December 31, 2017. Research and development expenses included \$0.8 million to acquire the rights under the Biocon License, \$0.3 million in salary and consulting expenses and \$0.2 million related to translational research activities.

# General and Administrative Expenses

General and administrative expenses were \$0.4 million for the period ended December 31, 2017. General and administrative expenses included \$0.2 million in legal fees, \$0.1 million in consulting expenses, and \$0.1 million in overhead and other expenses.

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#### Interest Expense

Interest expense was \$0.4 million for the period ended December 31, 2017. Interest expense consisted of non-cash interest expense, including accretion of debt premium and issuance costs in relation to our convertible promissory notes.

Change in Fair Value of Biocon Anti-Dilution Right

Change in fair value of the Biocon Anti-Dilution Right was \$0.2 million for the period ended December 31, 2017. The change in fair value of the Biocon Anti-Dilution Right primarily reflects the increase in the likelihood that the right will be settled.

#### Liquidity and Capital Resources

#### Sources of Liquidity

From inception through June 30, 2018, we have raised gross proceeds of \$9.4 million from the issuance of convertible promissory notes to fund our operations. The convertible promissory notes accrue interest at a rate of 6% per year, mature two years from their issuance and automatically convert into equity securities sold pursuant to a qualified financing transaction from which we receive total gross proceeds of not less than \$15.0 million at a conversion price equal to 90% of the per share price paid by investors for such securities if the closing of the financing occurs on or prior to the six month anniversary of the issuance of convertible promissory notes, or at a conversion price equal to 80% of the per share price paid by investors for such securities if the closing of the financing occurs after the six month anniversary of the issuance of convertible promissory notes. If we consummate a change in control prior to the conversion or repayment in full of the convertible promissory notes, we shall pay each holder in cash in an amount equal to the outstanding principal amount of the convertible promissory note plus any unpaid accrued interest on the original principal plus 1.0 times the outstanding principal amount of the note.

As of June 30, 2018, we had \$6.6 million in cash and cash equivalents.

### **Funding Requirements**

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance clinical development of EQ001. In addition, we expect to incur additional costs associated with operating as a public company following the completion of this offering. We expect that our primary uses of capital will be third-party clinical research and development services, manufacturing, clinical trial costs, legal and other regulatory compliance expenses, compensation and related expenses, and general overhead costs.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our currently planned operations for at least the next 24 months. In particular, we expect that the net proceeds from this offering will allow us to fund a Phase 1b/2 clinical trial of EQ001 for aGVHD, a Phase 2 clinical trial of EQ001 for cGVHD and a proof-of-concept clinical trial of EQ001 for severe asthma. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Furthermore, our operating plans may change, and we may need additional funds sooner than planned. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. Because the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of EQ001 or whether, or when, we may achieve profitability.

Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our planned clinical trials for EQ001;
- the number and scope of indications we decide to pursue for EQ001 development;
- the cost, timing and outcome of regulatory review of any BLA we may submit for EQ001;
- the costs and timing of manufacturing for EQOO1, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

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 our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of EQ001;

- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing EQ001, if approved for commercial sale.

Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. The sale of additional equity or convertible debt could result in additional dilution to our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. The incurrence of debt financing would result in debt service obligations and the governing documents would likely include operating and financing covenants that would restrict our operations. If we raise additional funds through collaboration or license agreements, 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 that may reduce the value of our common stock. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. Any of these actions could have a material effect on our business, financial condition and results of operations. We have experienced net losses and negative cash flows from operating activities since our inception and expect to continue to incur net losses into the foreseeable future. We had an accumulated deficit of \$2.3 million and \$5.6 million at December 31, 2017 and June 30, 2018, respectively. We expect operating losses and negative cash flows to continue for at least the next several years as we continue to incur costs related to the development of EQ001. We have prepared cash flow forecasts which indicate that based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern without raising additional capital within 12 months after the date that the financial statements for the six months ended June

The following table sets forth the cash flow from operating, investing and financing activities for the period March 16, 2017 (inception) through December 31, 2017 and the period March 16, 2017 (inception) through June 30, 2017 and the six months ended June 30, 2018:

	MA (I	THE PERIOD RCH 16, 2017 NCEPTION) FHROUGH CEMBER 31, 2017	MA (II	THE PERIOD RCH 16, 2017 NCEPTION) IHROUGH JUNE 30, 2017	SIX MONTHS ENDED JUNE 30, 2018
				(unaudit	ed)
Net cash used in operating activities	\$	(662,201)	\$	(183,541)	\$(2,057,681)
Net cash used in investing activities		(2,199)		_	(21,823)
Net cash provided by financing activities		7,767,953		1,000,000	1,602,394
Net (decrease) increase in cash and cash equivalents	\$	7,103,553	\$	816,459	\$ (477,110)

Comparison of the Period March 16, 2017 (Inception) Through June 30, 2017 and the Six Months Ended June 30, 2018

#### Operating Activities

Net cash used in operating activities was \$0.2 million during the period ended June 30, 2017 as compared to \$2.1 million during the six months ended June 30, 2018. The increase in cash used in operating activities of \$1.9 million was primarily the result of the increase in operating expenses in 2018.

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## Investing Activities

Net cash used in investing activities was \$0 and \$21,823 during the period ended June 30, 2017 and the six months ended June 30, 2018, respectively. The increase in cash used in investing activities of \$21,823 was the result of the purchase of property and equipment.

#### Financing Activities

Net cash provided by financing activities was \$1.0 million during the period ended June 30, 2017 as compared to \$1.6 million during the six months ended June 30, 2018. The increase in cash provided by financing activities of \$0.6 million was the result of an increase in convertible promissory notes issued in 2018.

#### Period March 16, 2017 (Inception) Through December 31, 2017

# Operating Activities

Net cash used in operating activities was \$0.7 million during the period ended December 31, 2017. The cash used in operating activities was primarily the result of wages, consulting fees, legal fees, and preclinical research expenses.

#### Investina Activities

Net cash used in investing activities was \$2,199 during the period ended December 31, 2017. The cash used in investing activities was the result of the purchase of property and equipment.

#### Financing Activities

Net cash provided by financing activities was \$7.8 million during the period ended December 31, 2017. The cash provided by financing activities was the result of the issuance of convertible promissory notes.

#### **Contractual Obligations**

The following summarizes our significant contractual obligations as of June 30, 2018:

	PAYMENT DUE BY PERIOD				
CONTRACTUAL OBLIGATIONS	TOTAL	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	AFTER 5 YEARS
Operating leases	\$ 214,255	\$ 57,522	\$ 156,733	<del>\$</del> —	<del>\$</del> —
Principal under convertible notes payable, excluding accrued interest	9,407,474	_	9,407,474	_	_
Interest payable on convertible promissory notes	336,550	_	336,550		
	\$9,958,279	\$ 57,522	\$9,900,757	<u> </u>	\$ <u> </u>

In addition, we have payment obligations under the Biocon License that are contingent upon future events such as our achievement of specified development and commercial milestones and are required to make certain cash royalty payments upon our achievement of target levels of revenue from sales of EQ001, if approved. As of June 30, 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 the Biocon License, including our payment obligations thereunder, see Note 5 to our financial statements appearing elsewhere in this prospectus.

We enter into agreements in the normal course of business with vendors for research studies and other services and products for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts are cancelable at any time by us, generally upon written notice to the vendor, and therefore we believe that our non-cancelable obligations under these agreements are not material.

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## **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, and similarly did not and do not have any holdings in variable interest entities.

#### Critical Accounting Policies and Significant Judgement and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

#### Accrued Research and Development Expense

We are required to estimate our expenses resulting from obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from our estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred

# Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of employee and non-employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option grants using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model requires the use of subjective assumptions, including the risk- free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. See Note 7 to our 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 during the six months ended June 30, 2018. No stock options were granted during the period ended December 31, 2017. Total employee and non-employee stock-based compensation expense related to unvested stock option grants not yet recognized as of December 31, 2017 and June 30, 2018 was \$0 and \$10,343, respectively, and the weighted-average period over which these grants are expected to vest is 0.0 and 3.73 years, respectively.

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Determination of the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value calculations using the Black-Scholes option pricing model. Because our common stock is not currently publicly traded, the fair value of the common stock underlying our stock-based awards has been determined on each grant date by our board of directors, with input from management, considering our most recently available third-party valuation of common shares. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Our determination of the value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the AICPA Practice Aid. In addition, our board of directors considered various objective and subjective factors to determine the fair value of our common stock, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- the anticipated capital structure that will directly impact the value of the currently outstanding securities;
- our results of operations and financial position;
- the status of our research and development efforts;
- the composition of, and changes to, our management team and board of directors;
- the lack of liquidity of our common stock as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- external market conditions affecting the life sciences and biotechnology industry sectors;
- U.S. and global economic conditions;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering, or IPO, or a sale of our company, given prevailing market conditions; and
- the market value and volatility of comparable companies.

The AICPA Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our company's future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics.

In accordance with the AICPA Practice Aid, we considered the various methods for allocating the enterprise value to determine the fair value of our common stock at the valuation date. Under the option pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The value of the common stock is inferred by analyzing these options. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class

To date, we have utilized the precedent transaction method to value our common stock which derives the implied equity value for one type of equity security from a contemporaneous transaction involving another type of equity security. We determined the precedent transaction method was the most appropriate method given the early stage of our company. The OPM was then used to allocate the enterprise value to our common stock as it was determined to be the most reliable given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate exit values given our stage of development and financial position.

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There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been significantly different.

Following the closing of this offering, the fair value of our common stock will be equal to the closing price of our common stock as reported on the date of the grant.

Based on the initial public offering price of \$14.00 per share, the intrinsic value of stock options outstanding as of June 30, 2018 would have been \$1.5 million, of which \$0.0 million and \$1.5 million would relate to stock options that were vested and unvested, respectively, at that date.

We intend to perform a retrospective reassessment to determine the stock-based compensation expense related to stock options granted in the third quarter of 2018.

## **Biocon Anti-Dilution Right**

We classify the Biocon Anti-Dilution Right as a liability on our balance sheets, as an obligation exists to issue a variable number of shares and that obligation is not indexed to our own stock. The Biocon Anti-Dilution Right was initially recorded at fair value on date of grant and is subsequently remeasured to fair value at each balance sheet date. The Biocon Anti-Dilution Right is estimated at fair value using the Precedent Transaction Method. The Precedent Transaction Method was applied to solve for our enterprise value under two scenarios: with the Biocon Anti-Dilution Right and without the Biocon Anti-Dilution Right. The resulting difference in the enterprise value under these two scenarios is the estimated fair value of the Biocon Anti-Dilution Right. The estimates used to determine our enterprise value are based, in part, on subjective assumptions and could differ materially in the future. Fluctuations in the fair value of the Biocon Anti-Dilution Right are impacted by unobservable inputs, most significantly our estimated fair value and probability of achieving different financing scenarios. If we do not receive proceeds from an equity financing, the fair value of the Biocon Anti-Dilution Right would be zero. Alternatively, if an equity financing results in gross proceeds of \$15.0 million or greater, the fair value of the Biocon Anti-Dilution Right could be as high as \$3.6 million. Changes in our estimated fair value and the probability of achieving different financing scenarios can have a significant impact on the fair value of the Biocon Anti-Dilution Right are reported in Other expense (income) in the statement of operations and comprehensive loss.

#### Other Information

# Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2017, we had federal and California tax net operating loss carryforwards of \$0.9 million and \$0.9 million, respectively, which begin to expire in 2037 and 2037, respectively, unless previously utilized. As of December 31, 2017, we also had federal and California research and development tax credit carryforwards of \$23,355 and \$14,344, respectively. The federal research and development tax credit carryforwards will begin to expire in 2037. The California research and development tax credit carryforwards are available indefinitely.

Utilization of the net operating losses and credits may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended. The annual limitation may result in the expiration of our net operating losses and credits before we can use them. We have recorded a valuation allowance on all of our deferred tax assets, including our deferred tax assets related to our net operating loss and research and development tax credit carryforwards.

In December 2017, the Tax Cuts and Jobs Act, or the 2017 Tax Act, was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact us, most notably a reduction of the U.S. corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017. The 2017 Tax Act also provides for the acceleration of depreciation for certain assets placed in service after September 27, 2017 as well as prospective

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changes beginning in 2018, including limitations on the deductibility of interest and capitalization of research and development expenditures. We measure deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid. Accordingly, our deferred tax assets and liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate from 35% to 21%, resulting in a \$198,687 increase in tax expense for the period ended December 31, 2017 and a corresponding \$198,687 decrease in net deferred tax assets as of December 31, 2017. The impact was offset by our valuation allowance.

#### **Recent Accounting Pronouncements**

See Note 2 to our financial statements included elsewhere in this prospectus for information concerning recent accounting pronouncements.

# **Quantitative and Qualitative Disclosures About Market Risk**

Our cash and cash equivalents and short-term investments as of June 30, 2018 consisted of cash and money market funds. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation.

Our convertible promissory notes bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates.

## Internal Control Over Financial Reporting

Pursuant to Section 404(a) of the Sarbanes-Oxley Act of 2002, as amended, commencing the year following our first annual report required to be filed with the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff, as well as potentially upgrade our information technology systems.

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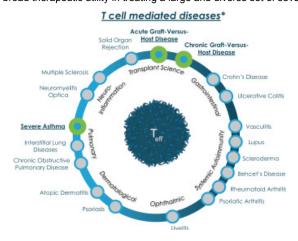
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## **BUSINESS**

#### Overview

We are a biotechnology company leveraging deep understanding of immunobiology to develop products for severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our initial product candidate, EQ001 (itolizumab), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of effector T cells, or Teff cells. Activated Teff cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe EQ001 may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.



\* We are focusing our initial development efforts on EQ001 for the treatment of the diseases underlined in bold and are evaluating additional T cell driven indications for future development.

Our pipeline is focused on developing EQ001 as a potentially best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. We plan to initiate a Phase 1b/2 clinical trial of EQ001 for the treatment of acute graft-versus-host disease, or aGVHD, in early 2019, and expect top-line data from the Phase 1b part of this trial within 12 months of initiation. Our Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for aGVHD was accepted in July 2018. Additionally, in the first half of 2019, we plan to commence a Phase 2 clinical trial of EQ001 for the treatment of chronic graft-versus-host disease, or cGVHD, initiate a proof-of-concept clinical trial for the treatment of severe asthma and select one or more additional indications for future development. The following chart summarizes our initial development plans for EQ001.

equillum EQ001					
Therapeutic Area	Indication	Phase 1*	Phase 1b / 2	Phase 3	Expected Milestones
Transplant	aGVHD		IND open		Phase 1b/2 aGVHD trial to initiate early 2019
Science	cGVHD				Phase 2 cGVHD trial to initiate H1 2019
Pulmonary	severe asthma				severe asthma proof-of-concept trial to initiate H1 2019

\* The Phase 1 clinical trial was conducted by Biocon, our collaboration partner, in Australia.

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We have an ongoing translational biology program to assess the therapeutic utility of EQ001 in additional indications where the CD6 pathway and activated  $T_{\text{eff}}$  cells play an important role in the pathogenesis of T cell mediated diseases. Our selection of additional indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing EQ001 into further development.

We acquired U.S. and Canadian rights to itolizumab in May 2017, pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon). Following completion of a Phase 3 clinical trial conducted outside of North America, itolizumab was approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon as ALZUMAb. Today, India is the only jurisdiction where ALZUMAb is approved or marketed. EQ001 has been evaluated in one Phase 1 clinical trial to date, conducted by Biocon, and is not approved for commercial sale in the United States or Canada. Our partnership with Biocon includes an exclusive supply agreement for clinical and commercial drug product of EQ001. Biocon currently manufactures EQ001 at commercial scale in a facility regulated by the FDA.

We have assembled an accomplished team that includes veterans in drug discovery, development and commercialization. Notably, our Chief Executive Officer is Daniel Bradbury, who has over 30 years of experience bringing novel medicines to market. Mr. Bradbury was the President, Chief Executive Officer and Director of Amylin Pharmaceuticals, Inc., where during his 18 year tenure he oversaw the development and launch of three first-in-class medicines, which ultimately led to the acquisition of Amylin Pharmaceuticals, Inc. by Bristol-Myers Squibb.

#### Strategy

Our goal is to become a leading, fully-integrated biotechnology company focused on therapies for severe immuno-inflammatory disorders. To achieve our goal, we intend to:

- Advance EQ001 through clinical development for aGVHD and cGVHD. Based on our deep and proprietary understanding of the CD6 pathway, our translational research, and prior clinical studies targeting CD6, we are initially focused on aGVHD and cGVHD as our initial indications for the clinical development of EQ001. We plan to initiate a Phase 1b/2 clinical trial of EQ001 as a front-line therapy concomitant with steroids in patients with aGVHD in early 2019 and expect top-line data from the Phase 1b part of this trial within 12 months of initiation. In this trial we will assess safety, overall response rate, survival, steroid taper and incidence of cGVHD. In addition, we plan to initiate a Phase 2 clinical trial of EQ001 in patients with cGVHD in the first half of 2019.
- **Develop EQ001 for the treatment of severe asthma.** We believe that the unique mechanism of action of EQ001 has the potential to treat severe asthma patients characterized by an immunophenotype of low T<sub>h</sub>2 and high T<sub>h</sub>17 and who consequently have a poor response to high dose inhaled and/or oral steroids. There are a sizeable number of these patients who are underserved by currently available therapies and for which there are no FDA-approved biologic or other targeted treatments. We plan to initiate a proof-of-concept clinical trial of EQ001 in patients with severe asthma in the first half of 2019.
- Expand clinical development of EQ001 into additional indications based on our translational biology program. We will continue to conduct studies in animal models and human tissue, as well as EQ001 clinical trials, to help inform the selection of additional indications for further development. In the first half of 2019, we intend to select a fourth indication for future EQ001 development.
- Opportunistically expand our pipeline of product candidates. We will leverage the collective talent within our organization to opportunistically acquire or in-license other high-value therapeutic programs that may complement our core strategy or have the potential for synergistic therapeutic benefit in combination with EQ001.
- Build a commercial infrastructure. If approved, we intend to commercialize EQ001 ourselves in indications that can be efficiently
  targeted using a specialty sales force, such as aGVHD and cGVHD. For other indications, we intend to commercialize EQ001 either
  independently or through collaborations with other parties.

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## Understanding the Basis of Our Approach: The Role of CD6 in Autoimmunity

The role of the immune system is to defend the body against foreign organisms and cells, including cancerous cells, and in doing so must distinguish accurately between self- and non-self entities, a process called tolerance. Autoimmunity is an immune response directed against the body's own healthy cells and tissues, and is the underlying process in many inflammatory diseases. Autoimmunity results from a loss of tolerance caused in part by an imbalance in the relationship between Teff and regulatory T cells, or Treq cells, see **Figure 1**.

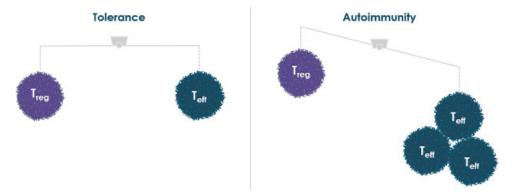


Figure 1: Autoimmunity is a balancing act. T<sub>reg</sub> cells play an important role in preventing T<sub>eff</sub> cells targeting of self-antigens that can lead to autoimmunity and tissue destruction

Immune checkpoints are critical regulators of immune activation pathways and can be either co-stimulatory (activating) or co-inhibitory (inhibiting). These pathways are crucial for maintaining immune balance and preventing autoimmunity. Immune checkpoints have been targeted for the treatment of cancers, where blockade of co-inhibitory signals results in an increased immune response against tumor cells, and such approaches have resulted in the approval of several novel therapeutics. We believe co-stimulatory checkpoints are attractive drug targets for the treatment of immuno-inflammatory diseases and more recently they have become a focus of development in immuno-inflammation. However, identifying checkpoints that allow for the selective modulation of T<sub>eff</sub> cell activity while preserving T<sub>reg</sub> cell activity in order to promote tolerance has proven challenging.

CD6 is a novel, tightly-regulated, co-stimulatory receptor that plays an integral role in modulating T cell activation, proliferation, differentiation and trafficking. CD6 serves as a key checkpoint in regulating  $T_{\rm eff}$  cells that are central to autoimmune responses. Preclinical and clinical studies have shown that blockade of CD6 co-stimulation leads to selective inhibition of pathogenic  $T_{\rm eff}$  cell activity and trafficking, while preserving the important regulatory function of  $T_{\rm reg}$  cells. Such studies and new insights into the underlying biology highlight CD6 as a resurgent target for the treatment of multiple immuno-inflammatory diseases.

CD6 is predominantly expressed on T helper cells, or  $T_h$  cells, and regulates T cell responses. Once activated, naïve  $T_h$  cells become  $T_{eff}$  cells and carry out specialized immune functions depending on their specific phenotype such as  $T_h1$ ,  $T_h2$  and  $T_h17$  cells. The expression levels of CD6 are increased on  $T_{eff}$  cells and are associated with autoreactivity in cells, leading to autoimmunity. Conversely, the lack of expression of CD6 on  $T_{reg}$  cells suggests that CD6 is not required for their regulatory function. See **Figure 2**.

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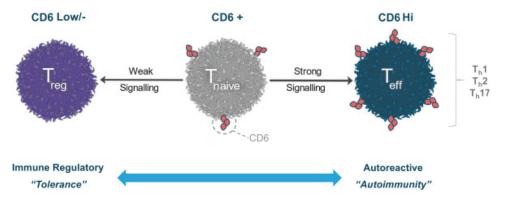


Figure 2: CD6, a novel, tightly-regulated, co-stimulatory checkpoint central to autoimmunity. The expression levels of CD6 are increased on T<sub>eff</sub> cells such as T<sub>h</sub>1, T<sub>h</sub>2 and T<sub>h</sub>17 cells and are associated with autoreactivity. Conversely, the lack of expression of CD6 on T<sub>reg</sub> cells suggests that CD6 is not required for their regulatory function.

Activated leukocyte cell adhesion molecule, or ALCAM, is a ligand of CD6 that is expressed on hematopoietic tissues such as antigen-presenting cells, where it is important for immune synapse formation and optimal co-stimulation. Binding of ALCAM to domain-3 of CD6 leads to the downstream activation of several mitogen activated protein kinase, or MAPK, pathways related to T cell activation, proliferation, differentiation and survival. See **Figure 3**.

Studies have shown that co-stimulation of CD6 by ALCAM enhances T cell activation and resulted in a five-fold increase in IL-2 receptor mediated  $T_{\text{eff}}$  cell proliferation. Moreover, CD6 co-stimulation promotes a preferentially pro-inflammatory response and increased secretion of  $T_{\text{eff}}$  cytokines IFN- $\gamma$ , TNF- $\alpha$  and IL-6 . Additionally, CD6 co-stimulation leads to increased expression and activation of validated targets for the treatment of immuno-inflammatory disease, including signal transducer and activator of transcription 3, or STAT3, and retinoid acid-related orphan receptor, or ROR $\gamma$ t, the master transcriptional regulator of  $T_{h}17$  cells. This results in increased expression of IL-23R and high levels of IL-17, both markers of pathogenic  $T_{h}17$  cell activity and resistance to steroid treatment, which is a first-line therapy in many immuno-inflammatory diseases.  $T_{h}17$  cells play an especially important role in autoimmunity:  $T_{h}17$  and  $T_{reg}$  cells are reciprocally regulated and thus an increase in  $T_{h}17$  cells and associated cytokines leads to suppression of  $T_{reg}$  cell activity and loss of tolerance. Studies have shown that co-stimulation through CD6 is superior to CD28 co-stimulation in driving  $T_{h}17$  cell development and thus represents an attractive target for the treatment of immuno-inflammatory diseases, especially those resistant or refractory to steroid treatment.

ALCAM is also expressed on non-hematopoietic tissues such as the vascular endothelium, blood-brain barrier, skin, lung and gut, where it selectively facilitates the trafficking of T cells expressing CD6. Studies have shown that, in the presence of the pro-inflammatory cytokine IFN- $\gamma$ , the expression of ALCAM is increased on a number of cell types, suggesting an important dual role for CD6 and ALCAM in autoimmune responses.

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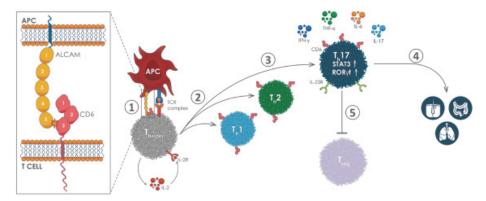


Figure 3: CD6 co-stimulation drives pathogenic T cell development and activity. (1) Co-stimulation occurs through the binding of ALCAM to domain-3 of CD6, (2) leading to synergistic activation resulting in a five-fold increase in IL-2 receptor mediated T<sub>eff</sub> cell proliferation. (3) Co-stimulation through CD6 promotes a pro-inflammatory response including the activation of pSTAT3 and ROYa resulting in increased expression of IL-23R and pathogenic secretion of several pro-inflammatory cytokines. (4) ALCAM expressed on tissues such as the skin, lung and gut, selectively facilitates the trafficking of T cells expressing CD6. (5) T<sub>h</sub>17 cells and associated cytokines suppress T<sub>reg</sub> cell activity leading to a high T<sub>h</sub>17:T<sub>reg</sub> ratio.

## Modulation of Teff Cell Activity with EQ001

EQ001 is a humanized antibody that selectively binds to human CD6 and inhibits the interaction of CD6 with its ligand ALCAM, preventing co-stimulation, and thereby reducing  $T_{eff}$  cell activity and trafficking. Preclinical studies of EQ001 have shown that blockade of CD6 leads to a reduction in  $T_{eff}$  cell proliferation and downregulation of several important pathways that contribute to  $T_{eff}$  cell development. Critically, CD6 blockade leads to the downregulation of important cellular pathways that control inflammation, including STAT3 and ROR $\gamma$ t. The downregulation of these pathways is accompanied by decreased secretion of the pro-inflammatory  $T_{eff}$  cytokines IFN- $\gamma$ , TNF- $\alpha$ , IL-6 and IL-17. See **Figure 4**.

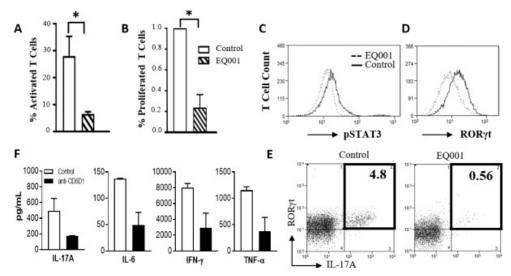


Figure 4: Blockade of CD6 reduces T cell activation, proliferation and differentiation. (A-C) Human peripheral blood mononuclear cells, or PBMC, were stimulated in Th17 polarizing conditions in the presence of EQ001 or a control antibody. On Day 3 post-stimulation, EQ001 reduced the percentage of activated T cells, shown in panel A, and the percentage of proliferating T cells, shown

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in panel B. EQ001 also reduced levels of pSTAT3, a Th17 signature transcription factor, shown in panel C. (D and E) PBMC cells were re-stimulated with PMA-Ionomycin for five hours and analyzed for expression of intracellular cytokine IL-17A and another Th17 signature transcription factor RORγt. Day 6 representative histogram of RORγt is shown in panel D and the corresponding dot plots of RORγt and IL-17A gated on lymphocyte scatter and CD3 expressing T cells are shown in panel E. (F) Splenocytes were isolated from mice treated with anti-CD6D1, a mouse surrogate anti-CD6 antibody, or a control antibody and stimulated ex vivo. Anti-CD6D1 treatment resulted in a substantially reduced response to stimulation and the splenocytes secreted lower levels of pro-inflammatory T cell cytokines IL-17A, IL-6, IFN-γ and TNF-α, shown in panel F. \*p<0.05.

Additionally, inhibiting the binding of ALCAM to CD6, either by anti-CD6 monoclonal antibodies or by deletion of the gene expressing CD6, modulates lymphocyte trafficking and results in reduced T<sub>eff</sub> cell infiltration into inflamed tissues. Based on its broad multi-modal mechanism, we believe EQ001 has the potential to treat multiple immuno-inflammatory diseases including those that are resistant or refractory to existing therapies. See **Figure 5**.

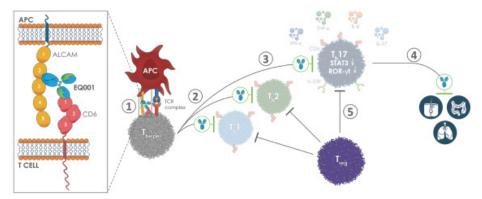


Figure 5: Blockade of CD6 by EQ001 inhibits T<sub>eff</sub> cell activation, proliferation, differentiation and trafficking. (1) EQ001 selectively binds to domain-1 of CD6 and inhibits the interaction of ALCAM, preventing co-stimulation (2) and thereby reducing T<sub>eff</sub> cell proliferation. (3) Blockade of CD6 downregulates pSTAT and RORγt resulting in reduced expression of IL-23R and secretion of pro-inflammatory T<sub>eff</sub> cytokines IFN-γ, TNF-α, IL-6 and IL-17. (4) Additionally, inhibiting the binding of ALCAM to CD6, reduces lymphocyte trafficking into inflamed tissues. (5) Reduction of T<sub>reg</sub> cells inhibiting T<sub>h</sub>17 cells restores immune balance and promotes tolerance.

# **Experimental Evidence for Targeting CD6 in Immuno-Inflammation**

We are leveraging our deep understanding of immunobiology and translational biology program to assess the importance of CD6 in disease pathogenesis and therapeutic utility of CD6 blockade using well-characterized model systems and human tissues. As a leader in the field of CD6 immunobiology, our objective is to inform selection of indications in specific disease areas that are likely to respond to CD6 targeting by EQ001.

The role of CD6 in pathogenic T<sub>eff</sub> cell development has been independently validated *in vivo* both genetically and pharmacologically in experimental models of immuno-inflammation, as summarized in **Table 1**.

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Table 1: Published, independent studies supporting the role of CD6 in immuno-inflammatory diseases.

ANIMAL MODEL/INDICATIONS	METHOD	RESULTS & CONCLUSIONS
Experimental Autoimmune Uveitis	CD6-/- mouse†	<ul> <li>Decreased retinal inflammation (80% reduction in the mean histopathological scores)*</li> <li>Decreased autoreactive T cell responses (&gt;70% reduction in T<sub>h</sub>1 and T<sub>h</sub>17 cytokine production)*</li> </ul>
Zhang et al. 2018 —  Journal of Autoimmunity	Mouse anti-CD6D1**	<ul> <li>Decreased retinal inflammation (80% reduction in the mean histopathological scores)*</li> <li>Decreased T cell infiltration in the eyes (79% reduction in infiltrating T cell numbers)*</li> </ul>
Experimental OVA-induced Asthma  Kim et al. 2018	ALCAM-/- mouse†	■ Decreased pro-inflammatory T <sub>h</sub> 2 cell responses* ■ Decreased T cell trafficking into the lung
The Journal of Translational Immunology	Mouse anti-CD6D1**	■ Decreased T cell proliferation*
Experimental Autoimmune Encephalomyelitis  Multiple Sclerosis, Neuromyelitis Optica, Acute Disseminated Encephalomyelitis	CD6-/- mouse†	<ul> <li>Decreased clinical disease scores*</li> <li>Decreased pathogenic T cell responses (significant reduction in T<sub>h</sub>1 and T<sub>h</sub>17 cytokine production)*</li> <li>Blocked pathogenic T cell infiltration into the CNS</li> </ul>
Li et al. 2017  Proceedings of the National Academy of Sciences	Mouse anti-CD6D1**	■ Decreased clinical disease scores* ■ Decreased T <sub>h</sub> 1 and T <sub>h</sub> 17 cell responses* ■ Decreased inflammation and demyelination in the CNS
Imiquimod-induced Psoriasis  Consuegra-Fernandez et al. 2017  Cellular and Molecular Immunology	CD6-/- mouse†	<ul> <li>Decreased skin inflammation (epidermal thickness)*</li> <li>Decreased pro-inflammatory cytokines*</li> <li>Decreased Th17 cell differentiation in vitro*</li> </ul>
Experimental OVA-induced Allergy  Kim et al., 2018	ALCAM-/-	■ Decreased pro-inflammatory T <sub>h</sub> 2 cell responses* ■ Decreased disturbance of intestinal tissue ■ Decreased T <sub>h</sub> 2 cytokines (IL-4, IL-5 and IL-13)
Clinical & Experimental Immunology	anti-mouse CD6	■ Decreased T cell proliferation*

CD6-/- is a mouse with a homozygous null gene deletion of CD6. ALCAM -/- is a mouse with a homozygous null gene deletion of ALCAM. Represents a statistically significant result (p<0.05). Mouse surrogate anti-CD6 antibody.

In addition to these published studies, we have demonstrated the activity of EQ001 (or anti-CD6D1, its mouse surrogate anti-CD6 antibody) in a number of disease models. Described below are findings from studies in models of several key immuno-inflammatory disease areas, including GVHD, inflammatory bowel disease and neuroinflammation, which illustrate blockade of CD6 inhibiting pathogenic T cell activity. We believe the results of these published studies and our internal translational program support our approach in targeting CD6 in the treatment of immunoinflammation.

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Treatment with EQ001 Attenuates GVHD

GVHD is a multisystem disease commonly associated with hematopoietic stem cell transplants in which transplanted donor lymphocytes attack host tissues. GVHD is predominantly driven by T cells that express high levels of CD6. Prior clinical studies have implicated cells expressing CD6 in the development of GVHD, suggesting that CD6 is a highly relevant target to this disease.

The Hu-PBMC-NSG model is a humanized xenograft mouse model of GVHD generated by injection of human peripheral blood mononuclear cells, or Hu-PBMC, into an NSG mouse, which is an immunodeficient mouse. In this well-characterized, gold standard model, disease is aggressively driven by a human T cell response against host tissue. The severity of disease is assessed by survival, weight loss, prevalence of human cells in peripheral blood and trafficking of human cells into tissues. EQ001 can be assessed in this model because human T cells are present. In the model, we tested a high dose of EQ001 (300µg/dose), a low dose of EQ001 (60µg), and as comparator controls, two CTLA4-lg based modulators of CD28 co-stimulation, Nulojix (belatacept) and Orencia (abatacept), which are both FDA-approved drugs that also target activated Teff cells.

Treatment with both high and low dose EQ001 resulted in no deaths by Day 35 compared to the 90% mortality seen in vehicle treated control animals. See **Figure 6.** This is a direct result of inhibition of human T cell proliferation and infiltration into tissues. Animals treated with EQ001 demonstrated a profound reduction in human T cells at Days 10 and 35 with a prevalence of 0.2% (both days), whereas vehicle treated animals exhibit a prevalence of 17.5% human T cells by Day 10. The ability of EQ001 to prevent T cell establishment compared highly favorably to both Nulojix and Orencia.

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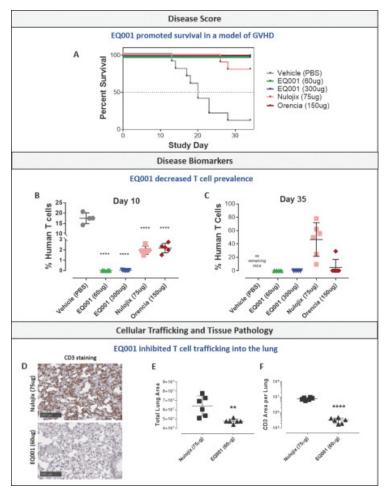


Figure 6: Treatment with EQ001 attenuates GVHD. (A) Kaplan-Meier survival curve of mice treated with either EQ001, Nulojix, Orencia or vehicle prior to injection with human PBMCs. Mice treated with EQ001 experienced 100% survival. (B and C) Proportion of human T cells detected in the periphery was statistically significantly lower in Hu-NSG-PBMC mice treated with EQ001 vs. vehicle control at Day 10 (B) and remains low at Day 35 (C). (E and F) CD3 staining in lung tissue shows infiltration of T cells. No statistically significant presence of T cells was detected in the lungs of mice treated with EQ001. \*\*\*\*p<0.0001 and \*\*p<0.01.

#### Treatment with Anti-CD6 Antibody Inhibits Inflammatory Bowel Disease

Inflammatory bowel disease, or IBD, such as Crohn's disease and ulcerative colitis, is characterized by chronic inflammation resulting from persistent activation of immune cells in the gut. Activated  $T_{\text{eff}}$  cells, such as  $T_h17$ , which express CD6, are associated with IBD and its severity. Data from human genetic studies have demonstrated an association between CD6 and the development and severity of IBD. Inhibition of  $T_{\text{eff}}$  cells, such as  $T_h17$  cells, have been shown to reduce IBD disease severity and progression, confirming the relevance of the CD6 pathway in this disease.

The 2,4,6-trinitrobenzenesulfonic acid, or TNBS, model is a standard model of IBD that is driven by  $T_h1$  and  $T_h17$  cell responses. Exposure to TNBS leads to inflammation, diarrhea, tissue destruction and shortening of the colon. In

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this model, we tested blockade of CD6 using anti-CD6D1, which binds to the same CD6 domain-1 in mice that EQ001 binds on human CD6. As comparator controls, separate groups of mice were treated with either anti-IL-12p40 (a therapeutic mechanism of action similar to Stelara, an FDA-approved therapy for Crohn's disease), dexamethasone or vehicle. Blockade of CD6 inhibits the TNBS-induced immune response as exhibited by decreases in serum and tissue pro-inflammatory cytokines, see **Figure 7**. This is accompanied by statistically significant decreases in inflammation-mediated colon shrinkage, histological measures of necrosis, edema and mucosal inflammation, and diarrhea/loose stool. The results of anti-CD6D1 treatment were comparable to high dose anti-IL-12p40 treatment, another inhibitor of the Th1 and Th17 cell pathways. Results of this model are relevant not only to IBD but also other immuno-inflammatory gut conditions, including GVHD.

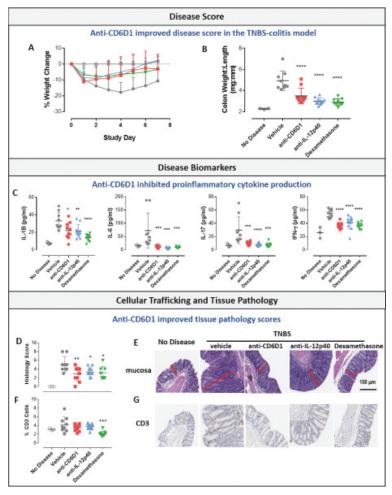


Figure 7: Treatment with anti-CD6D1 inhibits inflammatory bowel disease. (A and B) Anti-CD6D1 treatment decreased disease scores as measured by (A) a reduction in body weight loss and (B) the statistically significant reduction of colon weight to length ratio compared to vehicle control. (C) CD6 blockade decreased serum pro-inflammatory cytokines. (D and E) Tissue pathology scores were statistically significantly improved by anti-CD6D1 treatment. Red line denotes width of colon mucosa, delineating mucosal hyperplasia (tissue thickening). Hyperplasia was greatest in vehicle animals and was reduced in anti-CD6D1, anti-IL-12p40 and dexamethasone treated animals. (F and G) Anti-CD6D1 treatment reduced trafficking of T cells into the colon, as demonstrated by CD3, a pan T cell marker.

\*\*\*\*Pc0.0001, \*\*\*pc0.001, \*\*pc0.01 and \*pc0.05.

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## Treatment with Anti-CD6 Antibody Reduces Neuroinflammation

CD6 is overexpressed on activated  $T_h17$  cells isolated from multiple sclerosis patients and has been implicated in the pathogenesis of neuroinflammation. On the vascular endothelium of the blood-brain-barrier, ALCAM is upregulated by IFN- $\gamma$ , providing a potential mechanism for the entry of T cells expressing CD6 into the central nervous system, or CNS. Increased levels of CD6 are correlated to increased infiltration of  $T_{eff}$  cells into the CNS and the development of neuroinflammation.

Experimental autoimmune encephalomyelitis, or EAE, is a well-established mouse model of neuroinflammation that is commonly used to study disorders such as multiple sclerosis and neuromyelitis optica. In this model, an autoimmune response leads to T cell infiltration across the blood-brain barrier and into the tissues of the CNS (including spinal cord and optic nerve). Mice with EAE exhibit muscle weakness progressing to paralysis due to increasing neuronal damage. Blockade of CD6 by anti-CD6D1 results in reduced disease severity as demonstrated by statistically significant improvements in disease model scores (i.e., less weakness and paralysis), decreased autoimmune T cell activity and decreased T cell trafficking, resulting in decreased demyelination of the spinal cord, see **Figure 8**.

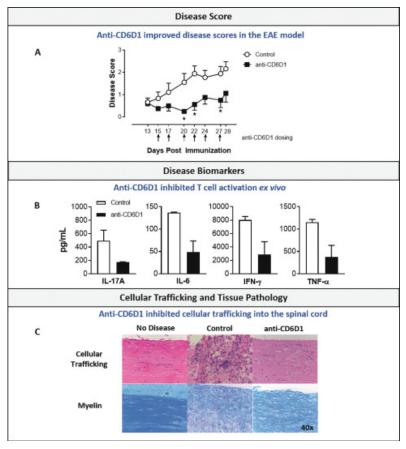


Figure 8: Treatment with anti-CD6D1 attenuates neuroinflammation. (A) Antagonism of the CD6 pathway during EAE induction results in statistically significant decreases in disease model scores. (B) Isolated T cells stimulated *ex vivo* exhibit a substantially reduced response to stimulation, secreting lower levels of important T cell cytokines IL-17A, IL-6, IFN-γ, and TNF-α. (C) Amelioration of EAE

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is supported by decreased cellular trafficking into the spinal cord and reduced demyelination. Anti-CD6D1 treated animals appear similar to normal, disease-free animals. \*p<0.01.

## Itolizumab: Clinically Validated in the Treatment of Immuno-Inflammatory Diseases

Itolizumab has shown activity in clinical trials in patients with rheumatoid arthritis and psoriasis. Itolizumab has been approved for the treatment of moderate to severe plaque psoriasis in India and is marketed by Biocon under the brand name ALZUMAb.

Psoriasis is a chronic immuno-inflammatory disease characterized by inflammation and aberrant hyperproliferation of keratinocytes. The pathogenesis of psoriasis is complex and numerous components of the immune system play a role, including T<sub>h</sub>17 cells and associated cytokines, most notably IL-17.

Biocon has completed three clinical studies of ALZUMAb in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb at dose levels ranging from 0.2 mg/kg to 1.6 mg/kg. An overview of these clinical studies is presented in Table 2

Table 2: Overview of the Biocon clinical development program of itolizumab

PHASE 2	STUDY NUMBER	NUMBER OF PATIENTS	DOSE LEVELS (MG/KG)	DURATION (WEEKS)	INDICATION
2	CLG007/BIO004/ RA/CD6/2006	70	0.2, 0.4, and 0.8	12	Rheumatoid arthritis
2	T1hAb-CT1-001-07	40	0.4, 0.8, and 1.6	8	Chronic plaque psoriasis
3	T1hAb-CT3-002-09 (TREAT- PLAQ)	223	0.4 and 1.6	52	Chronic plaque psoriasis

In addition to the clinical trials described above, 35 patients have received itolizumab in prior clinical trials conducted in Cuba for the treatment of rheumatoid arthritis.

The Phase 3 TREAT-PLAQ trial was a randomized, double-blind, placebo controlled, multi-arm, multi-dose, one-way crossover design studying 223 psoriasis patients. Results from this trial demonstrated that ALZUMAb had a favorable safety and tolerability profile and durable efficacy as measured by psoriasis area and severity index, or PASI. The primary end point was the proportion of patients with at least 75% improvement in PASI score, or PASI 75, at Week 12.

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In Arm A patients received ALZUMAb at 0.4 mg/kg weekly for the first four weeks, then 1.6 mg/kg every two weeks until Week 12; in Arm B patients received ALZUMAb at 1.6 mg/kg every two weeks until Week 12. At Week 12 only 2.3% of patients receiving placebo achieved PASI 75 compared to 27.0% and 36.4% of patients achieving PASI 75 by Week 12 in Arms A (p value = 0.0172) and B (p value = 0.0043), respectively. At Week 12, patients in the placebo arm crossed over to treatment with ALZUMAb. Following Week 28, patients that responded to ALZUMAb (those that reached PASI 75) were re-randomized to one of two groups, either cessation of drug (n =40) or maintenance therapy (n = 39, with 1.6mg/kg of drug given every 3 weeks). Prior ALZUMAb treatment produced a durable effect in patients that were no longer given drug, with 53% of patients maintaining PASI 75 and 75% at PASI 50. 67% of patients that continued ALZUMAb treatment had maintained PASI 75 scores, while 85% maintained PASI 50. Histologically, skin biopsy data show that treatment with ALZUMAb statistically significantly reduces the trafficking of T cells in to the dermis and this is consistent with observed reduced severity of disease and therapeutic mechanism. See **Figure 9**.

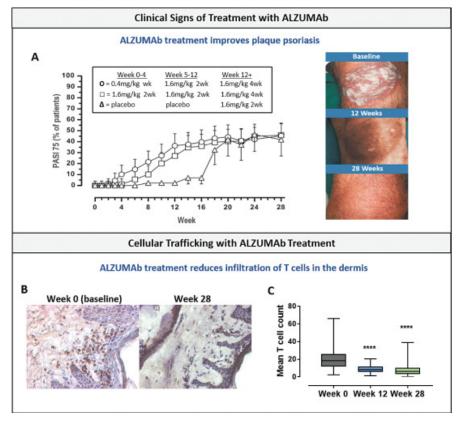


Figure 9: ALZUMAb, an approved treatment for psoriasis in India. (A) The proportion of patients who achieved a PASI 75 response at each visit until Week 28. (B) Treatment with ALZUMAb statistically significantly reduces the trafficking of T cells into the dermis. Compared to Visit 1, at Visit 16 there were statistically significantly fewer T cells in the dermis, as shown by CD3 labeling, a pan T cell marker. (C) Histogram shows the mean T cell count in the dermis was statistically significantly reduced in Week 12 and Week 28, compared to Week 0, which was consistent with the observed reduced severity of disease. \*\*\*\*\*p<0.0001.

The underlying pathophysiology of different immuno-inflammatory diseases can vary substantially, and therefore drugs that operate by different mechanisms can demonstrate diverging levels of efficacy in each condition. For example, the PASI 75 scores achieved at three months by subjects treated with ALZUMAb (36%) in its pivotal trial

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in psoriasis were in line with Enbrel (46-47%), an effective psoriasis drug, but they were less than the newly approved anti-IL-17 agents such as Cosentyx (66-82%). We believe the explanation for this result is that while Th17 cells play a role in psoriasis, there are also non-T cell mediators that contribute to disease pathogenesis, suggesting that psoriasis may not be an ideal indication for this therapeutic approach. Based on published clinical trial data from multiple studies that were not conducted on a head-to-head basis, it appears that ALZUMAb has demonstrated superior PASI 75 scores in psoriasis compared to modulation of CD28 co-stimulation using Orencia (16.4%), which is approved for the treatment of psoriatic and rheumatoid arthritis. Also, a recent meta-analysis comparing efficacy across trials indicated that Orencia demonstrated superior efficacy in ACR 50 scores, a common clinical test for determining improvement in a person's rheumatoid arthritis, than Cosentyx in certain populations of psoriatic arthritis patients. These observations illustrate the importance of matching disease pathology and therapeutic mechanism in order to optimize therapeutic benefit.

ALZUMAb was well tolerated by the patients in the Phase 3 TREAT-PLAQ trial, with infusion reactions and related events, which are expected for an antibody infusion, as the main adverse events, or AEs, attributed to ALZUMAb. The incidence of infusion reactions dropped sharply after the first few infusions. ALZUMAb did not appear to increase the rate of infections compared to placebo, and the incidence of severe adverse events, or SAEs, was low (a total of five SAEs were reported). SAEs included exfoliative dermatitis (widespread redness and peeling of the skin), erythrodermic (severe) psoriasis, infusion-related reaction, adjustment disorder with anxiety, and bacterial arthritis. No SAEs led to discontinuation or reduction of drug dosage. See **Table 3** for a summary of adverse events seen during the Phase 3 trial.

Table 3. Adverse events that occurred in >5% of subjects in either ALZUMAb treatment arm, placebo arm, or overall in the trial.

Weeks 1-12	ALZUMAb (n = 180) n(%)	Placebo (n = 43) n(%)	
Any Adverse Event	72 (40.0%)	20 (46.5%)	
Infusion Reaction (acute)	33 (18.3%)	1 (2.3%)	
Infection	6 (3.3%)	4 (9.3%)	
Pruritus (itching)	5 (2.8%)	3 (7.0%)	
Weeks 13-52	(n =	JMAb 223) %)	
Any Adverse Event		19.8%)	
Infusion Reaction (acute)	38 (17.0%)		
Pyrexia (fever)	19 (8.5%)		
Infection	17 (7.6%)		
Pruritus	12 (5.4%)		

An examination of lymphocyte counts in the study noted a mild decrease in the mean absolute lymphocyte count, or ALC, in the two ALZUMAb treatment arms at the initiation of treatment during the placebo controlled portion of the study (weeks 1-12). No further decrease was observed after the first dose. See **Figure 10**. These observed changes were not associated with an increase in secondary infection.

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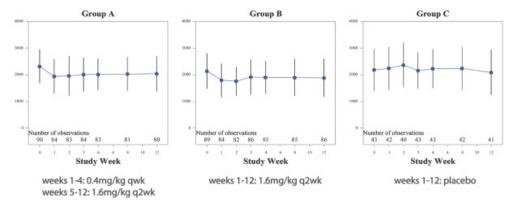
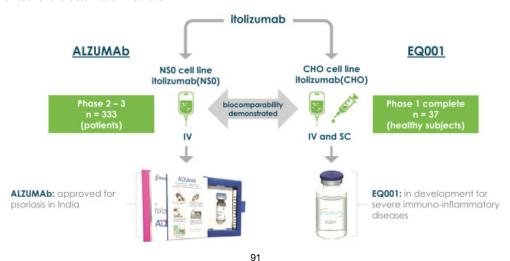


Figure 10: Lymphocyte counts in the peripheral blood of psoriasis patients during treatment with ALZUMAb. Graphs depict mean ALC (+/- standard deviation) of each treatment group during the first 12 weeks following initiation of treatment. The treatment regimen of each group is specified beneath the respective graph. Groups A and B, which received ALZUMAb, exhibited a modest decrease in ALC after the first dose but not subsequent doses.

Since approval and as of the current cut-off date of August 10, 2017 for the most recent Periodic Safety Update Report, ALZUMAb has accrued approximately 275 patient-years of use. Post-market safety surveillance has demonstrated 27 AE reports in that time period, of which four have been noted as serious, including infusion reaction, type 1 hypersensitivity, diarrhea and urticaria. The overall safety profile is favorable and has remained largely unchanged from the time of approval.

# **EQ001 Product Development**

ALZUMAb is produced in an NS0 cell line and is currently available only in an intravenous, or IV, formulation. EQ001 contains the identical monoclonal antibody sequence produced in a Chinese hamster ovary, or CHO, cell line and is available in IV and subcutaneous injection, or SC, formulations. CHO cell lines are the industry-standard antibody therapeutic production system. EQ001 is manufactured by Biocon at commercial scale in an FDA regulated manufacturing facility. We have received a "study may proceed" letter from the FDA in response to our IND submission, which contained data from Biocon demonstrating biocomparability of EQ001 and ALZUMAb using industry-standard physicochemical and biofunctional characterization methods.



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## **EQ001 Phase 1 Clinical Trial in Healthy Subjects**

Biocon conducted a Phase 1 clinical trial of EQ001 in 37 healthy subjects that was completed in Australia in the fourth quarter of 2017. The study was conducted in two stages, with the first stage designed to assess the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and immunogenicity of ascending single doses of EQ001 SC, and the second stage designed to compare the PK of EQ001 IV to ALZUMAb and determine the absolute bioavailability of EQ001 SC.

Stage 1 was a randomized, double-blind, placebo controlled, ascending single dose evaluation of EQ001 SC. Thirty-two subjects completed Stage 1: 24 subjects (six per cohort) were administered EQ001 SC in single doses of 0.8 mg/kg, 1.6mg/kg, 2.4 mg/kg, or 3.2 mg/kg, and eight subjects were administered placebo. Serum concentrations of EQ001 were measurable at Day 57, and the mean half-life ranged from 532 hours to 616 hours across dose cohorts. The PK for exposure following EQ001 SC administration were dose proportional, with the peak serum concentration generally achieved within 168 hours after dosing for most subjects. Saturation of CD6 receptors by EQ001 was seen at all dose levels. During Stage 1, a transient decrease in T cells expressing CD4, and to a lesser extent CD8, here observed, as well as a two- to three-times increase in the proportion of T<sub>reg</sub> cells.

The administration of single doses of EQ001 SC in Stage 1 was found to be well tolerated, with a low incidence (2/24) of low titer anti-drug antibodies. There were no SAEs, dose limiting toxicities, or DLTs, or study drug discontinuations reported. No clinically meaningful changes in physical examinations or vital signs was observed, whereas transient decreases in lymphocyte counts without clinical consequences were seen in 11/24 (46%) subjects. There were five subjects who experienced grade 3 treatment emergent adverse events, or TEAEs, of lymphocyte count decreases (two subjects each in the 1.6 mg/kg and 3.2 mg/kg dose cohorts and one subject in the 2.4 mg/kg dose cohort). Mild to moderate injection site reactions were observed in 15/24 (63%) of the patients. The other most common TEAEs with EQ001 SC were headache in 7/24 (29%), urticaria (hives) in 4/24 (17%), and pyrexia (fever) in 3/24 (13%) of the subjects. In general, observed AEs were transient, mild to moderate in severity, were not dose dependent, and most were consistent with those observed in prior clinical experience with ALZUMAb.

Stage 2 was a comparability study of the PK of EQ001 IV, and ALZUMAb, and the absolute bioavailability of EQ001 SC. The trial featured a randomized, single-blind, parallel group design for the comparability component, and an open-label design for the absolute bioavailability component. Seven subjects enrolled in the study and received single doses of 0.4 mg/kg (one subject each EQ001 SC, EQ001 IV, ALZUMAb, and placebo) and 0.8 mg/kg (one subject each EQ001 SC, EQ001 IV, and ALZUMAb); five subjects completed the study, and one subject each that received EQ001 IV and ALZUMAb in the 0.8 mg/kg group discontinued dosing early due to AEs (one subject experienced persistent cough and dizziness; one subject experienced nausea). The infusion of single doses of both EQ001 IV and ALZUMAb was associated with the development of transient, reversible, grade 2 to 3 decreases in lymphocyte counts in the healthy subjects. As a result, Stage 2 of the trial was terminated early following the enrollment of seven subjects, yielding limited overall safety data and insufficient PK data for evaluation. There were no SAEs reported. No other clinically meaningful abnormalities or trends were noted in clinical chemistry, hematology, and urinalysis parameters. Similar to Stage 1, a transient decrease in T cells expressing CD4, and to a lesser extent CD8, a two- to three-times increase in the proportion of T<sub>reg</sub> cells, and saturation of CD6 receptors were observed across EQ001 and ALZUMAb cohorts.

While similar decreases in lymphocyte counts have not been reported with ALZUMAb previously, the timing of hematologic assessments in prior clinical studies may not have occurred at sufficiently early time-points to detect this transient response. Additionally, ALZUMAb had previously only been dosed in patients with active autoimmune disease and not healthy subjects. Importantly, the magnitude and kinetics of lymphocyte decreases were similar for EQ001 IV and ALZUMAb in Stage 2, while administration of EQ001 SC demonstrated milder decreases in lymphocyte counts, which would be expected based on the different PK properties of SC versus IV formulations. Furthermore, ALZUMAb had been well tolerated with demonstrated safety and clinical activity in three clinical studies in India in patients with rheumatoid arthritis and chronic plaque psoriasis, with a total of 333 patients exposed to ALZUMAb to date in clinical trials at doses ranging from 0.2 mg/kg to 1.6 mg/kg over a period of four years. Therefore, we believe the transient decreases in lymphocyte counts seen in the Phase 1 clinical trial in healthy subjects represents a PD property of both EQ001 and ALZUMAb that will be monitored going forward, and the results of the Phase 1 clinical trial support the advancement of EQ001 SC and IV into further clinical development in patients with immuno-inflammatory disease.

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## **Our Planned Initial Clinical Indications**

We plan to initially develop EQ001 for the treatment of aGVHD, cGVHD, severe asthma and at least one additional indication. We expect to initiate a Phase 1b/2 clinical trial of EQ001 in patients with aGVHD in early 2019 and a Phase 2 clinical trial of EQ001 in patients with cGVHD in the first half of 2019. We also plan to initiate a proof-of-concept clinical trial in severe asthma in the first half of 2019. We continue to evaluate additional indications for future development and plan to select a fourth indication in the first half of 2019.

#### Graft-Versus-Host Disease Market Overview

aGVHD and cGVHD are multisystem disorders that are common complications of allogeneic hematopoietic stem cell transplants, or allo-HSCT, caused by the transplanted immune system recognizing and attacking the recipient's body. GVHD is the leading cause of non-relapse mortality in patients receiving an allo-HSCT. The risk of GVHD limits the number and type of patients receiving HSCT and we believe that a therapy that can attenuate GVHD risk could significantly expand the patient population eligible for allo-HSCT.

According to the Center for International Blood & Marrow Transplant Research, there were more than 8,500 allo-HSCT's performed in the United States in 2016 and the number of procedures has grown at an average annual growth rate of approximately 4% since 2007. Approximately 50% of HSCT recipients develop GVHD. HSCT recipients are at risk of developing either or both aGVHD and cGVHD with approximately 30-70% of HSCT recipients developing aGVHD, 50% of which will get cGVHD, and another 30-70% developing cGVHD independent of aGVHD. Five year survival for patients that respond to first-line treatment with corticosteroids has been reported to be as low as 53% while steroid refractory aGVHD mortality has been reported to be as high as 95%. Additionally, cGVHD is the leading cause of non-relapse mortality in patients surviving more than two years. We estimate that the incidence of aGVHD in 2018 is up to 5,000 patients and the total prevalence of GVHD could be up to 25,000 patients. We estimate that by the year 2025, the annual incidence of aGVHD will be up to 6,000 patients and the total prevalence of GVHD could be up to 35,000 patients.

#### Rationale for EQ001 for the Treatment of GVHD

#### Third-party clinical experience with targeting CD6 in GVHD

Clinical evidence to support the rationale of treating GVHD with EQ001 comes from previously-reported third-party clinical experience with CD6 expressing T cell depletion in patients receiving bone marrow transplants for hematologic malignancies where it has been demonstrated that using an anti-CD6 monoclonal antibody to deplete T cells from donor bone marrow or lymphocyte infusions has the potential to prevent aGVHD. In a study evaluating the clinical effects of selective *in vitro* CD6 expressing T cell depletion of donor allogeneic bone marrow using a monoclonal antibody to CD6 and rabbit complement, Soiffer et al. reported that *in vitro* T cell depletion with an anti-CD6 monoclonal antibody effectively reduced the incidence of both acute and chronic GVHD after allogeneic bone marrow transplant without compromising engraftment.

Subsequent studies further confirmed the feasibility of CD6 expressing T cell depletion in patients undergoing allogeneic bone marrow transplantation from human leukocyte antigen identical related and unrelated donors. In these studies, CD6 expressing depletion of the donor stem cell product was the sole method for GVHD prophylaxis. The low incidence of aGVHD reported in patients receiving allogeneic bone marrow treated with anti-CD6 monoclonal antibodies was attributed to the early appearance of a population of peripheral CD3 expressing T lymphocytes with a CD6-negative phenotype, which showed diminished reactivity to allogeneic stimulation in mixed lymphocyte reaction assays. Although the above described approach is one of ex vivo CD6 expressing T cell depletion, we believe that it further supports the role of CD6 expressing T cells in aGVHD pathogenesis and validates CD6 as a potentially important target for modulation for the treatment of GVHD.

#### EQ001 selectively targets GVHD pathogenesis

There is a high unmet medical need for a safe, effective and targeted treatment in GVHD. We believe EQ001 has the potential to be a best-in-class treatment for both aGVHD and cGVHD based on its ability to target the underlying biology of GVHD in a highly selective way.

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It is well established that Th17 cells, driven by pSTAT3 signaling, play a role in the pathogenesis of both aGVHD and cGVHD, and studies have shown that pSTAT3 was significantly increased in T cells of GVHD patients. In aGVHD, additional studies have reported that Th17 cells and IL-17 serum levels were significantly elevated in patients at onset compared with HSCT patients without aGVHD. As the disease progresses, Th17 cells traffic from the peripheral blood into GVHD target tissues where they trigger damage. Furthermore, the expansion of Th17 cells in the early phase of aGVHD plays a role in the transition to cGVHD. In GVHD patients, studies have shown a high Th17:Treg ratio suggesting a loss of tolerance. Notably the increased number of circulating Th17 cells was accompanied by a decrease in Treg cells, suggesting a loss of Teff cell regulation. Such regulatory mechanisms are crucial for eliminating alloreactive T cell activity, thus preventing sustained autoimmune responses and tissue destruction in GVHD.

We believe EQ001 can selectively target elements of the underlying pathogenesis of both aGVHD and cGVHD by: a) inhibiting  $T_{eff}$  cells proliferation; b) downregulating the STAT3 pathway associated with development of pathogenic  $T_h17$  cells driving GVHD pathogenesis; c) inhibiting trafficking of  $T_{eff}$  cells into GVHD target tissues preventing further inflammation and organ damage; and d) reducing the  $T_h17:T_{reg}$  ratio associated with the development of GVHD and thereby promoting tolerance.

# Development Plan in GVHD

We plan to initiate a Phase 1b/2 multicenter clinical trial in approximately 84 patients in order to evaluate the safety, tolerability, PK and clinical activity of EQ001 IV in newly diagnosed aGVHD patients in early 2019 and expect top-line data from the Phase 1b part of the trial within 12 months of initiation. All patients will be administered EQ001 as a front-line therapy concomitant with steroid use upon first presentation of aGVHD.

The Phase 1b part of the trial will be an open-label, cohort based, dose escalation study that will enroll up to 24 adult patients in successive cohorts of three to six patients treated with multiple doses of EQ001 IV. The primary objective of this part of the trial will be to assess the safety and tolerability of EQ001 and to determine the optimal dose. Secondary objectives include assessing pharmacological activity of EQ001. Once an optimal dose is determined, and if the observed safety, tolerability, and pharmacological activity of EQ001 warrants, we will commence the Phase 2 part of the trial.

The Phase 2 part of the trial will be a randomized, double-blind, placebo-controlled study that will enroll up to 60 additional patients, randomized in a 2:1 ratio with 40 patients on active treatment of EQ001 and 20 patients on placebo. The primary objective of the Phase 2 part of the trial will be to assess the clinical activity of EQ001 and secondary objectives include further characterizing safety and tolerability.

We also plan to initiate a Phase 2 clinical trial of EQ001 for the treatment of cGVHD in the first half of 2019 under our existing IND.

## Severe Asthma Market Overview

Asthma is a heterogeneous disease characterized by both allergic ( $T_h2$  driven) and autoimmune mechanisms ( $T_h17$  driven), leading to chronic airway inflammation. Asthma is now recognized as a disease with two predominant subtypes categorized by the degree of  $T_h2$ -associated inflammation present in the airways. One subtype of asthma, often characterized as allergic asthma, includes patients with high levels of  $T_h2$ -associated inflammation, or  $T_h2$ -high, in the airways, often accompanied by high levels of eosinophils, and production of immunoglobulin E, or  $T_h2$ -high subtype. These  $T_h2$ -high patients often respond to treatment with steroids and recently approved biologic therapies which target  $T_h2$ -cytokines.

Another subtype of asthma is characterized by low levels of  $T_h2$ -associated inflammation, or  $T_h2$ -low, in the airways. These  $T_h2$ -low patients typically do not respond to treatment with corticosteroids or recently approved biologic therapies, have more severe disease, and have low levels of eosinophils. We estimate that 50–60% of the poorly controlled severe asthma population fall within the  $T_h2$ -low subtype. A portion of  $T_h2$ -low patients have airway inflammation caused by  $T_h17$  cytokines such as IL-17.

Based on publicly available sources, we estimate that asthma impacts approximately 26 million individuals. Of these, 5–10%, or approximately 1.3–2.6 million individuals, suffer from severe disease, and approximately half of

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these patients are poorly controlled with the current standard of care. We estimate that 325,000 to 650,000 of poorly controlled patients do not respond to therapies targeting  $T_h2$ -driven disease. Notably, these patients account for most asthma-related treatment costs and economic burden

# Rationale for EQ001 for Severe Asthma

Current therapies for severe asthma and their limitations

Patients with mild-to-moderate asthma accompanied by  $T_h2$ -high inflammation respond well to currently available treatments, including inhaled corticosteroids, or ICS, and long-acting beta agonists. Patients with  $T_h2$ -low or severe disease are often not adequately controlled by these therapies, resulting in a large unmet need.

Recently, several biologic therapies that specifically target IgE or  $T_h2$ -associated cytokines have been approved by the FDA for the treatment of moderate to severe asthma. While these therapies have proven effective for  $T_h2$ -high inflammation they have had a minimal impact in patients with  $T_h2$ -low inflammation. Genentech Inc.'s Xolair, or omalizumab, is an anti-IgE approved for the treatment of moderate to severe persistent allergic asthma that is not controlled by ICS. Other recently approved biologic therapies that are directed against IL-5 or the IL-5 receptor, which together mediate eosinophil development and inflammation of the airways, include mepolizumab (marketed under the name Nucala by GlaxoSmithKline plc), reslizumab (marketed under the name CINQAIR by Teva Pharmaceutical Industries Limited) and benralizumab (marketed under the name Fasenra by AstraZeneca plc).

In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC have filed a BLA for the approval of Dupixent (dupilimab), an anti-IL-4 receptor antibody, for the treatment of moderate to severe asthma.

## EQ001 for T<sub>h</sub>2-low inflammation in asthma pathogenesis

There is a high unmet medical need for a safe, effective and targeted treatment for patients with severe asthma. We believe that the unique mechanism of action of EQ001 has the potential to treat severe asthma patients characterized by an immunophenotype of low  $T_h2$  and high  $T_h17$  and who consequently have a poor response to high dose inhaled and/or oral steroids. There are a sizeable number of these patients who are underserved by currently available therapies and for which there are no FDA-approved biologic or other targeted treatments. Studies have shown that  $T_h2$  and  $T_h17$  cells are reciprocally regulated. More specifically,  $T_h2$  cytokines can negatively regulate  $T_h17$  cytokine expression which means that  $T_h2$ -high patients cannot also be  $T_h17$ -high patients. As a result, if a drug only downregulates  $T_h2$  associated inflammation, then a  $T_h2$ -high patient may experience increased inflammation caused by  $T_h17$  cells, and vice versa. We believe that targeting both  $T_h2$  cytokines and  $T_h17$  cytokines, such as IL-17, may maximize therapeutic efficacy for  $T_h2$ -low patients with inflammation caused by  $T_h17$  cytokines by avoiding a potential increase in inflammation caused by  $T_h17$  cells. By selectively targeting elements of the underlying pathogenesis of severe asthma by inhibiting proliferation of both  $T_h2$  and  $T_h17$  cells and associated cytokines driving  $T_h2$ -low inflammation, EQ001 has the potential opportunity to provide a meaningful benefit to severe asthma patients. See **Figure 11**.

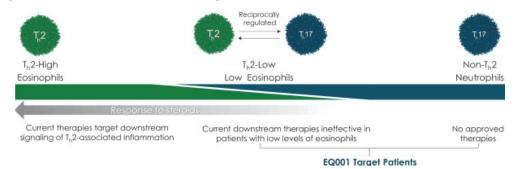


Figure 11:  $T_h$ 17 cells expressing CD6 drive severe refractory asthma. Current approved therapeutic approaches target downstream signaling of  $T_h$ 2-associated inflammation and are largely ineffective in patients with low levels of eosinophils. We believe the upstream mechanism of EQ001 can uniquely address both the  $T_h$ 2 and  $T_h$ 17 inflammation driving severe refractory asthma pathogenesis.

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Translational research program supporting EQ001 in severe asthma

To further validate the use of EQ001 in severe asthma, we have an ongoing translational research program assessing the role of CD6 in severe asthma, specifically in  $T_h2$ -low asthma. Preliminary findings derived from analysis of gene expression datasets support the presence of increased CD6, CD4 T cells, and ALCAM in the lungs of severe asthma patients. Gene expression in cells collected from the lungs of non-asthma, steroid-sensitive moderate asthma, and steroid-insensitive severe asthma patients, suggest that CD6 is significantly elevated in severe asthma, likely due to increases in CD4 T cells as supported by higher CD4 gene expression. In a separate set of patients, analysis of gene expression in lung tissue suggests higher expression of the CD6 ligand ALCAM within the airway of patients who have died from asthma. See Figure 12.

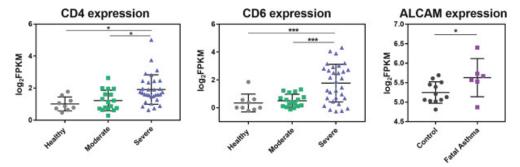


Figure 12: CD6 is upregulated in cells collected from lungs of severe asthma patients. (A and B) Analysis of gene expression in cells collected from lungs of healthy non-asthma, moderate asthma and severe asthma patients as part of two multi-center prospective observational studies (Study of the Mechanisms of Asthma (MAST; NCT00595153); Bronchoscocipic Exploratory Research Study of Biomarkers in Corticosteroid-refractory Asthma (BOBCAT) study) shows higher levels of (A) CD4 expression and (B) CD6 expression in severe asthma, indicating the presence of CD6 in severe asthma and the presence of CD4 T cells. (C) Gene expression in smooth airway muscle from lung tissue of fatal asthmatic patients suggest elevation of ALCAM. \*\*\*y<0.001, \*p<0.05.

#### **Development Plan in Asthma**

We plan to file an IND and initiate a proof-of-concept clinical trial of EQ001 for the treatment of severe asthma in the first half of 2019. The initial proof-of-concept study will focus on the treatment of non-eosinophilic severe asthma refractory to steroids with EQ001 administered subcutaneously. The study objectives will include an assessment of safety, pharmacokinetic/pharmacodynamic markers, dose finding and efficacy.

## **Partnerships**

# Collaboration and License Agreement with Biocon

In May 2017, we entered into a collaboration and license agreement with Biocon, as amended in September 2018, or the Biocon License, pursuant to which Biocon granted us an exclusive license in the United States and Canada, or the Equillium Territory, to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit EQ001 and any pharmaceutical composition or preparation containing or comprising EQ001, or collectively, a Biocon Product, that uses Biocon technology or Biocon know-how. However, unless we achieve certain regulatory and development milestones within a specific time period, the licensed rights, other than development rights, are limited to the fields of orphan indications and the treatment of asthmatic conditions. We also have the right to sublicense through multiple tiers to third parties, provided such sublicenses comply with the terms of the Biocon License and we provide Biocon a copy of each sublicense agreement within 30 days of execution. Under the Biocon License, we granted back to Biocon a license to use our technology and know-how related to EQ001 and Biocon Products in certain countries outside of the Equillium Territory.

In consideration of the rights granted to us by Biocon, we issued Biocon shares of our common stock equal to 19.5% of our outstanding shares at the time of the execution of the Biocon License. Biocon also has certain anti-dilution

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rights which are described in "Description of Capital Stock — Anti-Dilution Rights." In addition, we are obligated to pay Biocon up to an aggregate of \$30 million in regulatory milestone payments upon the achievement of certain regulatory approvals and up to an aggregate of \$565 million in sales milestone payments upon the achievement of first commercial sale of product and specified levels of product sales. We are also required to pay quarterly tiered royalties based on a percentage from the mid-single digits to sub-teen double digits of net sales of Biocon Products, subject to adjustments in certain circumstances. Biocon is also required to pay us royalties at comparable percentages for sales of EQ001 outside of the Equillium Territory if the approvals in such geographies included or referenced our data, including data from certain of our clinical trials, subject to adjustments in certain circumstances. Under the Biocon License, net sales are calculated on a country-by-country basis and are subject to adjustments, including whether the Biocon Product is sold in the form of a combination product.

The Biocon License will continue until the expiration of all royalty obligations, unless terminated earlier. Our royalty obligations expire on a product-by-product and country-by-country basis upon the later of ten years from the first commercial sale of such Biocon Product in such country, the expiration of regulatory exclusivity, and the expiration of the last-to-expire Biocon patent covering such Biocon Product in such country. We may terminate the Biocon License unilaterally, with or without reason, upon 120 days' prior written notice and either party may terminate the Biocon License in the event of the other party's material breach of the Biocon License that remains uncured for 90 days after receipt of notice from the non-breaching party. Upon termination by us unilaterally or by Biocon for our material breach, Biocon will retain its license to use our intellectual property related to EQ001 and Biocon Products in certain countries outside the Equillium Territory, and we also will grant Biocon a non-exclusive license, and a right of first negotiation to an exclusive license, to use our intellectual property related to EQ001 and Biocon Products in the Equillium Territory. Further, we are subject to certain diligence obligations related to development, commercialization and funding activities and if we fail to comply with these obligations Biocon may, in certain circumstances, terminate the Biocon License and, in certain other circumstances, such failure may result in the permitted fields of use for licensed Biocon Products being limited to orphan indications and the treatment of asthmatic conditions.

#### Clinical Supply Agreement with Biocon

In May 2017, in connection with the Biocon License, we entered into a clinical supply agreement, or the Biocon Supply Agreement, with Biocon, pursuant to which Biocon agreed to be our exclusive supplier of EQ001 clinical drug product for up to three concurrent orphan drug clinical indications at no cost until our first U.S. regulatory approval and all other clinical drug product at cost. The Biocon Supply Agreement will remain in effect until the expiration or termination of the Biocon License.

# 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 candidate, novel biological discoveries, epitopes, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we initially pursue patent protection covering compositions of matter, antibody sequence diversity, epitopes, functional activity and methods of use. Throughout the development of our product candidates, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use and biomarker and companion diagnostic related claims.

As of June 30, 2018, our patent portfolio related to EQ001 included patents and patent applications exclusively licensed from Biocon in the United States and Canada, as well as a pending U.S. provisional patent application that we own. The terms of the Biocon License are discussed above in "Business—Partnerships—Collaboration and License Agreement with Biocon and Clinical Supply Agreement with Biocon."

Specifically, as of June 30, 2018, our licensed rights from Biocon related to EQ001 include four issued patents in the United States, two issued patents in Canada, three pending patent applications in the United States, one pending patent application in Canada, and two pending international applications filed under the Patent Cooperation Treaty, or PCT. Our issued U.S. patents are expected to expire in 2028 (absent any patent term extension for regulatory delays) and include claims directed to the antibody sequence of EQ001 and methods of formulating and

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using EQ001 alone or in combination with other agents to treat various T cell mediated diseases and disorders including GVHD and transplant rejection. Our issued Canadian patents are expected to expire between 2027 and 2030. Patents that may issue from our pending in-licensed patent applications are expected to expire between 2027 and 2037, absent any patent term adjustments or extensions.

Additionally, Equillium owns one pending U.S. provisional patent application related to methods of using EQ001 to treat severe asthma. If granted, this patent is expected to expire in 2039, absent any patent term adjustments or extensions. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application.

We file U.S. non-provisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 152 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of 2 1/2 years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first 2 1/2 years of filing.

We intend to prosecute the pending applications that we own and in-license and to pursue patent issuance and protection in key commercial markets where we expect significant product sales may occur.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. 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 reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our products and services. It is uncertain whether the issuance of any third party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our

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future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention. For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non- provisional patent application related to the patent. A U.S. patent also may be accorded a PTA under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

#### Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. 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.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be

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significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or diseases as our lead product candidate EQ001.

#### Graft-Versus-Host Disease

Corticosteroids, or steroids, remain the first-line of therapy for both aGVHD and cGVHD. There are currently no FDA-approved therapies for the treatment of aGVHD, and second-line therapy consists of off-label immunosuppressives for which the therapeutic benefit has not been established. Additionally, there is only one approved therapy for cGVHD, Imbruvica (ibrutinib), approved for cGVHD after failure of one or more lines of therapy.

In addition, we are aware of a number of companies with development programs in aGVHD and cGVHD, including AbbVie Inc., Amgen Inc., Biogen Inc., Bristol-Myers Squibb Company, CSL Behring LLC, Jazz Pharmaceuticals plc, Kadmon Holdings, Inc., Kalytera Therapeutics, Inc., Kamada Ltd., Mesoblast Limited, Novartis AG, Prometheus Laboratories Inc. and Xenikos B.V. Incyte Corporation is developing both Jakafi (ruxolitinib), for steroid-refractory aGVHD as well as cGVHD, and itacitinib, a JAK1 inhibitor, for first-line treatment of aGVHD, currently in Phase 3 clinical development.

#### Severe Asthma

Several biologic therapies that specifically target IgE or T<sub>n</sub>2-associated cytokines have been approved by the FDA for the treatment of asthma including products developed by AbbVie Inc., Amgen Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited.

In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC have filed a BLA for the approval of Dupixent (dupilimab), an anti-IL-4 receptor antibody, for the treatment of moderate to severe asthma. We are also aware of several companies with development programs in this indication including, AbbVie Inc., Amagen Inc., AnaptysBio, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Sanofi-Aventis U.S. LLC.

#### 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 EQ001 in the United States. 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 do not own or operate manufacturing facilities for the production of EQ001 or any future product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Biocon, our third-party contract manufacturer, pursuant to the Biocon License and Biocon Supply Agreement, for all our required raw materials, drug substance and drug product needs for preclinical research, clinical trials and commercial supply of EQ001. If EQ001 is approved, we have agreed to enter into a separate exclusive supply agreement with Biocon in the future. Biocon currently manufactures EQ001 at its FDA regulated facility in Bangalore, India.

With respect to any future product candidates, we expect to rely on third-party contract manufacturers for all our required raw materials, drug substance and drug product needs for preclinical research, clinical trials and commercial supply.

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## **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 biologics such as those we are developing. 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.

In the United States, the FDA regulates biologics under both the Federal Food, Drug and Cosmetic Act, or FDCA, and the Public Health Services Act, or PHSA, and their implementing regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a 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 cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- FDA review and approval, or licensure, of the 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(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the 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 time 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

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independent IRB 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 IRB 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. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination 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 with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- 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 BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological 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.

#### BLA Submission, Review and Approval

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 a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, 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 a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten 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 a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held

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meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a 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 a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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 a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, 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 BLA, 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 BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA 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.

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 BLA 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**

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy and accelerated approval.

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, 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 (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is

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submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

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 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.

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 and approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval but may expedite the development or approval process.

## **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 designation must be requested before submitting a BLA. After the FDA grants orphan 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 designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product 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. Orphan exclusivity does not prevent 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 BLA application fee.

A designated orphan product may not receive orphan 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 or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

# 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 quality control and quality assurance,

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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 FDA assesses an annual program fee for each product identified in an approved BLA. Biologic 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 cGMP, 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 cGMP 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 cGMP and other aspects of regulatory compliance.

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, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or 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; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. 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. 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 Reference Product 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-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the 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

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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 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. 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 from adequate and well-controlled clinical trials 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.

## Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. 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 and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case

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law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, 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, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, 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 the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, 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.

We may be subject to data privacy and security regulations 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 its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such

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metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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.

#### Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration

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authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective: and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available on is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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#### Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and 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 the ability to profitably sell product candidates for which marketing approval is obtained. 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/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic
  agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which
  through subsequent legislative amendments, will be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs
  to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under
  Medicare Part D:
- extension of manufacturers' 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 additional
  individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the
  federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount 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;
- expansion of healthcare fraud and abuse laws, including the FCA and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President

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Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-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. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, CMS announced that it is suspending further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, 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. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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 Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints,

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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.

# The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

#### Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

# Government Regulations Related to Economic Sanctions

Pursuant to various laws, regulations, and executive orders, the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC, administers and enforces economic and trade sanctions that prohibit or restrict certain activities with embargoed countries, sanctioned entities, and sanctioned individuals for particular foreign policy and national security reasons. The scope of the sanctions varies significantly, but may include comprehensive restrictions on imports, exports, investment, and facilitation of foreign transactions involving a sanctioned jurisdiction, entity or person, as well as non-sanctioned persons and entities acting on behalf of sanctioned jurisdictions, entities or people.

One such set of regulations is the Cuban Assets Control Regulations, or CACR. The CACR prohibits U.S. persons from engaging in virtually all transactions involving property of the government of Cuba or Cuban nationals, or property in which the government of Cuba or any Cuban national has at any time on or since July 8, 1963 had any interest of any nature whatsoever, direct or indirect. Where activity is prohibited by the CACR, engagement in such activity must be authorized by a general or specific license granted by OFAC. The antibody sequence for both EQ001 and ALZUMAb was developed exclusively by Cuban nationals. We currently rely on a general license issued by OFAC under CACR, relating to Cuban-origin pharmaceuticals to import and conduct clinical trials relating to EQ001. Although we believe our current and planned activities related to EQ001 qualify for, and are authorized under, the OFAC general license and we have maintained compliance with the general license requirements, OFAC has not confirmed the applicability of the general license to EQ001. We have submitted to OFAC a request for interpretive guidance confirming the applicability of the general license, or in its absence, a specific license authorization from OFAC. We have simultaneously requested that OFAC treat our submission as a voluntary disclosure if OFAC concludes that our determination that the general license applies to EQ001 was in error.

# Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

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# **Employees**

As of June 30, 2018, we employed seven employees, all of whom are full-time and engaged in research and development activities, operations, finance, business development and administration. Two of our employees hold doctorate degrees (Ph.D., M.D. or PharmD.).

#### **Research and Development**

We have invested \$1.3 million and \$1.2 million in research and development for the period March 16, 2017 (inception) through December 31, 2017 and the six months ended June 30, 2018, respectively.

#### **Property and Facilities**

We lease approximately 1,750 square feet of space for our current headquarters in La Jolla, California under an agreement that expires in February 2022. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

# **Legal Proceedings**

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this prospectus, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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#### **MANAGEMENT**

The following table sets forth information about our executive officers and directors as of August 30, 2018.

NAME	AGE	POSITION(S)
Executive Officers	<u></u>	
Daniel M. Bradbury	57	Chief Executive Officer and Chairman of the Board of Directors
Bruce D. Steel	51	President, Chief Business Officer and Director
Stephen Connelly, Ph.D.	37	Chief Scientific Officer and Director
Jason A. Keyes	47	Chief Financial Officer
Krishna R. Polu, M.D.	45	Chief Medical Officer
Non-Employee Directors		
Martha J. Demski (1)(2)	66	Director
Bala S. Manian, Ph.D. (1)(2)	73	Director
Charles McDermott (1)(3)	46	Director
Mark Pruzanski, M.D. (3)	50	Director

- (1) Member of the audit committee
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

# **Executive Officers**

Daniel M. Bradbury has served as our Chief Executive Officer since June 2018 and as a member and the chairman of our board of directors since March 2017. Mr. Bradbury is a co-founder of Equillium and served as our President from March 2017 until June 2018. Mr. Bradbury is the founder and has served as the managing member of BioBrit, LLC, a life sciences consulting and investment firm, since September 2012. Mr. Bradbury served as President, Chief Executive Officer and a director of Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from March 2007 until Amylin's acquisition by Bristol-Myers Squibb Company in August 2012. Prior to Amylin, Mr. Bradbury worked in marketing and sales for 10 years at SmithKline Beecham Pharmaceuticals, a privately-held pharmaceutical company. Mr. Bradbury serves on the board of directors of numerous private companies and the following publicly-held companies: Biocon Limited, Corcept Therapeutics Incorporated, Geron Corporation and Intercept Pharmaceuticals, Inc. Mr. Bradbury previously served on the board of directors of BioMed Realty Trust, Inc., a publicly-held real estate investment trust company, from 2013 to 2016; Illumina, Inc., a publicly-held biotechnology company, from 2004 to 2017; and Syngene International Ltd., a publicly-held science research company, from 2015 to 2016. Mr. Bradbury holds a Bachelor of Pharmacy from Nottingham University and a Diploma in Management Studies from Harrow and Ealing Colleges of Higher Education in the United Kingdom.

Our board of directors believes that Mr. Bradbury's experience as our Chief Executive Officer and his other executive and board experience qualify him to serve on our board of directors.

Bruce D. Steel has served as our President and as our Chief Business Officer since June 2018 and as a member of our board of directors since March 2017. Mr. Steel is a co-founder of Equillium. Mr. Steel is the founder and has served as the Managing Director of BioMed Ventures, an investment firm owned by BioMed Realty, LP, since 2010. From 2008 to 2010, Mr. Steel served as the Chief Business Officer at Anaphore, Inc., a privately-held pharmaceutical company. Prior to that, Mr. Steel was co-founder and Chief Executive Officer of Rincon Pharmaceuticals, Inc., a genetic engineering biotechnology company, from 2005 until its acquisition in 2008. Mr. Steel also previously served as the Head of Corporate Development at Ambit Biosciences Corporation from 2002 to 2005. Mr. Steel previously served on the board of directors of Zosano Pharma Corporation, a publicly-held biopharmaceutical company, from 2012 to 2017. Mr. Steel serves on the board of directors of the following privately-held companies: Breathe Technologies, Inc. and Aegea Medical, Inc. Mr. Steel received his B.A. degree from Dartmouth College and M.B.A. degree from the Marshall School of Business at the University of Southern California, and he holds the designation of Chartered Financial Analyst.

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Our board of directors believes that Mr. Steel's experience in founding, managing and building companies and investment experience qualify him to serve on our board of directors.

Stephen Connelly, Ph.D. has served as our Chief Scientific Officer since January 2018 and as a member of our board of directors since March 2017. Dr. Connelly is a co-founder of Equillium and served as a consultant from March 2017 until January 2018. Dr. Connelly has served as a principal at BioMed Ventures, an investment firm owned by BioMed Realty, LP, since March 2016. From March 2014 to March 2016, Dr. Connelly served as the Director of Business Development and Therapeutic Alliances at aTyr Pharma, Inc., a publicly-held biotechnology company. Prior to that, Dr. Connelly was a Senior Scientist at The Scripps Research Institute from March 2012 to March 2014, where he worked on multiple drug discovery projects spanning different therapeutic areas. Dr. Connelly has broad experience in conducting novel and innovative research and has published over 30 original scientific papers and patents. Dr. Connelly received a B.S. in Medicinal Chemistry and a Ph.D. in Biological Chemistry from the University of Exeter, United Kingdom, and an M.B.A. from the Rady School at University of California, San Diego.

Our board of directors believes that Dr. Connelly's scientific and research expertise qualify him to serve on our board of directors.

Jason A. Keyes has served as our Chief Financial Officer since March 2018. From January 2013 to February 2018, Mr. Keyes held positions of increasing responsibility at Orexigen Therapeutics, Inc., a publicly-held pharmaceutical company which filed a voluntary petition for Chapter 11 bankruptcy in March 2018, most recently as Executive Vice President and Chief Financial Officer. Mr. Keyes held positions of increasing responsibility at Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from August 2007 until January 2013, most recently as Senior Director of Finance. Prior to joining Amylin, Mr. Keyes held positions of increasing responsibility in finance and corporate strategy at Amgen Inc., a publicly-held biopharmaceutical company, and Baxter Healthcare Corporation, a publicly-held healthcare company. Mr. Keyes is also a licensed professional engineer and has six years of experience in the environmental engineering industry. Mr. Keyes received his B.S. and M.S. degrees in Civil Engineering from Stanford University and an M.B.A. from the Anderson School at the University of California, Los Angeles.

Krishna R. Polu, M.D. has served as our Chief Medical Officer since August 2018. From February 2018 to August 2018, Dr. Polu served as Interim Chief Executive Officer of Scout Bio, Inc., a privately-held biotechnology company. Dr. Polu founded Expedition Therapeutics, Inc., a privately-held search company, in June 2017 and served as its Chief Executive Officer from June 2017 until August 2018. Dr. Polu also served as an Entrepreneur-in-Residence at Frazier Healthcare Partners, an investment firm, from February 2017 until August 2018. Prior to that, Dr. Polu served as the Chief Medical Officer of Raptor Pharmaceutical Corp., a publicly-held biopharmaceutical company, from January 2015 to December 2016. Dr. Polu also previously served as the Chief Medical Officer of CytomX Therapeutics, Inc., a privately-held biotechnology company, from March 2013 to June 2014. From July 2009 to March 2013, Dr. Polu served as Vice President of Clinical Development at Affymax, Inc., a publicly-held biotechnology company, from November 2007 to July 2009. Dr. Polu holds a B.A. in Human Biology from Stanford University and a M.D. from University of Texas Health Science Center, San Antonio. Dr. Polu also completed an internal medicine internship and residency at the University of Colorado as well as clinical and research fellowships in nephrology and transplant at Harvard Medical School in a joint program with Brigham and Women's Hospital and Massachusetts General Hospital.

# **Non-Employee Directors**

Martha J. Demski has served as a member of our board of directors since September 2018. From August 2011 to May 2017, Ms. Demski served as Senior Vice President and Chief Financial Officer of Ajinomoto Althea, Inc. (formerly Althea Technologies, Inc.), a privately-held fully-integrated contract development and manufacturing organization. From July 2008 to December 2010, Ms. Demski served as the Interim Chief Operating Officer and Chief Financial Officer of the Sidney Kimmel Cancer Center, a non-profit corporation that was engaged in biomedical research prior to voluntarily filing for Chapter 11 bankruptcy in 2009. Previously, Ms. Demski served as Vice President and Chief Financial Officer of Vical Incorporated, a publicly-held biopharmaceutical company, from

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December 1988 to June 2004. Ms. Demski currently serves as the chair of the board of directors of Chimerix, Inc., a publicly-held biopharmaceutical company, and on the board of directors, as the chair of the audit committee and as a member of the compensation and finance committees, of Adamas Pharmaceuticals, Inc., a publicly-held biotechnology company. Prior to 2018, Ms. Demski was a member of the board of directors, chair of the audit committee and member of the compensation committee, nominating and governance committee, and operating committee of Neothetics, Inc., a publicly-held biotechnology company. Ms. Demski is a National Association of Corporate Directors Board Governance Fellow. In 2017, she received the Director of the Year in Corporate Governance award by the Corporate Directors Forum. Additionally, Ms. Demski has over 13 years of banking experience with Bank of America and U.S. Trust. Ms. Demski earned a B.A. from Michigan State University and M.B.A. from The University of Chicago Booth School of Business with concentrations in accounting and finance.

Our board of directors believes that Ms. Demski's more than 30 years' experience in the fields of finance and biotechnology as well as her experience as a member of various boards of directors gualify her to serve on our board of directors.

Bala S. Manian, Ph.D. has served as a member of our board of directors since May 2017. Dr. Manian has served on the board of directors of Syngene International Ltd., a publicly-held contract research and manufacturing organization based in India, since June 2015 and on the board of directors of Vaccinex, Inc., a publicly-held biotechnology company, since December 2004. Dr. Manian has served as Chief Executive Officer and chairman of the board of directors of ReaMatrix, Inc., a privately-held biotechnology company, since 2004. Dr. Manian has served as Executive Chairman of LeukoDx Inc., a privately-held biotechnology company, since May 2017. Dr. Manian founded and served as chairman of the board of directors of Lumisys Incorporated, a publicly-held medical systems company, from 1987 to 1994, of Molecular Dynamics, Inc., a publicly-held genetic discovery and analysis company, from 1987 to 1994, and of Biometric Imaging, Inc., a privately-held biotechnology company, from 1993 to 1998. Dr. Manian also co-founded Quantum Dot Corporation and SurroMed Inc. Dr. Manian received a B.S. in Physics from Loyola College, Chennai, a postgraduate level Diploma in Instrumentation from the Madras Institute of Technology, Chennai, an M.S. in Applied Optics from the University of Rochester, and a Ph.D. in Mechanical Engineering from Purdue University.

Our board of directors believes that Dr. Manian's experience in founding, managing and building companies and scientific and research experience qualify him to serve on our board of directors.

Charles McDermott has served as a member of our board of directors since September 2018. From September 2017 to May 2018, Mr. McDermott served as President and Chief Business Officer of Impact Biomedicines, Inc., a privately-held biotechnology company. Prior to that, Mr. McDermott served as President and Chief Business Officer of Kala Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, from June 2015 to August 2017. Previously, he served as Interim President and Chief Business Officer of Kala from October 2014 to June 2015 and as Executive Vice President of Business Development of Kala from June 2013 to October 2014. Prior to joining Kala, Mr. McDermott served first as Director and then Vice President of Business Development, Eye Care and Drug Delivery at Allergan plc, a publicly-held global pharmaceutical company, where he worked from April 2005 to May 2013. Prior to joining Allergan, Mr. McDermott held a variety of business development positions at deCODE Genetics, Inc. (now DGI Resolutions, Inc.), a privately-held biopharmaceutical company, from January 2001 to March 2005. Prior to deCODE Genetics, Mr. McDermott was a research scientist in the angiogenesis pharmacology group at Agouron Pharmaceuticals, Inc. Mr. McDermott currently serves on the board of directors of Primmune Therapeutics, Inc., a privately-held biotechnology company. Mr. McDermott holds an M.B.A. from the University of San Diego, an M.A. in Molecular, Cellular and Developmental Biology from the University of California Santa Cruz and a Certificate in Clinical Trial Design and Management from the University of California San Diego Extension.

Our board of directors believes that Mr. McDermott's biopharmaceutical and executive experience qualify him to serve on our board of directors.

*Mark Pruzanski, M.D.* has served as a member of our board of directors since September 2018. Dr. Pruzanski is a co-founder and has served as President and Chief Executive Officer and as a member of the board of directors of Intercept Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, since 2002. Dr. Pruzanski has over 20

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years of experience in life sciences company management, venture capital and strategic consulting. Prior to co-founding Intercept, Dr. Pruzanski was a venture partner at Apple Tree Partners, an early stage life sciences venture capital firm that he co-founded, and an entrepreneur-in-residence at Oak Investment Partners, a venture capital firm. Dr. Pruzanski is a co-author of a number of scientific publications and is named as an inventor on several patents. Dr. Pruzanski currently serves on the boards of the Emerging Companies Section of the Biotechnology Innovation Organization, a biotechnology-focused trade association, and the Foundation for Defense of Democracies, a non-profit policy institute focusing on foreign policy and national security. Dr. Pruzanski received his M.D. from McMaster University in Hamilton, Canada, a M.A. degree in International Affairs from the Johns Hopkins University School of Advanced International Studies in Bologna, Italy and Washington, D.C., and a bachelor's degree from McGill University in Montreal, Canada.

Our board of directors believes that Dr. Pruzanski's experience in founding, managing and building life sciences companies as well as his venture capital experience qualify him to serve on our board of directors.

# **Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required.

Our board of directors has determined that all of our directors, other than Mr. Bradbury, Dr. Connelly and Mr. Steel, are independent directors, as defined by Rule 5605(a)(2) of The Nasdaq Listing Rules.

In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the completion of this offering, respectively, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of Dr. Connelly and Dr. Manian, whose terms will expire at our annual meeting of stockholders to be held in 2019.
- Class II, which will consist of Mr. McDermott and Mr. Steel, whose terms will expire at our annual meeting of stockholders to be held in 2020: and
- Class III, which will consist of Mr. Bradbury, Ms. Demski and Dr. Pruzanski, whose terms will expire at our annual meeting of stockholders to be held in 2021.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently seven members. The authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66-2/3% of our voting stock.

# **Board Leadership Structure**

Our board of directors is currently chaired by Mr. Bradbury who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Chairman has substantial ability to shape the work of the board of directors. We have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

# Role of the Board in Risk Oversight

The audit committee of our board of directors is primarily responsible for overseeing our risk management processes on behalf of our board of directors. Going forward, we expect that the audit committee will receive reports from

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management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to our board of directors, which also considers our risk profile. The audit committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

#### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

#### **Audit Committee**

Our audit committee consists of Ms. Demski, Dr. Manian and Mr. McDermott. Our board of directors has determined that each of the members of our audit committee satisfies The Nasdaq Stock Market and SEC independence requirements. Ms. Demski serves as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

Our board of directors has determined that Ms. Demski qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In

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making this determination, our board has considered Ms. Demski's prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of Sarbanes-Oxley, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

# Compensation Committee

Our compensation committee consists of Ms. Demski and Dr. Manian. Dr. Manian serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and satisfies The Nasdaq Stock Market independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers:
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs:
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of Sarbanes-Oxley, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us

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# Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. McDermott and Dr. Pruzanski. Mr. McDermott serves as the chair of our nominating and corporate governance committee. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Stock Market independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors:
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically
  reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to
  such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of Sarbanes-Oxley, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

# **Compensation Committee Interlocks and Insider Participation**

None of our current or former executive officers serve as a member of the compensation committee. None of our officers serve, or have served during the last completed fiscal year, on the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. Prior to establishing the compensation committee, our full board of directors made decisions relating to compensation of our officers. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see "Certain Relationships and Related Party Transactions."

# **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. Following this offering, a current copy of the code will be available on the Corporate Governance section of our website, www.equilliumbio.com.

# Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law allows a corporation to eliminate the personal liability of directors of a corporation to the corporation and its stockholders for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of his or her duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

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 unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or

transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, will remain available under Delaware law. These limitations also do not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Our amended and restated bylaws, which will become effective upon the completion of this offering, provide that we will indemnify our directors and executive officers and may indemnify other officers, employees and other agents, to the fullest extent permitted by law. Our amended and restated bylaws, which will become effective upon the completion of this offering, also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding and also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our amended and restated bylaws permit such indemnification. We have obtained a policy of directors' and officers' liability insurance.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, will require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

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.

Except as otherwise disclosed under the heading "Legal Proceedings" in the "Business" section of this prospectus, at present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

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#### **EXECUTIVE AND DIRECTOR COMPENSATION**

Due to our limited operations in 2017, we did not have an executive or board compensation program and we did not pay any executive compensation or issue any stock-based compensation to any executive or board member in 2017. Daniel M. Bradbury, our Chief Executive Officer, was our only executive officer during 2017 and accordingly is our only named executive officer for the period March 16, 2017 (inception) through December 31, 2017. During 2017, Mr. Bradbury served as our President. Our other current executive officers commenced employment with us during 2018. We have included information in the following narrative regarding our named executive officer and other current executive officers' 2018 compensation where it may be helpful to an understanding of our compensation program.

#### **Summary Compensation Table**

Mr. Bradbury did not receive any compensation from us for services in any capacity during the period March 16, 2017 (inception) through December 31, 2017.

#### **Annual Base Salary**

Other than with respect to Mr. Bradbury, the base salary of our executive officers is generally determined and approved in connection with the commencement of employment of the executive, by our board of directors. As of December 31, 2017, Mr. Bradbury did not receive an annual base salary. Effective June 1, 2018, in connection with his offer letter, the board of directors approved an annual base salary for Mr. Bradbury of \$400,000.

# **Bonus Compensation**

Mr. Bradbury was not entitled to and did not receive any bonus payments during 2017. Our board of directors or compensation committee may approve bonuses in the future for our executives based on individual performance, company performance or as otherwise determined appropriate.

Beginning in 2018, pursuant to his offer letter, Mr. Bradbury is entitled to an annual discretionary performance-based bonus. Mr. Bradbury's offer letter is described under "—Agreements with Executive Officers."

# **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 executive officers. The board of directors is responsible for approving equity grants. As of the date of this prospectus, we have not granted any equity awards to Mr. Bradbury.

In 2018, we granted stock options to each of Mr. Keyes and Dr. Polu, which are described in the section entitled "—Agreements with Executive Officers." Following this offering, we expect to use stock options or other stock awards as an incentive for long-term compensation to our executive officers at such times as our board of directors determines appropriate. Other than our founders, our executive officers generally are awarded an initial grant in the form of a stock option in connection with their commencement of employment with us. 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, we have granted all stock options pursuant to our 2017 Plan. Following this offering, we expect to grant equity incentive awards under the terms of our 2018 Plan. The terms of the 2017 Plan and the 2018 Plan are described below under "—Equity Benefit 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 awards generally vest over a four-year period subject to continued service and may be subject to acceleration of vesting and exercisability under certain termination and change in control events.

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# **Agreements with Executive Officers**

# Agreement with Mr. Bradbury

We did not maintain an agreement with Mr. Bradbury governing his services to us during 2017. In June 2018, we entered into an offer letter with Mr. Bradbury, which governs the terms of his employment with us. Under the terms of the offer letter, Mr. Bradbury is entitled to an annual base salary of \$400,000 and is eligible to receive an annual performance-based bonus opportunity at a target amount of 35% of his base salary, based on the attainment of individual and corporate objectives to be determined and approved by us. The payment and amount of the annual bonus will be in our sole discretion. The offer letter also provides for severance benefits described below under "—Potential Payments and Benefits upon Termination or Change in Control." In addition, Mr. Bradbury is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants.

# Agreement with Mr. Steel

In June 2018, we entered into an offer letter with Mr. Steel, our President and Chief Business Officer, which governs the terms of his employment with us. Under the terms of the offer letter, Mr. Steel is entitled to an annual base salary of \$375,000 and is eligible for an annual performance-based bonus opportunity at a target amount of 35% of his base salary, based on the attainment of individual and corporate objectives to be determined and approved by us. The payment and amount of the annual bonus will be in our sole discretion. The offer letter also provides for severance benefits described below under "—Potential Payments and Benefits upon Termination or Change in Control." In addition, Mr. Steel is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants.

# Agreement with Dr. Connelly

In January 2018, we entered into an offer letter Dr. Connelly, our Chief Scientific Officer, which governs the terms of his employment with us, and which was amended and restated in June 2018. Under the terms of his offer letter, Dr. Connelly is currently entitled to an annual base salary of \$300,000 and is eligible for an annual performance-based bonus opportunity at a target amount of 35% of his base salary, based on the attainment of individual and corporate objectives to be determined and approved by us. The payment and amount of the annual bonus will be in our sole discretion. The offer letter also provides for severance benefits described below under "—Potential Payments and Benefits upon Termination or Change in Control." In addition, Dr. Connelly is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants.

# Agreement with Mr. Keyes

In March 2018, we entered into an offer letter with Mr. Keyes, our Chief Financial Officer, which governs the terms of his employment with us. Under the terms of the offer letter, Mr. Keyes is entitled to an annual base salary of \$290,000 and is eligible for an annual performance-based bonus opportunity at a target amount of 30% of his base salary, based on the attainment of individual and corporate objectives to be determined and approved by us. The payment and amount of the annual bonus will be in our sole discretion. The offer letter also provides for severance benefits described below under "—Potential Payments and Benefits upon Termination or Change in Control." In addition, Mr. Keyes is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants.

The offer letter also contemplates the grant to Mr. Keyes of a stock option, which was granted to Mr. Keyes on June 6, 2018. The option provides that Mr. Keyes may purchase up to 148,720 shares of our common stock at an exercise price of \$0.05 per share, which vests as to 25% of the shares on April 1, 2019 with the balance of shares vesting in approximately equal monthly installments over the remaining 36 months, subject to Mr. Keyes' continued service with us, subject to full acceleration of all of the shares in the event Mr. Keyes is terminated by us without cause or resigns for good reason within 12 months after a change in control. In June 2018, Mr. Keyes early exercised his option in full and we issued him 148,720 shares of common stock, all of which are restricted shares subject to the vesting schedule described above.

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#### Agreement with Dr. Polu

On August 1, 2018, we entered into an offer letter with Dr. Polu, our Chief Medical Officer, which governs the terms of his employment with us. Under the terms of the offer letter, Dr. Polu is entitled to an annual base salary of \$375,000 and is eligible for an annual performance-based bonus opportunity at a target amount of 30% of his base salary, based on the attainment of individual and corporate objectives to be determined and approved by us. The payment and amount of the annual bonus will be in our sole discretion. The offer letter also provides for severance benefits described below under "—Potential Payments and Benefits upon Termination or Change in Control." In addition, Dr. Polu is eligible to participate in the employee benefit plans generally available to our employees, and is subject to customary confidentiality covenants. The offer letter also contemplates that Dr. Polu will, at our discretion, be reimbursed for up to \$50,000 per year, subject to adjustment based on our business needs, to commute to our offices in La Jolla.

The offer letter also contemplates the grant to Dr. Polu of a stock option, which was granted to Dr. Polu on August 16, 2018. The option provides that Dr. Polu may purchase up to 208,216 shares of our common stock at an exercise price of \$3.30 per share, which vests as to 25% of the shares on September 1, 2019 with the balance of shares vesting in approximately equal monthly installments over the remaining 36 months, subject to Dr. Polu's continued service with us, subject to full acceleration of all of the shares in the event Dr. Polu is terminated by us without cause or resigns for good reason within 12 months after a change in control.

# Potential Payments and Benefits upon Termination or Change in Control

Each of our executive officer's employment is at will and may be terminated by us at any time. Regardless of the manner in which an executive officer's service terminates, such executive officer is entitled to receive any and all accrued but unpaid amounts earned during his or her term of service, including unpaid salary and unused vacation, as applicable. In addition, the offer letter agreements with each of Messrs. Bradbury, Steel, and Keyes and Drs. Connelly and Polu each provide that, if we terminate such executive's employment without cause, the executive is entitled to receive (i) continuation of the applicable executive officer's then-current base salary for six months and (ii) payment of the premiums for group health insurance COBRA continuance coverage for six months or, if earlier, until the date on which the executive becomes eligible to receive comparable benefits from another employer.

Additionally, if we terminate the executive's employment without cause within one month prior to, or 12 months following, certain change of control and asset sale transactions, the executive is entitled to receive (i) continuation of the applicable executive officer's then-current base salary for 12 months, (ii) an amount equal to the applicable executive's target annual bonus and (iii) payment of the premiums for group health insurance COBRA continuance coverage for 12 months or, if earlier, until the date on which the executive becomes eligible to receive comparable benefits from another employer. In each case, the severance benefits are conditioned upon the execution and non-revocation of a general release of claims by the applicable executive in a form provided by us. Mr. Keyes and Dr. Polu are also entitled to vesting acceleration upon their respective terminations in connection with a change in control pursuant to the terms of their stock options granted on June 6, 2018 and August 16, 2018, respectively, as described above.

# **Outstanding Equity Awards at Fiscal Year-End**

Mr. Bradbury does not hold any unexercised options, stock that has not vested or equity incentive plan awards that were outstanding as of December 31, 2017.

We did not engage in any repricings or other modifications or cancellations to our named executive officer's outstanding equity awards during the period March 16, 2017 (inception) through December 31, 2017.

# Perquisites, Health, Welfare and Retirement Benefits

Our named executive officer and other executive officers, during their employment with us, are eligible to participate in our employee benefit plans, including our medical, dental, group term life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. In addition, we provide a 401(k) plan to our employees, including our named executive officer, as discussed in the section below entitled "—401(k) Plan."

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We generally do not provide perquisites or personal benefits to our named executive officer and other executive officers, except in limited circumstances. We do, however, pay the premiums for medical, dental, group term life, disability and accidental death and dismemberment insurance for all of our employees, including our named executive officer. 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.

#### 401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officer and other executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the U.S. Internal Revenue Code of 1986, as amended, or the Code. The 401(k) plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is \$18,000 and \$18,500 for calendar years 2017 and 2018, respectively. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar years 2017 and 2018 may be up to an additional \$6,000 above the statutory limit. We currently do not make matching contributions into the 401(k) plan on behalf of participants. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

# **Nonqualified Deferred Compensation**

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future, if it determines that doing so is in our best interests.

#### Equity Benefit Plans

The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

#### 2018 Plan

Our board of directors adopted our 2018 Plan in October 2018 and our stockholders approved our 2018 Plan in October 2018 prior to this offering. Our 2018 Plan is a successor to and continuation of our 2017 Plan. The 2018 Plan became effective in connection with the execution and delivery of the underwriting agreement related to this offering. No further grants will be made under the 2017 Plan.

Stock awards. Our 2018 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Code, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized shares. Initially, the maximum number of shares of our common stock that may be issued under our 2018 Plan is 2,229,773 shares, which is the sum of (1) 1,040,000 new shares, plus (2) the number of shares (not to exceed 1,189,773 shares) (i) that remain available for the grant of future awards under our 2017 Plan at the time our 2018 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under our 2017 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 2018 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2019 through January 1, 2028, in an amount equal to 5.0% 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 ISOs under our 2018 Plan is 6,689,319.

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Shares subject to stock awards granted under our 2018 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 2018 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 2018 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 2018 Plan.

The maximum number of shares of common stock subject to stock awards granted under the 2018 Plan or otherwise during a single 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 \$350,000 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 the board of directors, \$550,000.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2018 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 (1) designate employees (other than officers) to receive specified stock awards and (2) determine the number of shares subject to such stock awards. Under our 2018 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.

Under the 2018 Plan, the board of directors also generally has the authority to effect, with the consent of any adversely affected participant, (A) the reduction of the exercise, purchase, or strike price of any outstanding award; (B) the cancellation of any outstanding award and the grant in substitution therefore of other awards, cash, or other consideration; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

Stock options. ISOs and 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 2018 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 2018 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 2018 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 (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, or (5) 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,

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(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 (1) 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 (2) 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 restricted stock unit award. Except as otherwise provided in the applicable award 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 2018 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2018 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. 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. 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 2018 Plan permits the grant of performance-based stock and cash awards. Our compensation committee may structure awards so that the stock or cash 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) revenues; (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

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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 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, (a) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event or development; (b) 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 (c) 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: (i) to exclude the dilutive effects of acquisitions or joint ventures; (ii) 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 (iii) 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: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated net sales and operating earnings; (iii) to exclude the effects of changes to generally accepted accounting standards required by the Financial Accounting Standards Board; (iv) to exclude the effects of any items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (v) to exclude the effects to any statutory adjustments to corporate tax rates; and (vi) 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 (1) the class and maximum

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number of shares reserved for issuance under the 2018 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs, (4) the class(es) and maximum number of securities that may be awarded to any non-employee director, and (5) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. Our 2018 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 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 2018 Plan, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) 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 2018 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 2018 Plan, a change in control is generally (1) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock, (2) 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, (3) 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, (4) a complete dissolution or liquidation of the company, or (5) 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 etill in office.

Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2018 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 2018 Plan. No stock awards may be granted under our 2018 Plan while it is suspended or after it is terminated.

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#### 2017 Plan

Our board of directors and our stockholders approved our 2017 Plan in December 2017. As of June 30, 2018, there were 814,999 shares remaining available for the future grant of stock awards under our 2017 Plan. As of June 30, 2018, there were outstanding stock options covering a total of 107,084 shares of our common stock that were granted under our 2017 Plan. The shares that remained available for issuance under the 2017 Plan at the time the 2018 Plan became effective became available for issuance under the 2018 Plan. No further awards may be granted under the 2017 Plan as of and following the date the 2018 Plan became effective.

Stock awards. Our 2017 Plan provides for the grant of ISOs within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock, restricted stock units and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates. We have only granted stock options under the 2017 Plan.

Authorized shares. Subject to certain capitalization adjustments, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2017 Plan will not exceed 1,189,773 shares. The maximum number of shares of our common stock that may be issued pursuant to the exercise of ISOs under our 2017 Plan is 3,569,319 shares.

Shares subject to stock awards granted under our 2017 Plan that expire or otherwise terminate without being exercised in full or that are settled in cash rather than in shares do not reduce or otherwise offset the number of shares available for issuance under our 2017 Plan. Additionally, if any shares issued pursuant to a stock award are forfeited back to or repurchased because of the failure to meet a contingency or condition required to vest, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the 2017 Plan. Upon the 2018 Plan's effectiveness, any such shares will become available for grant under the 2018 Plan. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors to which the board delegates its administrative authority, will administer our 2017 Plan and is referred to as the "plan administrator" herein. The plan administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified options and stock appreciation rights (and to the extent permitted by applicable law, other stock awards) and (2) determine the number of shares subject to such stock awards; provided, however, that the board resolutions regarding such delegation must specify the total number of shares that may be subject to awards granted by such officer, and provided further, that no officer may grant an award under the 2017 Plan to himself or herself. Under our 2017 Plan, the plan administrator has the authority to, among other things, determine award recipients, dates of grant, 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 their exercisability and the vesting schedule applicable to a stock award, to construe and interpret the 2017 Plan and awards granted thereunder (and to establish, amend and revoke any rules and regulations for the administration of the 2017 Plan and any such awards), or to accelerate awards.

Under the 2017 Plan, the plan administrator also generally has the authority to effect, with the consent of any adversely affected participant, (A) the reduction of the exercise, purchase, or strike price of any outstanding award; (B) the cancellation of any outstanding award and the grant in substitution therefor of other awards, cash, or other consideration; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

Stock options. ISOs and 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 2017 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 (or 110% of the fair market value for certain major stockholders). Options granted under the 2017 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 2017 Plan, up to a maximum of 10 years (or five years, for certain major stockholders). If an optionholder's service relationship with us or any of our

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affiliates ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of up to 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 up to 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 up to 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 (1) cash, check, bank draft or money order payable to us, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, (5) a deferred payment arrangement, or (6) 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 optionholder 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 (1) 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 (2) 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 awards 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 restricted stock unit award. Except as otherwise provided in the applicable award 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.

Changes to capital structure. In the event of a "capitalization adjustment," the board of directors, in its discretion, will make appropriate and proportionate adjustments to (1) the class and maximum number of shares reserved for issuance under the 2017 Plan, (2) the class and maximum number of shares that may be issued on the exercise of ISOs, and (3) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards. For purposes of the 2017 Plan, "capitalization adjustment" generally means any change that is made in (or other events occurring with respect to) our common stock subject to the 2017 Plan or any award

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without the receipt of consideration by us through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, in property other than cash, large non-recurring cash dividend, stock split, reverse stock split, liquidating dividend, combination or exchange of shares, change in corporate structure, or other similar equity restructuring transaction (within the meaning of Statement of Financial Accounting Standards Board ASC Topic 718).

Corporate transactions. Our 2017 Plan provides that in the event of a "corporate transaction," 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 surviving or acquiring corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring 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 exercised before the effective time of the transaction, in exchange for a payment in such form as may be determined by our board of directors, equal to the excess, if any, of (A) the per share amount (or value of property per share) payable to holders of common stock in connection with the transaction, over (B) the per share exercise price under the stock award (if any), multiplied by the number of vested shares subject to the stock award;
- make a payment 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:
- suspend the exercise of the stock award, prior to the effective time of the transaction, for such period as our board of directors determines is necessary to facilitate the negotiation and consummation of the transaction; and
- if a stock award is eligible for "early exercise," cancel or arrange for the cancellation of any such "early exercise" rights upon the transaction, such that following the transaction, such stock award may only be exercised to the extent vested.

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 treat all participants in the same manner.

Under the 2017 Plan, a "corporate transaction" is generally defined as the consummation, in a single transaction or in a series of related transactions, of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) 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. A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control as may be provided in an applicable award agreement or other written agreement, but in the absence of such provision, no such acceleration will occur. Under the 2017 Plan, a "change in control" is generally defined as (1) certain acquisitions by a person or company of more than 50% of the combined voting power of our then outstanding stock, (2) 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, or (3) a sale, lease, exclusive license or other disposition of all or substantially all of our consolidated 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.

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Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2017 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. Unless terminated sooner, the 2017 Plan will automatically terminate on December 10, 2027. No stock awards may be granted under our 2017 Plan while it is suspended or after it is terminated.

#### 2018 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders approved, our ESPP in October 2018 prior to this offering. The ESPP became effective immediately prior to the execution and delivery 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.

Share reserve. Following this offering, the ESPP authorizes the issuance of 343,275 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, 2019 through January 1, 2028, by the lesser of (1) 1.0% 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 (2) 343,275 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 (1) and (2). 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. 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. Each offering will have 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 (1) 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: (1) being customarily employed for more than 20 hours per week, (2) being customarily employed for more than five months per calendar year, or (3) 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.

Changes to capital structure. In the event that there occurs a change in our capital structure 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: (1) the class(es) and maximum number of shares reserved under the ESPP, (2) the class(es) and

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maximum number of shares by which the share reserve may increase automatically each year, (3) the class(es) and number of shares subject to and purchase price applicable to outstanding offerings and purchase rights, and (4) 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: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, and (4) 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**

Historically, we have not paid or awarded any cash compensation to any of our non-employee directors for service on our board of directors. In addition, we have not paid equity compensation to our non-employee directors for service on our board of directors, except as set forth below.

During the period March 16, 2017 (inception) through December 31, 2017, we did not pay or award any compensation to any of our non-employee directors for service on our board and none of our non-employee directors were granted or held outstanding stock or option awards. The following table sets forth in summary form information concerning the compensation that we paid or awarded during the period March 16, 2017 (inception) through December 31, 2017 to each of our non-employee directors who served at any time during 2017. Ms. Demski, Mr. McDermott and Dr. Pruzanski were not members of our board of directors in 2017 and are not included in the table.

	ALL OTHER COMPENSATION	TOTAL
NAME	(\$)	(\$)
Stephen Connelly, Ph.D.	30,000 (1)	30,000
Bala S. Manian, Ph.D.	<del>-</del>	_
Bruce D. Steel	<del>-</del>	_

<sup>(1)</sup> Represents fees paid to Dr. Connelly for his consulting services to us during 2017. Dr. Connelly provided scientific and business-related consulting services to us from October 2017 through December 2017 pursuant to a consulting agreement with us effective as of October 16, 2017, which terminated in connection with his commencement as our Chief Scientific Officer in January 2018.

On June 6, 2018, we granted Dr. Manian an option to purchase 23,799 shares of common stock at an exercise price of \$0.05 per share. Dr. Manian's option vests in 48 successive equal monthly installments beginning on June 6, 2018, subject to Dr. Manian's continued service with us. In July 2018, Dr. Manian early exercised his option in full and we issued him 23,799 shares of common stock, which are restricted shares subject to the vesting schedule described in the preceding sentence.

On September 13, 2018, we granted each of Ms. Demski and Mr. McDermott an option to purchase 23,799 shares of common stock at an exercise price of \$3.87 per share. Each such option vests in 48 successive equal monthly installments beginning on September 13, 2018, subject to Ms. Demski's and Mr. McDermott's respective continued

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service with us. In September 2018, each of Ms. Demski and Mr. McDermott early exercised their option in full and we issued 23,799 shares of common stock to each of Ms. Demski and Mr. McDermott, which are restricted shares subject to the vesting schedule described in the preceding sentence

On September 14, 2018, we granted Dr. Pruzanski an option to purchase 23,799 shares of common stock at an exercise price of \$3.87 per share. Such option vests in 48 successive equal monthly installments beginning on September 14, 2018, subject to Dr. Pruzanski's continued service with us.

We have reimbursed and expect to continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

#### Non-employee Director Compensation Policy

Our board of directors adopted a new compensation policy in October 2018 that became effective upon the execution and delivery of the underwriting agreement for this offering and is applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of \$40.000:
- an additional cash retainer of \$20,000 to the chairman of the board of directors;
- an additional annual cash retainer of \$7,500, \$5,000 and \$4,000 for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of \$15,000, \$10,000 and \$8,000 for service as chairman of the audit committee, compensation committee and the nominating and corporate governance committee, respectively (in lieu of the additional cash retainer for committee membership);
- an initial option grant for each non-employee director who first joins our board of directors after this offering, in an amount to be
  determined by the board or compensation committee, on the date of commencement of service on the board, vesting over a three year
  period following the grant date; and
- an annual option grant for each non-employee director serving on the board of directors on the date of our annual stockholder meeting, in an amount to be determined by the board or compensation committee, vesting over the one year period following the grant date.

Each of the option grants described above will vest and become exercisable subject to the director's continuous service to us, provided that each option will vest in full upon a change in control (as defined in the 2018 Plan). The term of each option will be 10 years, subject to earlier termination as provided in the 2018 Plan, except that the post-termination exercise period will be for up to 12 months from the date of termination, if such termination is other than for death, disability or cause. The options will be granted under our 2018 Plan, the terms of which are described in more detail above under "—Equity Benefit Plans—2018 Plan."

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#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since March 16, 2017, our inception, to which we have been a party, in which the amount involved in the transaction exceeded \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive And Director Compensation."

# **Convertible Promissory Note Financing**

From May 2017 to June 2018, we issued and sold to investors convertible promissory notes in the aggregate principal amount of approximately \$9.4 million. The convertible promissory notes carry an interest rate of 6% per annum. The participants in this convertible promissory note financing included the following executive officers and members of our board of directors, or entities affiliated with them.

PARTICIPANTS Executive Officers and Directors	 AGGREGATE PRINCIPAL AMOUNT OF NOTES	
Daniel M. Bradbury	\$ 512,165.00 <sup>(1)</sup>	
Bruce D. Steel	\$ 512,164.00 (2)	

<sup>(1)</sup> Consists of convertible promissory notes held by (i) BioBrit, LLC, or BioBrit, in the principal amount of \$409,732.00 (which convertible promissory note was originally issued in May 2017 in principal amount of \$400,000.00 and was amended and restated in October 2017 in principal amount of \$409,732.00, which amount includes accrued interest from May 2017 to October 2017), or the BioBrit Note, and (ii) The Bradbury Family 2009 Irrevocable Trust dated September 1, 2009, or Bradbury Trust, in the principal amount of \$102,433.00 (which convertible promissory note was originally issued in May 2017 in principal amount of \$100,000.00 and was amended and restated in October 2017 in principal amount of \$102,433.00, which amount includes accrued interest from May 2017 to October 2017), or the Bradbury Trust Note. Mr. Bradbury, is the managing member of BioBrit.

The BioBrit Note, the Bradbury Note and the Steel Note will automatically convert upon the completion of this offering into an aggregate of 38,796 shares, 9,699 shares and 48,495 shares of our common stock, respectively, each based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018.

#### **Employment Arrangements**

We have entered into offer letters with Mr. Bradbury, Mr. Steel, Dr. Connelly, Mr. Keyes and Dr. Polu, each of which is described in the section titled "Executive and Director Compensation."

#### **Biocon Agreements**

In May 2017, we entered into the Biocon License and the Biocon Supply Agreement with Biocon, one of our 5% stockholders. Such agreements are described in "Business—Partnerships—Collaboration and License Agreement with Biocon" and "Business—Partnerships—Clinical Supply Agreement with Biocon." In connection with the Biocon License, we entered into a Common Stock Purchase Agreement with Biocon, pursuant to which we issued 2,088,074 shares of our common stock as consideration under the Biocon License.

In connection with the completion of this offering, we will issue to Biocon 228,060 shares of common stock pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share. Such anti-dilution rights are described in "Description of Capital Stock—Anti-Dilution Rights."

<sup>(2)</sup> Such convertible promissory note, or the Steel Note, was originally issued in May 2017 in principal amount of \$500,000.00 and was amended and restated in October 2017 in principal amount of \$512,164.00, which amount includes accrued interest from May 2017 to October 2017.

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#### **Investor Agreements**

In May 2017, we entered into an investor rights agreement and voting agreement with Biocon and certain other of our stockholders containing, among other things, voting rights, information rights, pre-emptive rights, co-sale rights, anti-dilution rights and potential future registration rights. These rights will terminate upon the closing of this offering.

#### **Indemnification Agreements**

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, as described in "Management—Limitation of Liability and Indemnification."

# Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our 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 five percent of our common stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

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, 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 thereto, 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-person 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.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. All of the transactions described in this section occurred prior to the adoption of this policy.

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# PRINCIPAL STOCKHOLDERS

The following table sets forth 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 directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

The percentage ownership information under the column entitled "Before Offering" is based on 11,082,848 shares of common stock outstanding as of August 30, 2018. The percentage ownership information under the column entitled "After Offering" is based on the sale of 4,670,000 shares of common stock in this offering and takes into account (i) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018 and (ii) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before October 29, 2018, which is 60 days after August 30, 2018. 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. 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.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Equillium, Inc., 2223 Avenida de la Playa, Suite 108, La Jolla, CA 92037.

	NUMBER OF SHARES BENEFICIALLY OWNED		PERCENTAGE OF SHARES BENEFICIALLY OWNED	
NAME AND ADDRESS OF BENEFICIAL OWNER	BEFORE OFFERING	AFTER OFFERING	BEFORE OFFERING	AFTER OFFERING
5% or Greater Stockholders				
Biocon SA (1)	2,088,074	2,316,134	18.8%	13.7%
Directors and Named Executive Officers				
Daniel M. Bradbury (2)	3,663,500	3,711,995	33.1%	22.0%
Bruce D. Steel (3)	3,663,500	3,711,995	33.1%	22.0%
Stephen Connelly, Ph.D.	1,293,000	1,293,000	11.7%	7.7%
Martha J. Demski	· · · · —	· · · · —	*	*
Bala S. Manian, Ph.D.	23,799	23,799	*	*
Charles McDermott	· <u> </u>	· —	*	*
Mark Pruzanski, M.D.	_	_	*	*
All current executive officers and directors as a group (9 persons) (4)	9,000,735	9,097,725	79.7%	53.3%

Represents beneficial ownership of less than 1%.

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(1) The number of shares beneficially owned after the offering includes 228,060 shares of common stock issuable upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share. The address of Biocon SA is c/o BDO SA, Rue de l'Avenir 2, 2800 Delémont, Switzerland.

(2) Consists of (i) 2,930,800 shares of common stock held by BioBrit, LLC, or BioBrit, of which Mr. Bradbury is the managing member, and (ii) 732,700 shares of common held by The Bradbury Family 2009 Irrevocable Trust dated September 1, 2009, or Bradbury Trust. The number of shares beneficially owned after the offering includes 48,495 shares of common stock issuable upon the conversion of a convertible promissory note in the principal amount of (a) \$409,732.00 plus accrued interest held by BioBrit and (b) \$102,433.00 plus accrued interest held by Bradbury Trust, each upon the completion of this offering based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018.
 (3) Consists of (i) 3,232,500 shares of common stock held by Bruce D. Steel, as trustee of the Steel Family Revocable Trust dated June 5, 2002, and (ii) 431,000 shares of

(3) Consists of (i) 3,232,500 shares of common stock held by Bruce D. Steel, as trustee of the Steel Family Revocable Trust dated June 5, 2002, and (ii) 431,000 shares of common held by Kevin N. Steel, as trustee of the Sierra Kathleen Steel Trust of January 1, 2005. The number of shares beneficially owned after the offering includes 48,495 shares of common stock issuable upon the conversion of a convertible promissory note in the principal amount of \$512,164.00 plus accrued interest held by Bruce D. Steel upon the completion of this offering based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018.

(4) Consists of (i) the shares described in Notes (2) and (3) above and the shares held by Dr. Connelly and Dr. Manian, (ii) 148,720 shares of common stock held by The Keyes Trust Dated September 10, 2004 and beneficially owned by Jason A. Keyes, our Chief Financial Officer, all of which are subject to a right of repurchase by us as of August 30, 2018 and (iii) 208,216 shares of common stock that Krishna R. Polu, M.D., our Chief Medical Officer, has the right to acquire from us within 60 days of August 30, 2018 pursuant to the exercise of stock options.

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# **DESCRIPTION OF CAPITAL STOCK**

Upon filing of our amended and restated certificate of incorporation and the completion of this offering, our authorized capital stock will consist of 200,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share. All of our authorized preferred stock upon the completion of this offering will be undesignated. The following is a summary of the rights of our common and preferred stockholders and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the completion of this offering, respectively, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law. As of the date of this prospectus, we have not issued any shares of preferred stock

#### **Common Stock**

#### **Outstanding Shares**

As of June 30, 2018, there were 10,975,764 shares of common stock issued and outstanding (including 267,690 shares of restricted common stock which are subject to a right of repurchase by us as of June 30, 2018) held of record by 12 stockholders. Based on the number of shares of common stock outstanding as of June 30, 2018, and assuming (1) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018, (2) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, based on the initial public offering price of \$14.00 per share, and (3) the issuance by us of 4,670,000 shares of common stock in this offering, there will be 16,752,658 shares of common stock outstanding upon the completion of this offering.

As of June 30, 2018, there were 107,084 shares of common stock subject to outstanding options under our 2017 Plan.

#### Voting

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

#### Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

# 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

Following the closing of this offering, no holders of our common stock will have preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The

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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.

#### Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

#### Stockholder Registration Rights

The holders of our capital stock do not have the right to require us to register with the SEC any such shares of capital stock.

#### **Anti-Dilution Rights**

Pursuant to that certain Investors' Rights Agreement, dated May 22, 2017, by and among us and certain of our stockholders listed therein, in the event we issue certain equity securities, in connection with such issuances we are obligated to issue to Biocon additional shares of our common stock in order to maintain Biocon's ownership interest of our outstanding shares. Such anti-dilution rights terminate at such time we have received aggregate cumulative gross proceeds from sales of equity securities equal to \$15,000,000 and will terminate in connection with this offering.

# Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Amended and Restated Bylaws and Delaware Law

#### Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which 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 commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) 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
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

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the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

#### Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the completion of this offering, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- 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 our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- 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;
- divide our board of directors into three classes;
- 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;
- 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 notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice:
- do 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); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

In addition, our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws, and (iv) any action asserting a claim against us governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. 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.

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The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

## The Nasdaq Global Market Listing

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "EQ."

## Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

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### SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of June 30, 2018, upon the completion of this offering and assuming (1) the 1-for-8.62 stock split of all outstanding shares of our capital stock, (2) the conversion of \$9.4 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes which will automatically convert upon the completion of this offering into an aggregate of 878,834 shares of our common stock based on the initial public offering price of \$14.00 per share, and assuming the occurrence of the conversion on October 16, 2018, (3) the issuance by us of 228,060 shares of common stock upon completion of this offering to Biocon pursuant to certain anti-dilution rights that will be satisfied in full upon such issuance, (4) no exercise of the underwriters' option to purchase additional shares of common stock and (5) no exercise of outstanding options, an aggregate of 16,752,658 shares of common stock will be outstanding. All of the shares sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, unless held by an affiliate of ours. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. In addition, any shares sold in this offering to entities affiliated with our existing stockholders and directors will be subject to lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- no restricted shares will be eligible for immediate sale upon the completion of this offering;
- up to 11,876,932 restricted shares will be eligible for sale under Rule 144 or Rule 701 upon expiration of lock-up agreements 180 days after the date of this offering; and
- the remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective holding periods under Rule 144, as described below.

### **Rule 144**

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the completion of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 167,527 shares immediately after this offering; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

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Notwithstanding the availability of Rule 144, the holders of all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

### **Rule 701**

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the
  manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance
  with the six-month holding period requirement of Rule 144.

As of June 30, 2018, options to purchase a total of 107,084 shares of common stock were outstanding, none of which were vested. Of the total number of shares of our common stock issuable under these options, all are subject to contractual lock-up agreements with us or the underwriters described below under "Underwriting" and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

### **Lock-Up Agreements**

We, along with our directors, executive officers and all of our other stockholders, noteholders, and optionholders, have agreed that for a period of 180 days, after the date of this prospectus, except with the prior written consent of Jefferies LLC and Leerink Partners LLC and subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant for the sale of, or otherwise dispose of or transfer, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of the common stock. Jefferies LLC and Leerink Partners LLC have advised us that it has no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up agreements.

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

## **Registration Rights**

The holders of our capital stock do not have any rights with respect to the registration of their shares under the Securities Act.

### **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 the 2017 Plan, the 2018 Plan and the ESPP. 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.

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### MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address any state, local or non-U.S. tax consequences or U.S. federal tax consequences other than income taxes (such as U.S. federal estate or gift tax consequences). Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code such as financial institutions, insurance companies, tax-exempt organizations, tax-qualified retirement plans, broker-dealers and traders in securities, commodities or currencies, government organizations, certain foreign citizens or long-term residents of the United States, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security," integrated investment or other risk reduction strategy, holders deemed to sell our common stock under the constructive sale provisions of the Code, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders who are subject to the alternative minimum tax or the federal Medicare contribution tax on net investment income, persons who have a functional currency other than the U.S. dollar, accrual method taxpayers subject to special tax accounting rules under Section 451(b) of the Code, partnerships and other pass-through entities, and investors in such pass-through entities or entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury regulations, published administrative pronouncements, rulings and judicial decisions thereunder as of the date hereof. Such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for any Non-U.S. Holders under their particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income tax and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences. In addition, significant changes in U.S. federal income tax laws were recently enacted. You should also consult with your tax advisor with respect to such changes in U.S. tax law as well as potential conforming changes in state tax laws.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that is not a U.S. Holder. A "U.S. Holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation that is created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. Also, partnerships and their partners, or other entities that are treated as partnerships for U.S. federal income tax purposes and their equity holders (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation) are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion.

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### **Distributions on Our Common Stock**

Subject to the discussion below regarding backup withholding and foreign accounts, distributions, if any, made on our common stock to a Non-U.S. Holder generally will constitute dividends for U.S. tax purposes to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. This certification 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, U.S. Treasury regulations and the 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 such certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit if any excess amount is withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, certifying that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates applicable to U.S. residents, unless a specific treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder's adjusted basis in our common stock as a non-taxable return of capital, but not below zero, and then any excess will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

### Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally should not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States or 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation," or a USRPHC, within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period.

If you are a Non-U.S. Holder described in clause (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in clause (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in clause (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of

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the United States), provided you have timely filed U.S. federal income tax returns with respect to such losses. With respect to clause (c) above, in general, we would be a USRPHC if interests in U.S. real property constituted (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other assets, there can be no assurance that we will not become a USRPHC in the future. Even if we are treated as a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period and (2) our common stock is regularly traded on an established securities market within the meaning of applicable U.S. Treasury regulations. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market. If any gain on your disposition of our common stock is taxable because we are a USRPHC and your ownership of our common stock may be required to withhold tax with respect to that obligation.

### Information Reporting Requirements and Backup Withholding

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock (even if payments are not subject to withholding) including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed 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 otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected within the United States or through certain U.S.-related brokers, unless the holder provides a properly executed 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 otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements 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 non-U.S. 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. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax refund or credit with respect to the amount withheld.

### **Foreign Accounts**

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by applicable rules), including when the foreign financial institution holds our common stock on behalf of a Non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to 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 may include certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United

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States governing these withholding and reporting requirements may be subject to different rules. This U.S. federal withholding tax of 30% will also apply to dividends on and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity 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 direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of these rules on their investment in our common stock.

The withholding provisions described above generally apply to payments of dividends, and will apply to payments of gross proceeds from a sale or other disposition of common stock after December 31, 2018.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

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### **UNDERWRITING**

Subject to the terms and conditions set forth in the underwriting agreement, dated October 11, 2018, among us and Jefferies LLC, Leerink Partners LLC and Stifel, Nicolaus & Company, Incorporated, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

<u>UNDERWRITER</u>	NUMBER OF SHARES
Jefferies LLC	1,751,250
Leerink Partners LLC	1,751,250
Stifel, Nicolaus & Company, Incorporated	1,167,500
Total	4,670,000

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### **Commission and Expenses**

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$0.588 per share of common stock. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

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Public offering price Underwriting discounts and commissions paid by us	\$ \$	14.00 0.98	\$ \$	14.00 0.98	\$65,380,000 \$ 4,576,600	\$75,187,000 \$ 5,263,090
Proceeds to us, before expenses	\$	13.02	\$	13.02	\$60,803,400	\$69,923,910

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$2.1 million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$25,000.

### **Determination of Offering Price**

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock was determined by negotiations between us and the representatives. Among the factors considered in these negotiations were prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

### Listing

Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "EQ."

### Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 700,500 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table

### No Sales of Similar Securities

We, our officers, directors and holders of all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable
  or exercisable for or convertible into shares of common stock hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Leerink Partners LLC.

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This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC and Leerink Partners LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

### Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out 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 shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any 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 shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

## **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and

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may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### Other Activities and Relationships

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments

### **NOTICE TO HOLDERS**

### Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

### You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

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### Canada

### Resale Restrictions

The distribution of our shares in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

### Representations of Canadian Purchasers

By purchasing our shares of common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—*Prospectus Exemptions*,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

### Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters proposing to sell into Canada are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document

### Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document 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 of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

### **Enforcement of Legal Rights**

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

### Taxation and Eligibility for Investment

Canadian purchasers of our shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the share in their particular circumstances and about the eligibility of the shares for investment by the purchaser under relevant Canadian legislation.

## **European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, an offer to the public of any common shares which are the subject of the offering

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contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the 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 the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or 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 of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

### Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals,"

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each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

### Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering 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, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

### Singapore

This prospectus has not been and will not be lodged or 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 securities may not be circulated or distributed, nor may the securities 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 under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), 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.

Where the securities 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; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,
- securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the notes pursuant to an offer made under Section 275 of the SFA except:
- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

### Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

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Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

## **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

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### **LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. The underwriters are being represented by Latham & Watkins LLP, San Diego, California.

### **EXPERTS**

The financial statements of Equillium, Inc. as of December 31, 2017 and for the period from March 16, 2017 (inception) to December 31, 2017 have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2017 financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations and net capital deficiency raise substantial doubt about the entity's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

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### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus 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 can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 2223 Avenida de la Playa, Suite 108, La Jolla, CA 92037 or telephoning us at (858) 412-5302.

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 inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.equilliumbio.com, 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. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

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## EQUILLIUM, INC.

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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors Equillium, Inc.:

## **Opinion on the Financial Statements**

We have audited the accompanying balance sheet of Equillium, Inc. (the Company) as of December 31, 2017, the related statements of operations and comprehensive loss, stockholders' deficit, and cash flows for the period from March 16, 2017 (inception) to December 31, 2017, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the period from inception to December 31, 2017, in conformity with U.S. generally accepted accounting principles.

## **Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. 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. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

San Diego, California

August 3, 2018, except for the stock split described in Note 11, as to which the date is October 1, 2018

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## EQUILLIUM, INC. **Balance Sheets**

	DECEMBER 31, 2017	JUNE 30, 2018 (unauc	Pro Forma JUNE 30, 2018
Assets		(unauc	iiteu)
Current assets:			
Cash and cash equivalents	\$ 7,103,553	\$ 6,626,443	
Prepaid expenses and other current assets	45,813	79,704	
Total current assets	7,149,366	6,706,147	
Property and equipment, net	2,077	21,987	
Total assets	\$ 7,151,443	\$ 6,728,134	
Liabilities and stockholders' (deficit) equity	<del></del>		
Current liabilities:			
Accounts payable	\$ 243,741	\$ 346,848	
Accrued expenses	325,079	570,341	233,791
Total current liabilities	568,820	917,189	580,639
Long-term deferred rent	· —	278	
Long term convertible promissory notes	6,994,847	9,355,699	_
Long-term convertible promissory notes, related party	1,064,019	1,162,197	_
Biocon anti-dilution right	775,842	878,122	_
Other non-current liabilities		8,150	
Total liabilities	9,403,528	12,321,635	
Commitments and contingencies			
Stockholders' (deficit) equity:  Common stock, \$0.0001 par value; 43,100,000 shares authorized at December 31, 2017 and June 30, 2018 (unaudited); 10,708,074 and 10,975,764 shares issued as of December 31, 2017 and June 30, 2018 (unaudited), respectively; and 10,708,074 and 10,975,764 shares outstanding as of December 31, 2017 and June 30, 2018			
(unaudited), respectively	124	127	236
Additional paid-in capital	9,665	10,405	11,742,864
Accumulated deficit	(2,261,874)	(5,604,033)	
Total stockholders' (deficit) equity	(2,252,085)	(5,593,501)	6,139,067
Total liabilities and stockholders' (deficit) equity	\$ 7,151,443	\$ 6,728,134	

See accompanying notes

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# EQUILLIUM, INC. Statements of Operations and Comprehensive Loss

	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH JUNE 30, 2017	SIX MONTHS ENDED JUNE 30, 2018 udited)
Operating expenses:		(unat	idited)
Research and development	\$ 1,333,721	\$ 801,364	\$ 1,202,917
General and administrative	378,328	187,173	958,691
Total operating expenses	1,712,049	988,537	2,161,608
Loss from operations	(1,712,049)	(988,537)	(2,161,608)
Other expense (income):			
Interest expense	379,385	7,069	1,108,197
Interest income			(29,926)
Change in fair value of Biocon anti-dilution right	170,440	18,887	102,280
Total other expense (income)	549,825	25,956	1,180,551
Net loss and comprehensive loss	<u>\$ (2,261,874)</u>	<u>\$(1,014,493)</u>	\$ (3,342,159)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.19)	\$ (0.31)
Weighted-average common shares outstanding, basic and diluted	8,030,029	5,307,596	10,711,788
Pro forma net loss per share, basic and diluted (unaudited)	\$ (0.21)		\$ (0.18)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)	8,300,869		11,679,293

See accompanying notes

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# EQUILLIUM, INC. Statements of Stockholders' Deficit

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	SHARES AMOUNT		DEFICIT	DEFICIT
Balance at March 16, 2017 (inception)	_	\$ —	\$ —	\$ —	\$ —
Issuance of founders' stock	8,620,000	100	_	_	100
Issuance of common stock to Biocon at \$0.005 per share					
for license	2,088,074	24	9,665	_	9,689
Net loss				(2,261,874)	(2,261,874)
Balance at December 31, 2017	10,708,074	\$ 124	\$ 9,665	<u>\$ (2,261,874)</u>	\$ (2,252,085)
Issuance of common stock, net of liability (unaudited)	267,690	\$ 3	\$ —	\$ —	\$ 3
Stock-based compensation expense (unaudited)		_	740	_	740
Net loss (unaudited)	_	_	_	(3,342,159)	(3,342,159)
Balance at June 30, 2018 (unaudited)	10,975,764	\$ 127	\$ 10,405	\$ (5,604,033)	\$ (5,593,501)

See accompanying notes

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## **Table of Contents**

## EQUILLIUM, INC. **Statements of Cash Flows**

	MA (INCEF	R THE PERIOD RCH 16, 2017 PTION) THROUGH ECEMBER 31, 2017	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH JUNE 30, 2017		SIX I	MONTHS ENDED JUNE 30, 2018	
				(unaudit	ed)		
Operating activities:	•	(0.004.074)	•	(4.04.4.400)	•	(0.040.450)	
Net loss	\$	(2,261,874)	\$	(1,014,493)	\$	(3,342,159)	
Adjustments to reconcile net loss to cash used in							
operating activities: Depreciation and amortization		122				1,913	
Stock-based compensation		122		_		740	
Deferred rent		<u></u>		_		278	
Non-cash interest expense		379,385		7,069		1,108,197	
Change in fair value of Biocon anti-dilution right		170,440		18,887		102,280	
Non-cash research license expense		615,091		615,091			
Changes in operating assets and liabilities:		0.0,00.		0.0,00.			
Prepaid expenses and other current assets		(45,813)		(4,497)		(26,404)	
Accounts payable		243,740		9,875		103,108	
Accrued expenses		236,708		184,527		(5,634)	
Net cash used in operating activities		(662,201)		(183,541)		(2,057,681)	
Investing activities:		, ,		, , ,		, , , ,	
Purchases of property and equipment		(2,199)		_		(21,823)	
Net cash used in investing activities	-	(2,199)	<u> </u>	_		(21,823)	
Financing activities:		. ,					
Proceeds from issuance of convertible promissory							
notes, net		6,767,853		_		1,599,012	
Proceeds from issuance of convertible promissory							
notes, related party		1,000,000		1,000,000		_	
Proceeds from issuance of common stock		100		_			
Proceeds from issuance of unvested common stock		_				3,382	
Net cash provided by financing activities		7,767,953		1,000,000		1,602,394	
Net decrease in cash and cash equivalents		7,103,553		816,459		(477,110)	
Cash and cash equivalents at beginning of period						7,103,553	
Cash and cash equivalents at end of period	\$	7,103,553	\$	816,459	\$	6,626,443	
Supplemental disclosures of noncash activities							
Issuance of common stock to Biocon for license		9,689		9,689		_	
	\$	9,689	\$	9,689	\$	_	
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u>-</u>		

See accompanying notes

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### 1. Organization and Basis of Presentation

### Description of Business

The Company was incorporated in the state of Delaware on March 16, 2017, under the name Attenuate Biopharmaceuticals, Inc. On May 18, 2017, the Company changed its name to Equillium, Inc. (the "Company"). The Company is engaged in the research and development of products for severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need.

The Company has devoted substantially all of its efforts on organizing and staffing our company, business planning, raising capital, in-licensing rights to EQ001, conducting preclinical research, filing our initial IND and preparing to commence clinical development of EQ001. In addition, the Company has a limited operating history, has not generated revenues from its principal operations, and the sales and income potential of its business is unproven. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

### Liquidity

The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of \$2.3 million and \$5.6 million at December 31, 2017 and June 30, 2018 (unaudited), respectively. In 2017, the Company used \$0.7 million in cash for operations. For the six month period ended June 30, 2018 (unaudited), the Company used \$2.1 million in cash for operations. At December 31, 2017 and June 30, 2018 (unaudited), the Company had cash and cash equivalents of \$7.1 million and \$6.6 million, respectively. Management expects operating losses and negative cash flows to continue for at least the next several years as the Company continues to incur costs related to the development of EQ001. Management has prepared cash flow forecasts which indicate that based on the Company's expected operating losses and negative cash flows, there is substantial doubt about the Company's ability to continue as a going concern without raising additional capital within 12 months after the date that the financial statements for the period March 16, 2017 (inception) through December 31, 2017 are issued.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management intends to raise additional capital through a combination of equity offerings, debt financings, and collaboration and license agreements. However, the Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products or proprietary technologies or grant licenses on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

## 2. Summary of Significant Accounting Policies

### Use of Estimates

The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of the Company's financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

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### Unaudited Interim Financial Information

The accompanying interim balance sheet as of June 30, 2018, and the statements of operations and comprehensive loss and cash flows for the period March 16, 2017 (inception) through June 30, 2017 and the six months ended June 30, 2018 and the statement of stockholders' deficit for the six months ended June 30, 2018 and the related footnote disclosures are unaudited. These unaudited interim financial statements have been prepared in accordance with GAAP. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in management's opinion, all adjustments of a normal, recurring nature that are necessary for the fair statement of the Company's financial position as of June 30, 2018 and its results of operations and cash flows for the period ended June 30, 2017 and the six months ended June 30, 2018. The results for the six months ended June 30, 2018 are not necessarily indicative of the results expected for the full fiscal year or any other period.

### Unaudited Pro Forma Balance Sheet Information

The unaudited pro forma balance sheet information as of June 30, 2018 gives effect to the issuance of \$9.4 million of convertible promissory notes issued in October 2017, November 2017, April 2018, and June 2018 (see Note 6) and the automatic conversion of such notes (including accrued interest thereon) into shares of common stock upon completion of this offering, at the initial public offering price of \$14.00 per share. The unaudited pro forma balance sheet assumes that the completion of the IPO had occurred as of June 30, 2018 and excludes shares of common stock issued in the offering and any related net proceeds.

### Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

### Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency gains and losses. Comprehensive loss is the same as the net loss for the period ended December 31, 2017 and six months ended June 30, 2018 (unaudited).

### Fair Value of Financial Instruments

The carrying amounts of all prepaid and other current assets, accounts payable, accrued expenses, and debt are considered to be representative of their respective fair values because of the short-term nature of those instruments.

### Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally two to five years, or the remaining term of the lease).

### Accrued Research and Development Expense

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its financial statements by matching those

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expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. The Company determines accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, the Company adjusts its rate of expense recognition if actual results differ from its estimates.

### Research and Development

Research and development expenses include salaries, benefits, costs to third-party contractors to perform research and development activities, and associated overhead expenses. Research and development costs are expensed as incurred.

#### Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the statement of operations

### Debt Costs

The Company capitalizes related debt issuance costs and amortizes them over the life of the loan using the effective interest method. Conversion discounts on the Company's convertible promissory notes based on a future round of financing are recognized as additional interest expense over the life of the debt using the effective interest method.

### **Deferred Rent**

Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company leases. The Company's leases for its facilities provide for fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease terms are being charged to rent expense ratably over the life of the leases.

### **Biocon Anti-Dilution Right**

The Company has committed to issue to Biocon SA (together with Biocon Limited, "Biocon") additional shares of common stock to maintain Biocon's ownership interest at 19.5% of the diluted Company shares outstanding (as defined in the License Agreements (as defined below)) until the Company has received aggregate cumulative gross proceeds from sales of equity securities of \$15.0 million ("Biocon Anti-Dilution Right"). As an obligation exists to issue a variable number of shares and that obligation is not indexed to the Company's common stock, the Biocon Anti-Dilution Right has been classified as a liability in the accompanying balance sheet. The Biocon Anti-Dilution Right is recorded at fair value using the Precedent Transaction Method. The fair value of the Biocon Anti-Dilution Right is re-measured at each financial reporting period with any changes in fair value recognized as a component of other expense (income).

## Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee and non-employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The exercise price for all stock options granted was at the estimated fair value of the underlying common stock as determined on the date of grant by the Company's Board of Directors.

### Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the

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differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2017, and as of June 30, 2018, the Company maintained valuation allowances against its deferred tax assets as the Company concluded it had not met the "more likely than not" to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

### Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include outstanding stock options under the Company's equity incentive plan and have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH JUNE 30, 2017	SIX MONTHS ENDED JUNE 30, 2018
Common stock options Biocon anti-dilution right	_	(unaudited) —	374,774
Total			374,774

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### Unaudited Pro Forma Net Loss Per Share

The following table summarizes the unaudited pro forma net loss per share:

		MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017 (unaudited)		
Net loss attributable to common stockholders	\$	(2,261,874)	\$ (3,342,159)	
Add:				
Interest expense on convertible promissory notes		379,385	1,108,197	
Change in fair value of Biocon anti-dilution right		170,440	102,280	
Pro forma net loss	\$	(1,712,049)	\$ (2,131,682)	
Weighted-average common shares outstanding, basic and diluted	-	8,030,029	10,711,788	
Add:				
Pro forma adjustments to reflect assumed conversion of convertible promissory notes and				
settlement of Biocon anti-dilution right into common shares		270,840	967,505	
Pro forma weighted-average common shares outstanding, basic and diluted		8,300,869	11,679,293	
Pro forma net loss per share attributable to common stockholders, basic and diluted		(0.21)	(0.18)	

FOR THE PERIOD

### Recent Accounting Pronouncements

In February 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2016-02, Leases (Topic 842), which amends the FASB Accounting Standards Codification and creates Topic 842, "Leases." The new topic supersedes Topic 840, "Leases," and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018. ASU 2016-02 mandates a modified retrospective transition method. The Company entered into a lease in 2018 and will evaluate the impact of adoption of the ASU on its financial statements.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230)*. ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice for certain cash receipts and cash payments. The standard is effective for annual reporting periods beginning after December 15, 2018 and interim periods reporting within fiscal years beginning after December 15, 2019, with early adoption permitted. The Company does not believe the adoption of this guidance will have a material impact on the financial statements.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Non-Employee Share-Based Payment Accounting (Topic 718)*. ASU 2018-07 aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance of share-based payments to employees, with certain exceptions. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date, which may lower their cost and reduce volatility in the income statement. The standard is effective in annual periods beginning after December 15, 2018 including interim periods within that fiscal year, with early adoption permitted but not before the Company adopts ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The Company early adopted this guidance as of January 1, 2018.

### 3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based

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measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities

**Level 2**—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

At December 31, 2017 and June 30, 2018, the Company did not have financial assets that are measured at fair value on a recurring basis. The carrying amounts of the Company's financial instruments, including cash and cash equivalents, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The Company believes the fair value of its convertible promissory notes approximates its carrying value. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The Company estimated the fair value of its Biocon Anti-Dilution Right (see Note 5) at the time of issuance and remeasures it at each reporting date using the Precedent Transaction Method. The Precedent Transaction Method was applied to solve for the enterprise value of the Company under two scenarios: with the Biocon Anti-Dilution Right and without the Biocon Anti-Dilution Right. The resulting difference in the enterprise value under these two scenarios is the estimated fair value of the Biocon Anti-Dilution Right. The estimates used to determine the enterprise value of the Company are based, in part, on subjective assumptions and could differ materially in the future. Fluctuations in the fair value of the Biocon Anti-Dilution Right are impacted by unobservable inputs, most significantly the estimated fair value of the Company and probability of achieving different financing scenarios. If the Company does not receive proceeds from an equity financing, the fair value of the Biocon Anti-Dilution Right would be zero. Alternatively, if an equity financing results in gross proceeds of \$15.0 million or greater, the fair value of the Biocon Anti-Dilution Right could be as high as \$3.6 million. Changes in the estimated fair value of the Company and the probability of achieving different financing scenarios can have a significant impact on the fair value of the Biocon Anti-Dilution Right.

Financial liabilities measured at fair value on a recurring basis consist of the Biocon Anti-Dilution Right. As of December 31, 2017 and June 30, 2018 (unaudited), the carrying amount of the Biocon Anti-Dilution Right was \$0.8 million and \$0.9 million, respectively, which approximates fair value and was determined based upon Level 3 inputs. As of December 31, 2017 and June 30, 2018, the Company did not hold any Level 1 or Level 2 financial liabilities that are recorded at fair value on a recurring basis.

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The following table presents activity for the Biocon Anti-Dilution Right measured at fair value using Level 3 unobservable inputs as of December 31, 2017 and June 30, 2018 (unaudited):

	AT RI DAT SIGI UNOB	UREMENTS EPORTING IE USING NIFICANT SERVABLE S (LEVEL 3)
Balance at March 16, 2017 (inception)	\$	_
Issuance of Biocon anti-dilution right		605,402
Changes in fair value of Biocon anti-dilution right		170,440
Balance at December 31, 2017		775,842
Changes in fair value of Biocon anti-dilution right		102,280
Balance at June 30, 2018 (unaudited)	\$	878,122

**FAIR VALUE** 

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DECEMBER 24

### 4. Accrued Expenses

Accrued expenses consist of the following:

	2017	2018
		(unaudited)
Accrued payroll and other employee benefits	\$ 15,548	\$ 137,487
Accrued interest	88,372	336,550
Preclinical studies	36,000	63,880
Accrued taxes	184,527	_
Other accruals	632	32,424
Accrued expenses	\$ 325,079	\$ 570,341
•		

### 5. Collaboration and License Agreement

In May 2017, the Company entered into a collaboration and license agreement, clinical supply agreement, investor rights agreement, and common stock purchase agreement (collectively "License Agreements") with Biocon. Pursuant to the License Agreements, Biocon granted the Company an exclusive license in the United States and Canada ("Company Territory") to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit EQ001 and any pharmaceutical composition or preparation containing or comprising EQ001 ("Biocon Product") that uses Biocon technology or Biocon know-how. Pursuant to the License Agreements, Biocon agreed to be the Company's exclusive supplier of EQ001 clinical drug product for up to three concurrent orphan drug clinical indications at no cost until the Company's first U.S. regulatory approval and all other clinical drug product at cost.

In consideration of the rights granted to the Company by Biocon, the Company issued Biocon shares of its common stock equal to 19.5% of its outstanding shares at the time of the execution of the License Agreements. Biocon also has a Biocon Anti-Dilution Right (see Note 2) which is recorded at fair value using the Precedent Transaction Method (see Note 3) and was determined to be \$605,402 at the time of issuance. As an obligation exists to issue a variable number of shares and such obligation is not indexed to the Company's common stock, the Biocon Anti-Dilution Right has been classified as a liability in the accompanying balance sheet. The fair value of the Biocon Anti-Dilution Right is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other expense (income). As of December 31, 2017, and June 30, 2018 (unaudited), the fair value of the Biocon Anti-Dilution Right was \$775,842 and \$878,122, respectively.

In addition, the Company is obligated to pay Biocon up to an aggregate of \$30 million in regulatory milestone payments upon the achievement of certain regulatory approvals and up to an aggregate of \$565 million in sales

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milestone payments upon the achievement of first commercial sale of product and specified levels of product sales. The Company is also required to pay quarterly tiered royalties based on a percentage from the mid-single digits to sub-teen double-digits of net sales of Biocon Products, subject to adjustments in certain circumstances. Biocon is also required to pay the Company royalties at comparable percentages for sales of EQ001 outside of the Company Territory if the approvals in such geographies included or referenced the Company's data. To date, the Company has not made or received payments in connection with the milestones or royalties within the agreement.

### 6. Convertible Promissory Notes

In May 2017, the Company issued \$1,000,000 in convertible promissory notes to its founders ("Founder Notes"). The Founder Notes accrued interest at a rate of 6% a year and mature one year from issuance. The Founder Notes are convertible at the option of the holder upon a Qualified Financing (as defined below).

In October 2017, November 2017, April 2018, and June 2018, the Company entered into note purchase agreements whereby the Company agreed to issue and investors (the "Noteholders") agreed to purchase \$9,407,474 in convertible promissory notes (the "Convertible Promissory Notes"). As part of the October 2017 Convertible Promissory Notes, the Founder Notes were amended and restated on terms matching the Convertible Promissory Notes and the then outstanding principal and accrued interest thereunder was included as the principal amount of each such amended and restated Convertible Promissory Note. The Convertible Promissory Notes accrue interest at a rate of 6% per year and mature two years from their issuance.

The Convertible Promissory Notes automatically convert into equity securities sold pursuant to a qualified financing ("Qualified Financing") transaction from which the Company receives total gross proceeds of not less than \$15 million at a conversion price equal to 90% of the per share price paid by investors for such securities if the closing of the financing occurs on or prior to the six month anniversary of the issuance of Convertible Promissory Notes or at a conversion price equal to 80% of the per share price paid by investors for such securities if the closing of the financing occurs after the six month anniversary of the issuance of Convertible Promissory Notes.

The Company recorded interest expense of \$379,385 and \$1,108,197 using the effective-interest method for the period ending December 31, 2017 and the six months ended June 30, 2018 (unaudited), respectively, in relation to stated interest and the estimated discount at which the Convertible Promissory Notes will convert.

The following is a summary of all debt obligations recorded on the balance sheet at December 31, 2017 and June 30, 2018:

	DE	CEMBER 31, 2017	JUNE 30, 2018
			(unaudited)
Convertible promissory notes (inclusive of related party)	\$	7,807,474	\$ 9,407,474
Accrued premium		251,392	1,110,422
Total convertible promissory notes	\$	8,058,866	\$10,517,896

## 7. Stockholders' Deficit

During 2017, the Company issued 8,620,000 shares of common stock to founders at a price of \$0.00001 per share and 2,088,074 shares of common stock to Biocon as partial consideration for the License Agreements (Note 5). The shares issued to Biocon were valued at \$0.005 per share, resulting in \$9,689 of research license expense.

## Stock Options

In December 2017, the Company adopted the 2017 Equity Incentive Plan (the "Plan"). The Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards. As of December 31, 2017 and June 30, 2018 (unaudited), the number of shares reserved under the Plan was 1,189,773.

There were 1,189,773 and 814,999 shares available for grant under the Plan as of December 31, 2017 and June 30, 2018 (unaudited), respectively. Options granted under the Plan are exercisable at various dates as

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determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the Board of Directors based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. Most option grants generally vest 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years and early exercise is permitted.

WEIGHTED

WEIGHTED

A summary of the Company's stock option activity under the Plan is as follows:

	TOTAL OPTIONS	AVE EXE PRIC	ERAGE ERCISE DE PER	AVERAGE REMAINING CONTRACT TERM	INT	REGATE RINSIC ALUE
Outstanding at December 31, 2017		\$	_	_	\$	_
Granted	374,774		0.05	10.0		2,609
Exercised	(267,690)		0.05	9.9		1,863
Cancelled	_					_
Outstanding at June 30, 2018 (unaudited)	107,084	\$			\$	
Vested and expected to vest at December 31, 2017		\$	_	_	\$	
Vested and exercisable at December 31, 2017		\$	_	_	\$	
Vested and expected to vest at June 30, 2018 (unaudited)	107,084	\$	0.05	9.9	\$	745
Vested and exercisable at June 30, 2018 (unaudited)	374,774	\$	0.05	9.9	\$	261

For the period ended December 31, 2017 and six months ended June 30, 2018 (unaudited), the total grant date fair value of vested options was \$0 and \$0.03 per share, respectively.

The weighted-average grant date fair value of employee option grants during the period ended December 31, 2017 and the six months ended June 30, 2018 (unaudited) was \$0 and \$0.03 per share, respectively.

### Liability for Early Exercise of Restricted Stock Options

Certain individuals were granted the ability to early exercise their stock options. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The cash received, net of par value, in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the accompanying balance sheets and will be transferred into additional paid-in capital as the shares vest. As of December 31, 2017 and June 30, 2018 (unaudited), there were 0 and 267,690, respectively, shares subject to repurchase by the Company. As of December 31, 2017 and June 30, 2018 (unaudited), the Company recorded \$0 and \$10,866, respectively, of liabilities associated with shares issued with repurchase rights.

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### Stock-Based Compensation Expense

The Company recognized stock-based compensation expense of \$0 for the period ended December 31, 2017 and \$740 for the six months ended June 30, 2018 (unaudited).

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	FOR THE PERIOD MARCH 16, 2017 (INCEPTION) THROUGH DECEMBER 31, 2017	(INCEPTION)	
		(unaudited)	
Risk-free rate of interest	_	<u>—</u>	2.86% - 2.88%
Expected term (years)	<del>-</del>	_	5.75 - 6.08
Expected stock price volatility	<del>-</del>	_	85.56%
Dividend yield	<del>_</del>	_	_

Risk-free interest rate. The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected volatility. Due to the Company's limited operating history and lack of company-specific historical or implied volatility as a private company, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

Expected term. The expected term of stock options represents the weighted-average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected dividend yield. The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

Forfeitures. The Company reduces stock-based compensation expense for actual forfeitures during the period.

As of December 31, 2017 and June 30, 2018 (unaudited), the unrecognized compensation cost related to outstanding employee and nonemployee options was \$0 and \$10,343, respectively, and is expected to be recognized as expense over approximately 0 years and 3.73 years, respectively.

## Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of December 31, 2017 and June 30, 2018:

	2017	JUNE 30, 2018
		(unaudited)
Stock options issued and outstanding	_	107,084
Authorized for future stock awards or options grants	1,189,773	814,999
Total	1,189,773	922,083

### 8. Income Taxes

Due to our net losses for the period ended December 31, 2017, and since we have a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded There were no components of current or deferred federal, state or foreign tax provisions for the period ended December 31, 2017.

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A reconciliation of the total income tax provision tax rate to the statutory federal income tax rate of 34% for the period ended December 31, 2017 is as follows:

	DECEMBER 31, 2017
Income Taxes at Statutory Rates	34.00%
State Income Tax, Net of Federal Benefit	0.00%
Permanent Items	-10.92%
Tax Law Change—Tax Reform	-8.78%
Federal Research Credit	0.41%
Change in Federal Valuation Allowance	14.7 <u>1</u> %
	0.00%

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2017 are as follows:

	DECEMBER 37	31,
Deferred tax assets:		_
Net operating loss carryforward	\$ 248,22	.2
Credits	43,16	2
Intangibles	198,29	0
Deferred tax assets	489,67	4
Deferred tax liabilities:		
Fixed Assets	(8	9)
Deferred tax liabilities	(8)	9)
Net deferred tax assets	489,58	5
Valuation allowance	(489,58	5)
Net deferred tax assets	\$ -	_

DECEMBED 2

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of \$489,585 as of December 31, 2017 as it does not believe it is more likely than not that certain deferred tax assets will be realized primarily due to the generation of pre-tax book losses in its first year, no ability to carryback losses, the lack of feasible tax-planning strategies, the limited existing taxable temporary differences, and the subjective nature of forecasting future taxable income into the future.

The Company increased its valuation allowance by approximately \$489,585 during the period ended December 31, 2017.

At December 31, 2017, the Company had federal and California tax loss carry forwards of approximately \$884,776 and \$893,787, respectively. The federal and state net operating loss carry forwards begin to expire in 2037 and 2037, respectively, if unused.

At December 31, 2017, we had federal and state tax credit carry forwards of approximately \$23,355 and \$14,344 respectively, after reduction for uncertain tax positions. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2037, if unused, and the state credits carry forward indefinitely.

Pursuant to the Internal Revenue Code ("IRC") of 1986, as amended, specifically IRC §382 and IRC §383, the Company's ability to use net operating loss and R&D tax credit carry forwards ("tax attribute carry forwards") to

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offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carry-forwards available to offset future taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, our deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC §382.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the Company, most notably a reduction of the U.S. corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017. The 2017 Tax Act also provides for the acceleration of depreciation for certain assets placed in service after September 27, 2017 as well as prospective changes beginning in 2018, including limitations on the deductibility of interest and capitalization of research and development expenditures. The Company measures deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid. Accordingly, the Company's deferred tax assets and liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate from 35% to 21%, resulting in a \$198,687 increase in tax expense for the period ended December 31, 2017 and a corresponding \$198,687 decrease in net deferred tax assets as of December 31, 2017. The impact was offset by the Company's valuation allowance.

The following table summarizes the reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2017:

	 2017
Unrecognized Tax Benefits—Beginning	\$ _
Gross increases—tax positions in prior period	_
Gross decreases—tax positions in prior period	_
Gross increase—current-period tax positions	18,849
Gross decrease—current-period tax positions	_
Settlements	_
Lapse of statute of limitations	_
Unrecognized Tax Benefits—Ending	\$ 18,849

DECEMBER 31.

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next 12 months.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheets as of December 31, 2017 and has not recognized interest and/or penalties in the Statement of Operations for the period ended December 31, 2017.

All tax years for both federal and state purposes remain open and subject to examination by tax jurisdictions.

### 9. Related-Party Transactions

In May 2017, the Company entered into License Agreements with Biocon, a pharmaceutical company in which the Company's Chief Executive Officer is on the Board of Directors.

In May 2017, the Company entered into Founder Notes with the Company's Chief Executive Officer and Chief Business Officer in the amounts of \$500,000 and \$500,000, respectively. These Founder Notes were subsequently amended and restated on terms matching the Convertible Promissory Notes and the then outstanding principal and accrued interest thereunder was included as the principal amount of each such amended and restated Convertible Promissory Note.

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### 10. Commitments and Contingencies

### Leases

The Company leases certain office space in San Diego, California under a non-cancelable operating lease, with a term through February 2022. Rent expense was \$0 and \$10,157 for the period ended December 31, 2017, and for the six months ended June 30, 2018 (unaudited).

The future minimum lease payments required under non-cancelable leases as of December 31, 2017, are summarized as follows:

 Year Ending December 31,
 \$ 47,935

 2018
 \$ 47,935

 2019
 57,522

 2020
 58,914

 2021
 59,193

 2022
 9,865

 Total minimum lease payments
 \$233,429

### Litigation

As of December 31, 2017 and June 30, 2018, there was no litigation against the Company.

### 11. Subsequent Events

For the purposes of the financial statements as of December 31, 2017 and the year then ended, the Company has evaluated the subsequent events through August 3, 2018, the date the audited annual financial statements were issued. For the purposes of the unaudited interim condensed financial statements as of June 30, 2018 and the six month period then ended, such evaluation of subsequent events has been performed through August 3, 2018.

### Forward Stock Split

On October 1, 2018, the Company amended its amended and restated certificate of incorporation to effect a one-for-8.62 forward stock split of every outstanding share of its common stock. The financial statements and accompanying footnotes have been retroactively restated to reflect the forward stock split.

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# 4,670,000 Shares



## **Common Stock**

## **PROSPECTUS**

Joint Book-Running Managers

## Jefferies Leerink Partners Stifel

October 11, 2018