424B4 1 elevation_424b4.htm 424B4

Table of Contents

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-299393

9,375,000 Shares



Common Stock

This is the initial public offering of shares of common stock by Aspen Neuroscience, Inc. We are offering 9,375,000 shares of our common stock. The initial public offering price is $15.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "ASPE."

We are an "emerging growth company" and a "smaller reporting company" under applicable Securities and Exchange Commission rules and 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 the section titled "Risk Factors" beginning on page 14 to read about factors you should consider before deciding to invest in shares of our common stock.

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.

	Per Share	Total
Initial public offering price	$ 15.00	$ 140,625,000
Underwriting discounts and commissions[(1)]	$ 1.05	$ 9,843,750
Proceeds, before expenses, to us	$ 13.95	$ 130,781,250

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

We have granted the underwriters an option for a period of 30 days to purchase up to 1,406,250 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 November 2, 2026, through the book-entry facilities of The Depository Trust Company.

Leerink Partners **Piper Sandler** **Stifel**

UBS Investment Bank **Oppenheimer & Co.**

Prospectus dated October 29, 2026

Table of Contents

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	14
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	83
MARKET AND INDUSTRY DATA	84
USE OF PROCEEDS	85
DIVIDEND POLICY	86
CAPITALIZATION	87
DILUTION	89
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	91
BUSINESS	111
MANAGEMENT	151
EXECUTIVE AND DIRECTOR COMPENSATION	159
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS	177
PRINCIPAL STOCKHOLDERS	181
DESCRIPTION OF CAPITAL STOCK	185
SHARES ELIGIBLE FOR FUTURE SALE	191
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS	194
UNDERWRITING	198
LEGAL MATTERS	205
EXPERTS	205
WHERE YOU CAN FIND MORE INFORMATION	205
INDEX TO FINANCIAL STATEMENTS	F-1

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of 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 of 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 our common stock and the distribution of this prospectus outside of the United States.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Special Note Regarding Forward-Looking Statements," and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "Aspen," the "Company," "we," "us," and "our" refer to Aspen Neuroscience, Inc.

Overview

Aspen Neuroscience, Inc. is a leading, clinical-stage regenerative medicine biotechnology company focused on developing autologous induced-pluripotent stem cell (iPSC)-derived therapies to address neurodegenerative diseases with high unmet medical need. Our lead product candidate, sasineprocel, is an investigational single-dose, autologous iPSC-based cell therapy being evaluated for the treatment of Parkinson's disease (PD). We believe sasineprocel has the potential to be disease-modifying by primarily replacing a patient's lost dopaminergic (DA) neurons with dopaminergic neuron precursor cells (DANPCs). In an ongoing Phase 1/2a ASPIRO clinical trial of sasineprocel in mid-stage to moderately advanced sporadic PD, patients have experienced, what we believe to be, sustained and clinically meaningful improvements in motor, quality of life, and non-motor symptoms as measured by comparison to clinically meaningful change benchmarks. Based on these findings, we believe sasineprocel has the potential to improve upon the current standard of care in PD and address the significant unmet need in PD for a disease-modifying therapy that may slow or halt the progression of this devastating disease.

PD is a progressive neurodegenerative disease primarily characterized by the loss of DA neurons as well as impaired DA neurotransmission that results in the progressive deterioration of motor and non-motor neurological function. It is the second most common neurodegenerative disorder, estimated to affect more than one million people in the United States and more than 10 million people globally. The prevalence has doubled globally over the past 25 years, making it one of the fastest growing central nervous system (CNS) diseases. PD patients suffer from characteristic motor symptoms, including movement, coordination and speech impairments, as well as non-motor symptoms, including loss of sense of smell, sleep behavior disorders, difficulty swallowing, urinary symptoms, constipation, orthostatic hypotension, depression, psychosis, dementia and cognitive impairment. These symptoms can severely impact a patient's quality of life, contribute to progressive disability and loss of independence, and are associated with increased morbidity and mortality over time.

The current standard of care is palliative dopamine replacement therapy (DRT), including levodopa and dopamine agonists, which addresses motor symptoms but does not replace lost DA neurons, nor does it slow continued neuronal degeneration. DRT inadequately addresses non-motor symptoms, decreases in effectiveness over time, and is associated with side effects that can significantly impact patient quality of life. As DRT loses its effectiveness or as its side effects become intolerable, advanced therapies, such as deep brain stimulation (DBS), are considered. While DBS can be effective in addressing certain motor symptoms of PD, it has not been shown to slow disease progression in mid-stage to moderately advanced PD patients and can potentially worsen cognition, gait, speech and other axial symptoms. DBS has other drawbacks as well, including frequent long delays in access and optimization, and multiple invasive surgeries with permanent implanted hardware, which includes risks such as hemorrhage, infection, and device failure. In contrast to DRT and DBS, cell replacement therapy holds significant promise as an approach to restore and replace lost dopamine neurons and neural circuitry necessary for normal motor and non-motor function. We believe our cell replacement approach represents a promising therapy that could provide long-term benefits from a single administration without the need for permanently implanted hardware.

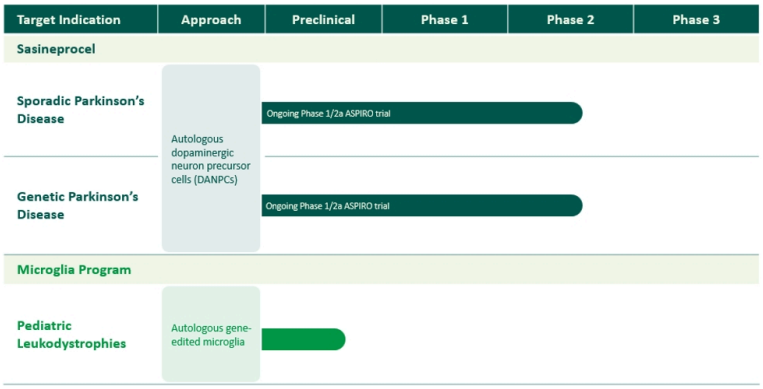
Table of Contents

Allogeneic approaches in development for PD can require one year or more of immunosuppressive therapy post-treatment, which is associated with increased risks of infection, organ toxicity, and metabolic complications. In contrast, autologous cell therapies are derived from a patient's own cells, which reduces the risk of immune rejection after transplantation. Our clinical trial of sasineprocel has not required any immunosuppression post-administration and is designed to support the formation of functional synaptic connections and neural circuitry without the need for immune suppression. In a third-party preclinical study in non-human primate (NHP) models of PD, autologous DA progenitor cell transplantation survived without immunosuppression and integrated more robustly and produced more sustained motor improvements than allogeneic transplants. Moreover, our autologous iPSC approach is designed to require minimal cell expansion, which may reduce the opportunity for genomic abnormalities to arise and for cells harboring growth-promoting abnormalities to become selectively enriched during extended culture. While this is designed to be a one-time therapy, the autologous nature of the product could allow for redosing, if valuable over a patient's multi-year course. We believe our autologous cell replacement strategy presents a significant advantage over both current standard-of-care therapies and allogeneic cell therapies in development for PD, and has the potential to deliver a tolerable, disease-modifying treatment with durable, long-term effectiveness.

Sasineprocel and our end-to-end autologous iPSC platform are based on advances in cellular reprogramming, including the Nobel Prize–winning discovery by Shinya Yamanaka and John B. Gurdon, which demonstrated that mature, specialized cells can be reprogrammed into iPSCs through the introduction of defined transcription factors (commonly referred to as Yamanaka factors). We combine these foundational reprogramming methods with our stem cell biology expertise, the latest artificial intelligence, machine learning (ML) and genomic approaches to optimize cell identity, purity and functional potential and to enable a scalable, reproducible, standardized, and data-driven manufacturing process for autologous cell therapy. Sasineprocel, our proprietary autologous iPSC-derived composition of DANPCs, CNS progenitors, and glial progenitors, is designed to establish a biologically active cellular microenvironment that supports cell engraftment, survival, and functional integration of transplanted cells with the goal of restoring functional dopamine signaling in PD patients. We believe the sustained benefit that has been observed in certain patients treated with sasineprocel provides evidence of neural circuitry reconstruction and is further supported by preclinical studies, in which we observed that DANPCs transplanted into PD animal models differentiated into DA neurons that integrated into the brain and restored dopamine signaling. We hypothesize that sasineprocel's combination of cells beyond DANPCs may play a key role in supporting neural synapse formation and general microenvironmental health to enable a broad and profound treatment effect in PD patients, including improvement in non-motor symptoms.

Our Pipeline

We are leveraging our proprietary platform to build a diversified pipeline of autologous iPSC-based therapies for the treatment of multiple CNS diseases, with an initial focus on sporadic and genetic PD. We have worldwide commercial rights to all our programs and have summarized our clinical and preclinical programs below.



We are developing sasineprocel, a single-dose, autologous iPSC-based therapeutic candidate for PD that is designed to replace a patient's lost dopamine neurons. We are currently conducting the open-label Phase 1/2a ASPIRO trial of a single dose of sasineprocel in mid-stage to moderately advanced PD patients. The trial consists of four cohorts at two dose levels, both of which were anticipated to be biologically active and have pharmacologic effects based on our preclinical modeling, with sasineprocel administered as a single bilateral intracranial injection into the post-commissural putamen using well-understood, standard stereotactic neurosurgical techniques.

As of August 18, 2026, the data cutoff date, 15 patients had been dosed, with seven participants receiving a low dose and eight participants receiving a high dose. Sasineprocel was observed to be generally well-tolerated with the majority of reported adverse events being mild to moderate. Among the patients dosed, 72 treatment-emergent adverse events (TEAEs) were reported. There was no evidence of graft-induced dyskinesias or graft rejection, and no clinically significant hemorrhages were observed post-operatively. As sasineprocel is autologous, with no requirement for immunosuppression, there were no immunosuppression-related events. Only one TEAE, myoclonus (sudden, uncontrollable muscle movement), was considered possibly related to sasineprocel, with sertraline, a selective serotonin reuptake inhibitor, identified as a co-suspect medication. One participant had two serious adverse events related to the surgical procedure. The most commonly reported TEAEs, defined as occurring in 10% or more of patients, were related to the surgery. See "Business—Our Pipeline—Lead Program: Sasineprocel for PD" for additional information regarding the safety profile observed in the ASPIRO trial. As of the data cutoff date, all 12 patients from the first three cohorts had at least one six-month or later follow up evaluation.

We assessed clinical efficacy outcomes every six months after administration of sasineprocel. We observed improvements across several secondary and exploratory endpoints, including changes in Good On Time and Movement Disorder Society-Sponsored Revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III OFF. Consistent with these motor improvements, we also observed improvements in activities of daily living and quality of life measures assessed by MDS-UPDRS Part II ON, and Parkinson's Disease Questionnaire (PDQ-39) scores, as summarized below. Certain of the secondary endpoints used in this trial, including Good On Time and MDS-UPDRS Part III OFF, are validated registrational endpoints used in previous PD registrational clinical trials. The mean improvements at 18 months in both cohorts and 24 months for the low dose cohort for Good On Time and MDS-UPDRS Part III OFF scores were above clinically meaningful change benchmarks. The mean PDQ-39 and MDS-UPDRS Part II ON scores improved above clinically meaningful change benchmarks in the low dose cohort at 18 and 24 months and were stable in the high dose cohort at 18 months. Fluorodopa (^{18}FDOPA) positron emission tomography (PET) imaging is also being used to evaluate the engraftment of cells. ^{18}FDOPA PET imaging showed elevated ^{18}FDOPA uptake values at six, 12, and 18 months following sasineprocel administration compared to baseline, which is evidence of the survival, viability, and integration of transplanted iPSCs. Clinically meaningful change benchmarks are reviewed on an ongoing basis during the trial and reflect management's belief based on a review of published literature, regulatory agency guidelines and precedent in PD clinical research, and discussions with key opinion leaders in the field. The benchmarks have not been discussed with the U.S. Food and Drug Administration (FDA) or any other government regulatory authority, and have not been independently validated by any third parties.

Additionally, the ASPIRO trial is exploring changes in DA medication as measured by levodopa equivalent daily dose (LEDD). As of the data cutoff date, in the low dose cohort, two, three, three, and three patients showed a reduction in LEDD at six, 12, 18 and 24 months, respectively, and one patient experienced an LEDD increase at 18 and 24 months. In the high dose cohort, at six months, three out of eight patients showed an LEDD reduction and one patient showed an LEDD increase; at 12 months, two out of four patients showed an LEDD reduction and one patient

Table of Contents

showed an LEDD increase; at 18 months, three out of four patients showed an LEDD reduction and one showed an LEDD increase.

	Low Dose n=4					High Dose n=8			
Month	Baseline (n=4)	6 (n=4)	12 (n=4)	18 (n=4)	24 (n=4)	Baseline (n=8)*	6 (n=8)	12 (n=4)	18 (n=4)
Mean Change in Good On Time (hrs) Hauser Diary (MCID > 1 hrs)	11.6 (2.21)	+1.6 (1.46)	+2.1 (1.46)	+2.2 (2.75)	+2.6 (1.78)	9.8 (2.48)	+2.3 (2.59)	+2.4 (1.26)	+2.7 (2.08)
Mean Change in OFF Time (hrs) Hauser Diary (MCID < 1 hrs)	4.1 (1.87)	-2.1 (1.70)	-2.0 (1.50)	-1.9 (2.46)	-2.3 (1.50)	5.5 (1.67)	-1.9 (2.31)	-2.4 (1.26)	-2.7 (2.08)
Mean Change in MDS-UPDRS part III OFF score (points) (MCID 4-5 points)	42.3 (5.32)	-17.5 (5.20)	-15.5 (9.61)	-13.0 (4.40)	-15.8 (7.54)	44.5 (9.75)	-9.6 (4.78)	-13.5 (13.87)	-19.3 (6.40)
Mean Change in MDS-UPDRS part II ON score (points) (MCID 2-4 points)	14.0 (3.46)	-7.0 (5.00)	-5.3 (5.44)	-6.0 (6.27)	-6.8 (7.14)	10.9 (7.41)	-1.4 (2.83)	-2.3 (3.30)	0.0 (3.16)
Mean Change in PDQ-39 (points) (MCID 4-5 points)	13.8 (4.21)	-5.7 (3.65)	-7.6 (7.41)	-5.0 (9.09)	-5.0 (6.30)	15.5 (12.40)	-3.1 (6.30)	-6.2 (6.88)	-3.9 (6.83)
Number of patients with LEDD reduction		2	3	3	3		3	2	3

Figure 1. Sustained improvements observed across multiple validated PD endpoints. Data summarized above is as of August 18, 2026. A decrease (negative number) compared to baseline is an improvement for MDS-UPDRS scores and PDQ-39. The numbers in parentheses represent standard deviations. Mean changes in data summarized above are driven by totality of data across patients and not driven by a limited number of patients exhibiting significantly better-than-average improvements. *For the four high dose patients for whom data was available at the 12-month and 18-month assessments, the baseline values for Good On Time (hours) Hauser Diary, Off Time (hours) Hauser Diary, MDS-UPDRS Part III OFF score, MDS-UPDRS Part II ON score, and PDQ-39 were: 11.7 (0.9), 4.3 (0.9), 44.0 (4.2), 9.5 (9.3), 16.1 (15.6), respectively. For the three low dose patients in Cohort 4, no data is yet available because six months have not elapsed since dosing for all three patients.

The Phase 1/2a ASPIRO trial is an open-label trial and does not include a placebo or control cohort. Open-label trials are subject to inherent limitations that may affect the interpretation of clinical results and may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control. See “Risk Factors—Risks Related to the Discovery, Development, and Regulatory Approval of Our Product Candidates” for additional information regarding the limitations of our clinical trial design.

Sasineprocel has received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for the treatment of levodopa-responsive PD, and Fast Track designation from the FDA for the treatment of PD to improve motor function. RMAT or Fast Track designation does not ensure a faster development or regulatory review or approval process and does not increase the likelihood that sasineprocel will receive regulatory approval. We anticipate that sasineprocel would be regulated as a combination product by the FDA because it is designed to be administered through drug delivery devices. See the section titled “Risk Factors—RMAT and Fast Track designation by the FDA for sasineprocel, and other expedited designations if granted in the future, may not lead to a faster development or regulatory review or approval process, and do not increase the likelihood that sasineprocel or any other product candidate which may receive such designations will receive regulatory approval” for more information. We expect to report further long-term data from the ASPIRO trial in the first half of 2028. We have begun enrolling patients and are preparing to initiate dosing a new cohort in the Phase 1/2a ASPIRO trial to evaluate sasineprocel in patients with genetic PD. We anticipate initiating biopsy collection for the Phase 3 trial by the end of 2026. Following feedback from the FDA, we anticipate dosing patients in the Phase 3 trial in the second half of 2027. In addition, we plan to dose a single cohort of approximately three to six patients with genetic PD in the ASPIRO trial. Pending results from this cohort, we intend to include all patients with PD (including both sporadic and genetic PD) in our Phase 3 program.

Table of Contents

We are also developing a microglia program initially targeting pediatric leukodystrophies, a group of rare, genetically defined neurological disorders that primarily affect the white matter of the CNS. Our approach is designed to generate autologous, gene-corrected microglia precursor cells derived from patient-derived iPSCs. We utilize targeted genome editing approaches to address disease-associated genetic variants. These gene-corrected cells are then differentiated into microglia precursor cells intended for administration to the CNS, where they are designed to engraft and replace dysfunctional microglia and support the restoration of key microglial functions within the CNS. We expect to initiate Investigational New Drug application (IND)-enabling studies in the second half of 2027.

Our Manufacturing Platform and Scientific Approach

We have developed an integrated, end-to-end autologous iPSC platform (our platform) designed to generate patient-specific cell therapies for neurodegenerative diseases. Our platform combines proprietary cell reprogramming methods, automated and scalable manufacturing processes, and comprehensive quality control (QC) systems, including advanced genomics and bioinformatics, to produce DANPCs with consistent identity, purity, and functional characteristics.

To manufacture sasineprocel, dermal fibroblast cells are generated from a PD patient via a minimally invasive skin biopsy (3mm), expanded, and reprogrammed into iPSCs using defined transcription factors (Yamanaka factors). These iPSCs undergo rigorous characterization to confirm sterility, identity, purity and pluripotency, and are subsequently differentiated into DANPCs using our proprietary processes. The final product consists primarily of DANPCs with defined levels of supporting neural progenitor cell types, and is cryopreserved and released based on established specifications for cell concentration, purity, identity, and potency before shipment for patient administration. We are reliant on a number of licenses from third parties for our manufacturing platform, as it relates to sasineprocel, including from iPS Academia Japan, Inc. and Sumitomo Pharma Co. Ltd. for transcription factors and reprogramming methods, the Scripps Research Institute for a specific cell characterization assay, and Cell X Technologies, Inc. (Cell X) and Cleveland Clinic Foundation (CCF) for automation. See “Business—Licensing and Collaboration Agreements” for additional information.

Our platform is designed to address key challenges associated with autologous cell therapies, including inter-patient variability, genomic instability, and inconsistent differentiation. To mitigate these risks, we utilize multiple orthogonal assays and proprietary reference datasets to assess genetic identity, genomic integrity, lineage specification, purity, and functional attributes prior to clinical use. Building on foundational work from our scientific founders, we have established rigorous product release criteria supported by these datasets to enable consistent product characterization, including DANPC identity, maturity, engraftment potential and dopamine release, complemented by *in vitro* bioassays assessing cellular functionality and post-cryopreservation stability. In parallel, we are developing an automated, robust, modular manufacturing framework designed to streamline and standardize production, reduce manual variability and support scalable, reproducible manufacturing with the capacity to treat hundreds of patients annually. This modular automation template has a small cleanroom footprint (approximately 5,000 square feet) and is intended to be replicated and scaled up to meet future patient demand. The production process is performed in three stages. Stage 1 (skin to fibroblast) has a manufacturing duration of approximately three weeks. Stage 2 (fibroblasts to iPSCs) has a duration of approximately eight weeks. Stage 3 (iPSCs to DANPCs) has a duration of approximately five weeks. Following each stage, we complete QC testing which typically takes a total of four to five weeks. However, following Stage 1 and Stage 2, we perform initial QC testing to conditionally release the fibroblasts and iPSCs to the next stage, which typically takes one to two weeks, before completing the full QC testing process.

Our History, Team and Investors

We have assembled a management team and scientific organization with substantial experience across neuroscience research, drug discovery and development, regulatory strategy, commercialization and manufacturing. Aspen Neuroscience was founded in 2018 based on more than two decades of research conducted by Jeanne F. Loring, Ph.D., Professor Emerita at the Scripps Research Institute and founding Director of the Center for Regenerative Medicine. Dr. Loring’s laboratory developed foundational methods for reprogramming adult human cells into iPSCs and subsequently differentiating them into dopamine-producing neurons, which form the basis of our autologous iPSC

platform and sasineprocel. Since inception, we have focused on translating this academic innovation into a clinically scalable, regulatory-compliant therapeutics platform.

Damien McDevitt, Ph.D., our Chief Executive Officer, previously served as Chief Executive Officer of Akcea Therapeutics, a rare diseases company, prior to its acquisition by Ionis Pharmaceuticals in 2020, and held several leadership roles at Ionis Pharmaceuticals, Acadia Pharmaceuticals, and GlaxoSmithKline Pharmaceuticals. Dr. McDevitt was involved in the commercialization, late-stage development or in-licensing of the following approved products: TEGSEDI (inotersen) for hereditary transthyretin-mediated amyloidosis, WAYLIVRA (volanesorsen) for familial chylomicronemia syndrome (approved in the European Union) and DAYBUE (trofinetide) for Rett syndrome. Lisa Johnson-Pratt, M.D., our Sasineprocel Development Lead and Chief Commercial Officer, has successfully led programs across the entire product life cycle with leadership roles in medical affairs, clinical development, product development, portfolio planning and new product strategy. Dr. Johnson-Pratt was involved in the launch of GARDASIL (human papillomavirus 9-valent vaccine, recombinant), IMITREX (sumatriptan) and MAXALT (rizatriptan benzoate), and new indication launches of SINGULAIR (montelukast sodium) and COZAAR (losartan potassium), and led new product strategy for BLENREP (belantamab mafodotin-blmf), WAINUA (eplontersen), and TRYNGOLZA (olezarsen).

The Executive Chairman of our Board of Directors, Faheem Hasnain, is the Co-Founder, Chairman and Chief Executive Officer of Gossamer Bio. Mr. Hasnain previously served as President, Chief Executive Officer and Director of Receptos, which was acquired by Celgene in 2015. He is joined by a distinguished group of Board members who bring additional operational, scientific, financial and strategic expertise. Since our inception, we have raised approximately $347 million from a syndicate of leading life sciences investors and organizations, including OrbiMed, ARCH Venture Partners, Frazier Life Sciences, Medical Excellence Capital, and Kite, a Gilead Company, as well as support from the California Institute for Regenerative Medicine (CIRM). We believe our investor base reflects confidence in our scientific approach, platform capabilities and development strategy. Prospective investors, however, should not rely on the investment decisions of our existing investors, as those investors may have different risk tolerances and may have acquired their shares at prices lower than the price to public investors in this offering.

Our Strategy

We are committed to developing and delivering novel autologous iPSC-derived cell replacement therapies for patients with significant unmet medical need, beginning with PD. Our strategy to achieve this mission includes the following key elements:

- Advance sasineprocel, our personalized potentially disease-modifying product candidate for PD patients, through Phase 3 trials for sporadic PD.
- Expand development of sasineprocel into genetic PD and maximize the therapeutic potential of sasineprocel across PD patients.
- Build scalable, automated autologous cell manufacturing to support potential commercialization in North America (United States and Canada) with plans in the future to expand globally.
- Maximize the commercial opportunity of sasineprocel and opportunistically engage in strategic collaborations.
- Expand our pipeline by leveraging our platform to identify and develop additional product candidates in CNS indications where cell replacement therapy offers meaningful therapeutic potential.

Summary of Risks Associated with Our Business

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

- We are a clinical-stage regenerative medicine biotechnology company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of product candidates and the prospects for our future viability.

Table of Contents

- We have incurred substantial operating losses since our inception and expect to incur substantial losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- Even if this offering is successful, we will require substantial additional capital to finance our operations, and failure to obtain additional capital when needed, or on acceptable terms, could cause us to delay, limit, reduce, or terminate product development programs, commercialization efforts or other operations.
- We currently depend on the success of sasineprocel, which is our lead product candidate. If we are unable to advance sasineprocel in clinical development, obtain regulatory approval for and ultimately commercialize sasineprocel or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially and adversely affected.
- Sasineprocel is based on a novel approach to treat PD, which makes it difficult to predict the time and cost of product candidate development and to obtain regulatory approval, if at all.
- Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our current or future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.
- We have concentrated our research and development efforts on the treatment of disorders of the CNS, a field that faces certain challenges in drug development.
- Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current, planned or potential future clinical trials or preclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.
- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We have not as an organization completed clinical trials or submitted a BLA, and we may be unable to do so for sasineprocel or other product candidates.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.
- The manufacture of sasineprocel as an autologous cell therapy involves significant variability that may result in manufacturing failures, treatment delays, or inconsistent product quality, any of which could have a material adverse effect on our business, financial condition, and results of operations.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, our product development programs and our ability to seek or obtain regulatory approval for or commercialize our products may be delayed.

Table of Contents

- We rely on third parties for certain manufacturing systems, materials and components for our product candidates and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not be able to manufacture sufficient quantities of our products or such quantities at an acceptable cost, which could delay, prevent, or impair, our development or commercialization efforts.
- Any product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.
- The commercial success of sasineprocel and other product candidates will depend upon the degree of market acceptance of such product by physicians, patients, healthcare payors, and others in the medical community.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- If we are unable to obtain, maintain, defend, and enforce patent or other intellectual property protection for our product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.
- We are aware of third-party patents containing claims that may cover certain methods that we may use to manufacture sasineprocel. Assertion of these patents could result in significant costs and could adversely affect our ability to manufacture, develop or commercialize sasineprocel.
- There has been no public market for our common stock. An active, liquid, and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your common stock at or above the initial public offering price or at all.
- The trading price of the shares of our common stock may be highly volatile, and purchasers of our common stock could lose all or part of their investment.

Corporate Information

We were incorporated in Delaware on May 18, 2018, under the name Aspen Biosciences, Inc. and changed our name to Aspen Neuroscience, Inc. in October 2018. Our principal executive offices are located at 10835 Road to the Cure, Suite 100, San Diego, CA 92121. Our telephone number is (858) 263-1222. Our website address is *www.aspenneuroscience.com*. Information contained on our website is not incorporated by reference into this prospectus, and it should not be considered to be part of this prospectus.

Trademarks, Trade Names and Service Marks

We use "Aspen Neuroscience," the Aspen Neuroscience logo, and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those 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 ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Table of Contents

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An emerging growth company may take advantage of certain reduced disclosure and other requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- 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 of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act);
- 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, unless the SEC determines the new rules are necessary for protecting the public;
- 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 stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the Securities Act). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), our annual gross revenues exceed $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and 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 in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Table of Contents

The Offering

Common stock offered by us	9,375,000 shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 1,406,250 additional shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	29,078,600 shares (or 30,484,850 shares if the underwriters exercise their option to purchase additional shares of our common stock in full).
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $125.8 million (or approximately $145.4 million if the underwriters exercise their option to purchase additional shares of our common stock in full) from the sale of the shares of common stock offered by us in this offering, based on the initial public offering price of $15.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, to fund the clinical development of sasineprocel, including the ongoing Phase 1/2a ASPIRO trial and the initiation of a Phase 3 trial in sporadic and genetic PD, to fund the research and development of our other product candidates and for working capital and general corporate purposes. See the section titled “Use of Proceeds” for additional information.
Risk factors	Investing in our common stock involves a high degree of risk. See the section titled “Risk Factors” and other information included in this prospectus for a discussion of risks you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	“ASPE”

The number of shares of our common stock to be outstanding after this offering is based on 19,703,600 shares of our common stock outstanding as of June 30, 2026 after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock immediately prior to the closing of this offering, and (ii) the treatment as outstanding of 622,707 shares of common stock previously subject to full recourse promissory notes, which became outstanding upon the forgiveness of the related promissory notes in August 2026 (561,646 shares) and September 2026 (61,061 shares) (the Note Forgiveness). See Note 13 to our unaudited interim financial statements included elsewhere in this prospectus for additional information related to the Note Forgiveness. The number of shares outstanding excludes:

- 3,043,497 shares of common stock issuable upon the exercise of stock options under our 2018 Stock Plan (2018 Plan) outstanding as of June 30, 2026, with a weighted-average exercise price of $6.75 per share;
- 27,314 shares of common stock issuable upon exercise of stock options granted under our 2018 Plan subsequent to June 30, 2026, with a weighted-average exercise price of $9.79 per share;

Table of Contents

- 6,799,243 shares of our common stock reserved for future issuance under the general share reserve of our 2026 Equity Incentive Plan (2026 Plan) (which number includes 3,634,825 new shares plus up to a maximum of 3,164,418 shares subject to outstanding awards granted under the 2018 Plan which after the effective date of the 2026 Plan are subsequently forfeited, cancelled, withheld or reacquired), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 872,358 shares of our common stock reserved for future issuance under the Executive Chair Reserve of our 2026 Plan, which is available solely for the issuance of shares pursuant to awards granted to our Executive Chair, Faheem Hasnain, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 290,786 shares of our common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan (ESPP), which became effective as of immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP, as more fully described under the terms of the ESPP as described in the section titled "Executive and Director Compensation—Employee Stock Plans"; and
- 17,778 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2026, at an exercise price of $7.71 per share.

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

- a 1-for-9.8821 reverse stock split of our common stock, effected on October 23, 2026 (the Stock Split);
- the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock immediately prior to the closing of this offering;
- the Note Forgiveness;
- no exercise of the outstanding stock options or warrants described above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

Table of Contents

Summary Financial Data

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the summary statements of operations data for the six months ended June 30, 2026 and 2025 and the summary balance sheet data as of June 30, 2026 from our unaudited financial statements included elsewhere in this prospectus. We have derived the summary statements of operations data for the years ended December 31, 2025 and 2024 from our audited financial statements included elsewhere in this prospectus. You should read these data together with our financial statements and related notes included elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

	Six Months Ended June 30,		Year Ended December 31,	
	2026	2025	2025	2024
(in thousands, except share and per share data)	(unaudited)	(unaudited)		
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 28,454	$ 20,812	$ 41,833	$ 35,593
General and administrative	9,764	10,074	17,472	17,865
Total operating expenses	38,218	30,886	59,305	53,458
Loss from operations	(38,218)	(30,886)	(59,305)	(53,458)
Other income (loss):				
Interest income	1,670	858	1,793	4,397
Other income (loss), net	2	(1,731)	(4,544)	504
Total other income (loss), net	1,672	(873)	(2,751)	4,901
Net loss	$ (36,546)	$ (31,759)	$ (62,056)	$ (48,557)
Net loss per common share, basic and diluted[1]	$ (33.39)	$ (30.73)	$ (59.43)	$ (51.81)
Weighted-average shares used in net loss per common share calculation, basic and diluted[1]	1,094,550	1,033,651	1,044,175	937,224
Pro forma net loss per common share, basic and diluted (unaudited)[2]	$ (1.86)		$ (4.64)	
Pro forma weighted-average shares used in pro forma net loss per common share calculation, basic and diluted (unaudited)[2]	19,688,581		13,774,106	

(1) See Note 12 to our audited financial statements included elsewhere in this prospectus for an explanation of the methods used to calculate historical net loss per share, basic and diluted, and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(2) Unaudited pro forma net loss per share, basic and diluted, attributable to common stockholders, is calculated giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, as if such conversion had occurred at the beginning of the period, or the issuance dates of such shares, if later, and (ii) the Note Forgiveness and the resulting treatment of 622,707 shares of common stock as outstanding, as if the Note Forgiveness had occurred on January 1, 2025. Unaudited pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss for the year ended December 31, 2025 includes estimated non-cash stock-based compensation expense of approximately $1.8 million resulting from the Note Forgiveness, which we expect to recognize in our historical results in the third quarter of 2026, and such expense is not reflected in unaudited pro forma net loss for the six months ended June 30, 2026. Unaudited pro forma net loss per share attributable to common stockholders for the six months ended June 30, 2026 and for the year ended December 31, 2025 was calculated using the weighted-average number of shares of common stock outstanding, including the pro forma effect of (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, as if such conversion had occurred at the beginning of the period, or the issuance dates of such shares, if later, and (ii) the treatment as outstanding of the 622,707 shares of common stock subject to the Note Forgiveness, as if the Note Forgiveness had occurred on January 1, 2025. See Note 13

Table of Contents

to our unaudited interim financial statements included elsewhere in this prospectus for additional information related to the Note Forgiveness.

(in thousands)	As of June 30, 2026		
	Actual (unaudited)	Pro Forma[1] (unaudited)	Pro Forma as Adjusted[2] (unaudited)
Balance Sheet Data:			
Cash, cash equivalents, and marketable securities	$ 72,377	$ 72,377	$ 198,158
Working capital[3]	58,243	58,243	184,024
Total assets	110,275	110,275	236,056
Total liabilities	22,540	22,540	22,540
Convertible preferred stock	338,808	—	—
Accumulated deficit	(264,886)	(266,709)	(266,709)
Total stockholder's (deficit) equity	(251,073)	87,735	213,516

(1) Gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, and (ii) the Note Forgiveness, including the recognition of estimated non-cash stock-based compensation expense of approximately $1.8 million. See Note 13 to our unaudited interim financial statements included elsewhere in this prospectus for additional information related to the Note Forgiveness.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above, and (ii) the issuance and sale of 9,375,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes included elsewhere in this prospectus and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. Please also see the section titled "Special Note Regarding Forward-Looking Statements." If any of the following risks are realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Our business, financial condition, results of operations, and prospects could also be harmed by additional risks and uncertainties that we are presently unaware of, or that we currently believe are not material.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are a clinical-stage regenerative medicine biotechnology company with a limited operating history and no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of product candidates and the prospects for our future viability.

We are a clinical-stage regenerative medicine biotechnology company with a limited operating history. We commenced operations in 2018, have no products approved for commercial sale, and have not generated any revenue from the sale of our products. Our operations to date have been limited to performing research and development activities, raising capital, recruiting management, technical and business development staff to support our operations, and conducting preclinical studies and clinical trials for our product candidates.

Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. In addition, only sasineprocel is in early clinical development, and our microglia programs remain in the preclinical stage. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biotechnology products.

Moreover, as an organization, we have not yet demonstrated an ability to complete late-stage or pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization or generate revenue. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biotechnology companies such as ours. If we are successful in achieving regulatory approval for our product candidates, we will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred substantial operating losses since our inception and expect to incur substantial losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Investment in biotechnology product development is highly speculative because development efforts entail substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable, have incurred substantial losses in each period since our inception and expect to incur significant losses for the foreseeable future. If we are unable to successfully develop, obtain requisite approval for and commercialize sasineprocel or other product candidates, we may never generate revenue.

Our net losses were $62.1 million and $48.6 million for the years ended December 31, 2025 and 2024, respectively. Our net losses for the six months ended June 30, 2026 and 2025 were $36.5 million and $31.8 million, respectively. As of June 30, 2026, we had an accumulated deficit of $264.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our programs will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if, and as, we:

- initiate additional clinical trials of sasineprocel and advance our preclinical programs through preclinical and clinical development;
- seek regulatory approval, prepare for and, if approved, proceed to commercialization of our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize our current or future product candidates, if approved;
- maintain, expand, scale and automate our in-house manufacturing capabilities for clinical development and commercialization of sasineprocel and other product candidates;
- maintain relationships with our key third-party suppliers and manufacturing partners, such as Cell X and Mytos Bio Limited (Mytos);
- attract, hire and retain qualified personnel;
- protect, maintain, expand, enforce and defend our rights in our intellectual property portfolio;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials; and
- incur additional costs, including legal, accounting and other expenses, associated with operating as a public company following the completion of this offering.

To become and remain profitable, we must succeed in discovering, developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including advancing our in-house manufacturing capacity, completing clinical trials of sasineprocel and preclinical studies of other product candidates, discovering additional product candidates, obtaining regulatory approval for these products, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnological industry. Because of the numerous risks and uncertainties associated with biotechnological 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. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, develop new product candidates, achieve our strategic objectives, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

We have incurred net losses and negative cash flows from operating activities since inception and have an accumulated deficit of $264.9 million as of June 30, 2026. As of June 30, 2026, the Company had cash, cash equivalents and marketable securities of $72.4 million. Based on our current operating plan and without giving effect to any proceeds from any financing transaction, we believe that our existing cash, cash equivalents and marketable securities will not be sufficient to fund our operations for the 12 months following the date of issuance of our unaudited

Table of Contents

financial statements contained elsewhere in this prospectus. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern.

If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement in our unaudited financial statements and the potential inability to continue as a going concern may materially adversely affect our ability to raise capital.

Even if this offering is successful, we will require substantial additional capital to finance our operations, and failure to obtain additional capital when needed, or on acceptable terms, could cause us to delay, limit, reduce, or terminate product development programs, commercialization efforts or other operations.

The development of biotechnological product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive, and uncertain process. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials and preclinical studies and potentially seek regulatory approval for our current product candidates and any future product candidates we may develop. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reliably estimate the actual amount of capital necessary to successfully complete the development and commercialization of our product candidates. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the second half of 2028. In particular, we expect that the net proceeds from this offering and our existing cash, cash equivalents and marketable securities will allow us to continue to fund the Phase 1/2a ASPIRO trial evaluating sasineprocel in patients with sporadic and genetic PD, to continue to fund the development of sasineprocel in PD patients, including initiating a Phase 3 trial, and to continue to fund the development of our microglia programs through the initiation of IND-enabling studies, and the remainder for working capital and other general purposes. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. The net proceeds of this offering, together with our existing cash, cash equivalents and marketable securities, will not be sufficient to complete the Phase 1/2a ASPIRO trial, the Phase 3 trial for sasineprocel, which we intend to initiate prior to the completion of the Phase 1/2a ASPIRO trial, or the development of sasineprocel or any other current or future product candidates. After this offering, we will require additional capital in order to advance our current and future product candidates through clinical trials, regulatory approval, and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, royalty financing and other similar arrangements. 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. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our product candidates that we are pursuing or may choose to pursue in the future, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities, and any third-party products used as delivery devices or consumables in our clinical trials;
- the costs and timing of manufacturing our product candidates, including expanding our in-house manufacturing capabilities to commercially manufacture sasineprocel at sufficient scale, if approved, including as a result of inflation, any supply chain issues or component shortages;
- the costs, timing, and outcome of regulatory meetings and reviews of our product candidates;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase and as we operate as a public company;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;
- the costs and timing of establishing or securing sales and marketing capabilities if sasineprocel is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Because we do not expect product revenue for many years, if at all, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events, or otherwise.

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 programs.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may 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 and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses, and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, sasineprocel and our other programs, our platform, research programs, intellectual property, or proprietary technology, 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 additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts, or grant rights to develop and market sasineprocel and our other programs that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose. Additionally, these circumstances could require that we undertake workforce reductions or restructuring activities in the future. Any of the above events could materially and adversely affect our business, financial condition, results of operations and prospects and cause the price of our common stock to decline.

Risks Related to the Discovery, Development, and Regulatory Approval of Our Product Candidates

We currently depend on the success of sasineprocel, which is our lead product candidate. If we are unable to advance sasineprocel in clinical development, obtain regulatory approval for and ultimately commercialize sasineprocel or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially and adversely affected.

Our lead product candidate, sasineprocel, is in early clinical development. Our business presently depends on our ability to successfully develop, obtain regulatory approval for, and commercialize sasineprocel in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active clinical development and may be able to better sustain the delay or failure of a lead product candidate. The success of sasineprocel will depend on several factors, including the following:

- allowance to proceed with clinical trials under Investigational New Drug Applications (INDs) by the FDA or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of sasineprocel and of our proposed designs of planned clinical trials of sasineprocel;
- the frequency and severity of adverse events observed in clinical trials and preclinical studies;
- maintaining and establishing relationships with contract research organizations (CROs) and clinical sites for the clinical development of sasineprocel, and ability of such CROs and clinical sites to comply with clinical trial protocols, Good Clinical Practices (GCPs) and other applicable requirements;
- demonstrating the safety, purity and potency (or efficacy) of sasineprocel to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of BLAs from the FDA;
- maintaining and expanding our in-house manufacturing capabilities and our ability to comply with cGMPs, as well as scaling and automating such capabilities at a cost and timeline sufficient to support commercialization;
- maintaining relationships with our key third-party suppliers and manufacturing partners, such as Cell X;
- establishing sales, marketing and distribution capabilities and launching commercial sales of sasineprocel, if and when approved, whether alone or in collaboration with others;
- obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for sasineprocel;
- maintaining an acceptable safety profile of sasineprocel following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell sasineprocel; and
- acceptance of our products, if approved, by patients, the medical community and third-party payors.

If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize sasineprocel, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed.

Sasineprocel is a novel approach to treat PD, which makes it difficult to predict the time and cost of product candidate development and to obtain regulatory approval, if at all.

We have concentrated our research and development efforts on sasineprocel, and our future success largely depends on the successful development of the autologous iPSC-based therapy approach underlying this product candidate. In particular, sasineprocel is designed to replace a patient's lost DA neurons with DANPCs. Although we believe sasineprocel has the potential to, if approved, be disease-modifying, there has never been a disease-modifying FDA-approved therapy that stops the neurodegeneration associated with PD and there is no guarantee sasineprocel will be successful at slowing or halting PD progression or addressing both the motor and non-motor symptoms of PD.

We expect the novel nature of sasineprocel to create further challenges in obtaining regulatory approval. Few stem-cell derived cell replacement therapies have been approved globally or by the FDA to date, and regulatory agencies have reviewed relatively few cell replacement therapy product candidates such as sasineprocel. In addition, we rely on stereotactic brain surgery for the administration of sasineprocel which carries risks, including infection, bleeding, stroke and brain swelling. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Further, any autologous cell therapies that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

In addition, the FDA, comparable foreign regulatory authorities and other public health authorities, have established specific requirements for the manufacture and handling of autologous cell therapy products, including requirements relating to donor eligibility, cell collection, processing, storage, and administration, which could establish additional hurdles for the development, manufacture or use of sasineprocel. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Our current or future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.

Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control. Despite promising preclinical or clinical results, our current or future product candidates, including sasineprocel, can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of our current or future product candidates, or a competitor's product candidate in the same class may not predict the results of later clinical trials of any product candidate, and interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. A product candidate in later stages of clinical trials may fail to show the desired characteristics despite having progressed through preclinical studies and initial clinical trials. For example, while we have conducted preclinical studies of sasineprocel and have reported interim data from our ongoing Phase 1/2a ASPIRO trial, we do not know whether sasineprocel will demonstrate comparable results in current or future clinical trials. The positive results we have observed for our product candidates in preclinical animal models and the ASPIRO trial may not be predictive of future results in our ongoing or future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, if unexpected observations or toxicities are observed in our preclinical studies, such results may delay or prevent the initiation of clinical trials for such program.

Additionally, our ongoing Phase 1/2a ASPIRO trial is an open-label trial and does not include a placebo or control cohort. The results of the ASPIRO trial or any other open-label trial that we may conduct may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Open-label clinical trials are subject to various limitations that may exaggerate any observed therapeutic effect as patients in open-label clinical trials are aware that they are receiving an experimental treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. If the limitations of our open-label clinical trial design cause us to overestimate the therapeutic effects of sasineprocel, we may experience setbacks in later-stage clinical development, which could delay or prevent regulatory approval. We expect to include a control group in our planned Phase 3 trial, which may include a sham surgery. In trials utilizing a sham control or surgical intervention, maintaining appropriate blinding presents substantial operational, clinical and logistical challenges compared to conventional placebo-controlled drug trials, and an inability to maintain a robust blinding protocol may undermine the results of any such trial. Further, even if we observe positive results in a controlled Phase 3 trial, there can be no assurance that such results will be sufficient to obtain regulatory approval.

Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate safety, purity or potency (or efficacy) in certain patient populations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

As a result, we cannot be certain that our ongoing and planned clinical trials or preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of sasineprocel in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have concentrated our research and development efforts on the treatment of disorders of the CNS, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing disorders of the CNS, such as PD. Efforts by biotechnology and biopharmaceutical companies in this field have faced certain challenges in drug development historically. In particular, these indications are often subject to a placebo effect, which may make it more challenging to isolate the beneficial effects of our product candidates. In particular, we are developing sasineprocel for the treatment of PD, and our ongoing Phase 1/2a ASPIRO trial relies on, and any future trial will rely on, subjective patient-reported outcomes as key endpoints which makes the results more difficult to evaluate than indications with more objective endpoints. Further, these subjective assessments can change significantly over time, complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement, and generally adversely impact a clinical development program by introducing additional uncertainties. There can be no guarantee that we will successfully overcome these challenges with our product candidates or that we will not encounter other challenges in the development of our product candidates.

Table of Contents

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

Before obtaining approval from regulatory authorities for the sale of sasineprocel or any other current or future product candidate, we must conduct extensive clinical trials to demonstrate the safety, purity and potency (or efficacy) of the product candidates in humans. In addition, before we can initiate clinical trials for any product candidate, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls (CMC) and our proposed clinical trial protocol, as part of an IND or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of developing our preclinical development programs.

Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any delays in the commencement or completion, or the termination or suspension, of our ongoing, planned, or potential future clinical trials or preclinical studies for our current or future product candidates could significantly affect our product development timelines and product development costs.

We do not know whether our planned clinical trials or preclinical studies will begin on time or if our ongoing or future trials or studies will be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and preclinical studies can be delayed for a number of reasons, including delays related to:

- inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- 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;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees (ECs) at clinical trial sites;
- IRBs/ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory requirements or guidelines in other countries;
- manufacturing sasineprocel or any other current or future product candidates and obtaining sufficient quantities of required raw materials or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and preclinical studies;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including patients failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from any future public health concerns;
- patients choosing alternative treatments for the indications for which we are developing sasineprocel or any other current or future product candidates, or participating in competing clinical trials;

- lack of adequate funding to continue the clinical trials or preclinical studies or costs being greater than we anticipate;
- patients experiencing severe or serious unexpected drug-related or procedure-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to sasineprocel or any future product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- delays or difficulties in scaling our in-house manufacturing processes to larger-scale production, failure to automate our manufacturing platform, or failure to make any necessary changes to our manufacturing process;
- failure of our third-party manufacturing partners to produce or supply specialized systems or components for the production of clinical trial materials, including drug delivery devices;
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. 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 or comparable foreign regulatory authorities. Such authorities may impose such a suspension, including a clinical hold, or termination due to a number of factors, including, among other reasons, failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, 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.

Further, we and any future collaborators may in the future conduct clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may in the future serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority 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 or comparable foreign regulatory authority 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 or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of sasineprocel or any other current or future product candidates.

Many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize sasineprocel or our other current or future product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidate could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations and prospects.

Table of Contents

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue certain clinical trials for sasineprocel or any other current or future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including:

- the size and characteristics of the patient population;
- the severity of the disease or condition under investigation;
- the proximity of patients to clinical and surgical sites;
- the availability, efficacy and safety of approved therapies for the disease or condition under investigation;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- the ability to monitor patients adequately during and after treatment;
- the risk that enrolled patients will not complete a clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development by us or third parties.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with sporadic PD, genetic PD, or the other conditions or diseases we intend to evaluate, which could adversely impact the timing and outcomes of our trials. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

Additionally, we may face challenges in recruiting and fully enrolling our clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, our ability to retain patients during the period after the biopsy and before surgical administration during the sasineprocel manufacturing process, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll and retain a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in

enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our current or future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon the product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.

As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with use of sasineprocel or any other current or future product candidates' use. Results of our or any future collaborators' clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational devices or drugs could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Moreover, if any of our product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their 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 such product candidate if approved. Unacceptable enhancement of certain toxicities may be seen when product candidates are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials.

It is possible that as we or any future collaborators test sasineprocel or any other current or future product candidates in larger, longer, and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts, and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. 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.

In addition, if sasineprocel or any other current or future product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;

- we may be subject to fines or criminal or civil penalties;
- we could be sued and held liable for harm caused to patients;
- we may suspend marketing of a product or remove a product from the marketplace;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance and/or physician adoption of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Surgical administration of sasineprocel could cause patient harm and adversely affect our clinical development, prospects for regulatory approval and ability to commercialize.

We use cannula-based delivery to targeted brain regions to administer sasineprocel. Despite reliance on well-understood standard of care stereotactic neurosurgical techniques for the administration of sasineprocel, stereotactic brain surgery under anesthesia carries risks, including infection, bleeding, stroke and brain swelling. Safe cannula-based administration depends on accurate cannula placement and controlled infusion. Cannula obstruction, kinking, misplacement, malfunction, or reflux/off-target distribution could cause suboptimal dosing, non-target exposure, acute complications, or irreversible injury, even with imaging guidance and standardized procedures. Further, because sasineprocel is thawed immediately prior to surgery, handling deviations in thawing, preparation, timing, or sterility may affect cell viability, potency, or distribution, increasing the risk of adverse events, reducing potential benefit, or creating variability across patients or sites. Inconsistent execution of the thaw-and-inject workflow could adversely affect development and approval prospects.

Procedure- or device-related adverse events could lead to regulatory actions and operational impacts, which could impair or prevent approval of sasineprocel and, even if approved, reduce commercial uptake of sasineprocel, materially harming our business, financial condition, and results of operations.

In addition, standard of care surgical administration requires highly trained clinicians and specialized facilities, which could limit use of sasineprocel to select healthcare centers and reduce physician willingness to adopt sasineprocel or other product candidates. Third party payors may also be reluctant to adequately reimburse therapies that require a costly stereotactic neurosurgery, which could adversely affect commercial uptake and revenue potential for sasineprocel or other product candidates.

We have not as an organization completed clinical trials or submitted a BLA, and we may be unable to do so for sasineprocel or other product candidates.

We are currently conducting the open-label Phase 1/2a ASPIRO trial of a single dose of sasineprocel in PD patients, and plan to advance sasineprocel into a Phase 3 trial following feedback from the FDA. We have not yet completed any later-stage or pivotal clinical trials for sasineprocel or any other product candidate. Carrying out later-stage clinical trials and the submission of a successful BLA or other comparable foreign regulatory submission is a complicated process. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted a BLA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of sasineprocel or any other product candidate will be required or how such additional trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of a BLA and regulatory approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our ongoing or planned clinical trials could prevent us from or delay us in submitting BLAs or other comparable foreign regulatory submissions for and commercializing our product candidates.

Additional time may be required to obtain marketing authorizations for any of our product candidates that we develop as combination products.

We are developing certain of our product candidates, including sasineprocel, to be administered through drug delivery devices. Accordingly, we expect that sasineprocel will be regulated as a combination product by the FDA and other regulatory authorities. Combination products require coordination within the FDA and within comparable regulatory agencies for review of the biologic product and device components. For example, the FDA's review of a marketing application for sasineprocel may include the participation of both the FDA's Center for Biologics Evaluation and Research and the FDA's Center for Devices and Radiological Health. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying biologic component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device which may delay the approval of the combination product.

Negative developments in the field of regenerative medicine and, in particular, stem cell-based therapies, could damage public perception of sasineprocel or our other product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on general public acceptance of the use of stem cell-based therapy for the prevention or treatment of human diseases. The use of embryonic cells and fetal tissue for research and stem cell therapy has been the subject of substantial national and international debate regarding related ethical, legal, and social issues. In the U.S., for example, until March 2009, federal government funding of embryonic stem cell research was limited to specifically identified cell lines and was not otherwise available. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our use of induced pluripotent stem cells from the use of embryonic stem cells or fetal tissue by others. This could result in a negative perception of us or our products or product candidates, thereby reducing demand, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Adverse events in clinical trials of sasineprocel or any other cell replacement therapy product candidates which we may develop, or in clinical trials of other biopharmaceutical companies developing similar products and the resulting publicity, as well as any other negative developments in the field of regenerative medicine that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for sasineprocel or any other stem cell-based product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cell replacement therapy is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our, our collaborators', or any future collaborators' clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Adverse developments in clinical trials of other cell replacement products based on stem cells may result in a disproportionately negative effect for sasineprocel or other product candidates as compared to other products in the field of regenerative medicine not based on stem cells. Future negative developments in the biotechnological or biopharmaceutical industries could also result in greater governmental regulation, stricter labeling requirements, and potential regulatory delays in the testing or approvals of sasineprocel or other product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates in the United States until we receive regulatory approval of a BLA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses, and in the case of biological products in the United States, that such product candidates are safe, pure and potent for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety, purity, and potency (or efficacy) of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the 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;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;

- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of a BLA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

We may not be successful in our efforts to investigate sasineprocel in additional indications. We may expend our limited resources to pursue a new product candidate or a particular indication for sasineprocel and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently conducting the open-label Phase 1/2a ASPIRO trial evaluating sasineprocel in patients with sporadic PD and we have begun enrolling genetic PD patients. Because we have limited financial and managerial resources, we focus on the development of sasineprocel for specific indications. We may fail to generate additional clinical development opportunities for sasineprocel for a number of reasons, including that sasineprocel may, in indications we are seeking or may seek in the future, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and/or achieve market acceptance in such potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for sasineprocel. Our spending on current and future research and development programs for new product candidates or additional target indications for sasineprocel may not yield any commercially viable product candidates or target indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or target indication, or relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or negotiate less advantageous terms for any such arrangements than is optimal.

Additionally, we may pursue in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We may in the future seek to engage in strategic transactions to acquire or in-license additional products, product candidates or technologies. If we are unable to realize the benefits from such transactions, it may adversely affect our ability to develop and commercialize an expanded pipeline of product candidates, negatively impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, product candidates or technologies that we believe will complement or augment our existing business. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in

developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

Following any such strategic transaction, we may not achieve any expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near-term and long-term expenditures, experience significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities; disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies; incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs; higher-than-expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges; increased amortization expenses; difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business; impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership; and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and could have a negative impact on the competitiveness of any product candidate that reaches market.

We may in the future conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We or any future collaborators may in the future conduct one or more of our clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, regardless of whether the applicable clinical trials were conducted under an IND, the FDA will generally not approve the application unless the data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of sasineprocel or another product candidate, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of such product candidate.

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;
- inconsistent standards for reporting and evaluating clinical data and adverse events;

- diminished protection of intellectual property in some countries; and
- public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

Interim, topline, and preliminary data from our clinical trials and preclinical studies 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 interim, topline, or preliminary data from our clinical trials and preclinical 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 interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are further 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 interim, topline or preliminary 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.

In addition, others, including regulatory authorities, 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. Moreover, 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 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 drug, product candidate or our business. If the interim, topline or preliminary 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 a product candidate may be harmed, which could harm our business, financial condition, results of operations and prospects.

Fast Track designation by the FDA for sasineprocel, and other expedited designations if granted in the future, may not lead to a faster development or regulatory review or approval process, and do not increase the likelihood that sasineprocel or any other product candidate which may receive such designations will receive regulatory approval.

The FDA has granted Fast Track designation for sasineprocel for the treatment of PD to improve motor function, and we may seek Fast Track designations for other indications or other product candidates. The Fast Track programs are intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the Sponsor pays any required user fees upon submission of the first section of the BLA.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate or development program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received Fast Track designation for sasineprocel for the treatment of PD to improve motor function, and even if we receive additional Fast Track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw a Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that sasineprocel or any other product candidate that may be granted Fast Track designation will receive marketing approval in the United States. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval. Access to an expedited program may expedite the development or approval process, but it does not change the standards for approval.

Furthermore, although we may pursue additional opportunities to accelerate the development of certain of our future product candidates through one or more of the FDA's expedited program designations, we cannot be assured that any of our product candidates will qualify for such programs. The FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program.

A Regenerative Medicine Advanced Therapy, or RMAT, designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive FDA approval.

The FDA has granted RMAT designation for sasineprocel for the treatment of levodopa-responsive PD, and may seek additional RMAT designations for sasineprocel or for our other product candidates. A biological product candidate is eligible for RMAT designation if: it meets the definition of a regenerative medicine therapy, which the FDA defines as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; the candidate is intended to treat, modify, reverse, or cure a serious disease or condition, and; preliminary clinical evidence indicates that the candidate has the potential to address unmet medical needs for such disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or through reliance upon data obtained from a meaningful number of sites, including through expansion to a sufficient number sites, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as appropriate, be able to fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, through the collection of larger confirmatory data sets, or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. RMAT designation is within the sole discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to make such designation. RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the product candidate fails to meet the qualifications as clinical data continue to emerge.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for sasineprocel or other current or future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For

the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022, among other things, provided the FDA statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking approval for sasineprocel or any other current or future product candidate, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for sasineprocel or any other current or future product candidate, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for sasineprocel or any other current or future product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved or licensed biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial personnel changes, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If any future prolonged government shutdown occurs, or if funding shortages, staffing limitations, policy changes or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We and any of our third-party suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.

We and any of our third-party suppliers and potential future collaborators may use biological materials, potent chemical agents, and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we nor our third-party suppliers can eliminate the risk of accidental injury or contamination from these materials or waste. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our or our suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, 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, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations, and prospects.

Our development timelines depend on numerous interdependent activities across our organization and third parties, and any failure of these activities to align as planned could delay, disrupt, or prevent development, regulatory approval or commercialization of our current and future product candidates.

Our ability to meet projected milestones for our current and future product candidates depends on the timely, coordinated execution of multiple, interdependent workstreams, including, but not limited to, manufacturing scale-up; third-party vendor performance; patient identification and enrollment; regulatory interactions; procurement of critical materials and components; and the various events and requirements discussed in the risks set forth in this prospectus. Disruptions in any one area can materially affect overall program timing, cost and the likelihood of regulatory approval and commercialization.

Because these activities are interdependent, a setback in one workstream can require re-sequencing, extend timelines, add unplanned costs and cause us to miss internal or publicly communicated milestones. If we cannot align manufacturing readiness, third-party performance, patient enrollment, regulatory expectations and supply reliability when needed, we may have to delay, limit, suspend or terminate studies or trials, modify development plans, or raise additional capital on unfavorable terms, materially harming our business, financial condition, results of operations and prospects.

Table of Contents

Risks Related to Manufacturing of Our Product Candidates

Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.

The manufacture and supply of cell therapy product candidates, including sasineprocel, are generally more complex and costly than those required, for example, for small molecule or antibody-based drugs and accordingly present significant challenges. Our autologous cell therapy product candidates, including sasineprocel, are engineered human cells, and the process of manufacturing such product candidates is complex, highly regulated and subject to numerous risks. Manufacturing our product candidates involves isolating dermal fibroblast cells from a patient's skin punch biopsy, expanding the fibroblast cells, testing for correct cell type identity, harvesting and formulating the fibroblast cells, converting the fibroblasts into iPSCs through cellular reprogramming, differentiating the iPSCs into DANPCs, harvesting and finishing the DANPCs, cryopreservation, storage and eventually shipment. Our ability to consistently and reliably manufacture autologous cell therapy product candidates is essential to our success, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with sourcing of materials, quality control, inter-patient variability, stability issues, consistency and timely availability of raw materials.

Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with autologous cell therapies, including the collection of patient cells, conversion and differentiation of cells, processing and quality control testing, shipping the final product to the clinical trial recipient, preparing the product for administration, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor error, inconsistency in cell growth and variability in product characteristics. Cells must maintain viability and quality throughout this process, and any disruption—including transportation delays, temperature excursions, cryopreservation failures, or mix-ups in autologous materials—could result in product loss or compromise product quality. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If we lose, destroy or otherwise impair the patient materials at any point, the manufacturing process for that patient may need to be restarted, for example if sufficient starting materials are still available; the resulting delay may adversely affect that patient's outcome due to the risk of disease progression. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any failure in the manufacturing processes could render a batch of product unusable, could impact supply and delay the progress of our clinical trials, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates.

Our manufactured product candidates may fail to meet the required specifications for any of a variety of reasons, including variability in starting material, deviations from normal manufacturing process, or insufficient optimization of specific process steps. This failure to meet specifications could result in supply shortages, or delays related to obtaining additional regulatory, site and patient approvals to continue dosing the clinical trial for sasineprocel. If the required additional approvals cannot be obtained, additional delays may occur as manufacturing would need to be restarted and/or the patient may be unable to remain in the study. Any delay in the clinical development or commercialization of sasineprocel or our other product candidates could materially adversely affect our business, financial condition, results of operations and growth prospects.

We are still developing an optimized, automated manufacturing process for Phase 3 clinical and commercial-scale manufacturing of sasineprocel, and we may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as to control costs, achieve scale, enhance automation, decrease processing time, increase manufacturing success rate, address intellectual property considerations, or for other reasons. Changes to our manufacturing process carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials, or the performance of the product once commercialized. Changes to our process made during the course of clinical development could require us to show the comparability of the product candidate used in earlier clinical phases or at earlier portions of a trial to the product candidate used in later clinical

phases or later portions of the trial. For example, we are currently transitioning to an automated manufacturing process for our Phase 3 study from the manual process used in our Phase 1/2a ASPIRO trial, and this transition has required manufacturing process changes. Prior to the start of manufacturing for our Phase 3 study, we must establish comparability of our automated manufacturing process with the manual process used in the Phase 1/2 ASPIRO trial. It is difficult to establish comparability of autologous cell therapy products, and this may complicate efforts to verify process changes during scale up. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, or if regulatory authorities do not agree that comparability has been established, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Although we manufacture sasineprocel in our own internal manufacturing facility for the Phase 1/2a ASPIRO trial, and plan to manufacture other product candidates in our internal manufacturing facilities in the future, we may encounter problems with the internal production of our product candidates. We believe our current clinical GMP manufacturing facility will supply our anticipated clinical trial needs, but if the dose and number of cycles needed increases, our current manufacturing process may not be able to support the enrollment of trials which could lead to delays until we scale up the manufacturing. While we believe that we have a manufacturing facility with capabilities to meet increased production needs, it would still require an increase in staff and significant internal resources. We may face challenges in scaling our manufacturing operations to meet demand, as autologous manufacturing is inherently more difficult to scale than traditional biologic manufacturing, requiring individualized production runs for each patient rather than large batch production.

Further, our manufacturing facilities will be subject to compliance with regulatory requirements, which we may struggle to meet. We may encounter problems with properly staffing our internal manufacturing facilities due to hiring challenges or other issues. For example, factors such as public health pandemics or epidemics (such as the COVID-19 pandemic) and related restrictions could impact our ability to properly staff production of our product candidates. Current inflationary pressures are negatively affecting and could continue to negatively affect the costs of constructing our commercial-scale manufacturing facility. Global supply chain disruptions, including procurement delays and long lead times on certain materials, have adversely impacted and could continue to adversely impact the scheduled completion and/or costs of constructing our commercial-scale manufacturing facility. We may also encounter problems with training the staff we have to effectively manage and control the complex manufacturing process required to produce our product candidates and comply with all necessary regulations. We may also find it difficult to properly manage supply chain issues critical to the manufacturing process. If we are unable to build, maintain, and properly staff our manufacturing facilities, manage and control the manufacturing process, manufacture sasineprocel and other product candidates at sufficient scale or quality, and comply with regulations, the clinical development or commercialization of our product candidates could be significantly delayed, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

The manufacture of sasineprocel as an autologous cell therapy involves significant variability that may result in manufacturing failures, treatment delays, or inconsistent product quality, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Sasineprocel is an autologous cell therapy manufactured using cells derived from each individual patient. Unlike conventional biologic products or allogeneic cell therapies that are manufactured from standardized cell lines or donor-derived materials, the starting materials for sasineprocel are inherently variable because they depend on the unique biological characteristics of each patient. This patient-to-patient variability presents significant manufacturing challenges that could adversely affect our ability to develop and commercialize sasineprocel.

Because the quality and characteristics of each patient's cells may differ based on factors including age, disease state, prior treatments, genetic background, and overall health, the manufacturing process for sasineprocel may yield products with variable characteristics, even when the same manufacturing protocols are followed. Some patients' cells may fail to proliferate, differentiate, or otherwise meet release specifications during the manufacturing process, resulting in manufacturing failures that could prevent those patients from receiving treatment. If we experience a high rate of manufacturing failures, we may be unable to treat a meaningful proportion of patients enrolled in our clinical trials or, if sasineprocel is approved, patients who are prescribed our product, which could delay or prevent regulatory approval, harm our reputation, and limit revenue.

In addition, we rely on the treating physician performing the skin punch biopsy to collect the initial patient sample. Although we train treating physicians to ensure correct biopsy collection, we cannot guarantee that all physicians will have the necessary skills or experience to consistently perform such procedures that yield material suitable for manufacturing. For example, during our Phase 1/2a ASPIRO trial, several patients experienced biopsy failures, requiring re-collection of patient material, which delayed or necessitated a restart of the manufacturing process for those patients. Similar failures in the future, including any unexpected failures due to the characteristics of genetic PD patients, could result in manufacturing delays, supply disruptions, or the inability to manufacture a suitable product for a particular patient, any of which could adversely affect our clinical trials and, if our product candidates are approved, our ability to supply product to patients, and could materially adversely affect our business, financial condition, results of operations and growth prospects.

We are highly dependent on our San Diego, California manufacturing facility and any failure to maintain the use of this facility would have a material and adverse effect on our business.

We currently manufacture our product candidates at our manufacturing facility in San Diego, California, where we lease approximately 22,000 square feet of GMP cleanrooms, warehouse, QC laboratory, and office space. We are currently conducting technology transfer and implementation of our automated manufacturing process in the second phase clean rooms of our San Diego facility, and we have not completed implementation of our automated manufacturing process that we intend to utilize in our planned Phase 3 trial. We are entirely reliant on our manufacturing facility to manufacture our product candidates, including sasineprocel, and any failure to maintain the use of this facility would have a material and adverse effect on our business.

Our reliance on our manufacturing facility exposes us to a number of risks, including:

- any inability to maintain the facility and conduct its operations in compliance with regulatory requirements, including those specified by the FDA's regulations regarding cGMP, would have a material and adverse effect on our business and operations;
- we may have no back up manufacturing options, at least in the near term, and even if there were manufacturing alternatives, the third-party contract manufacturing organization, or CMO, we may contract may not be able to manufacture our product candidates for us in a quantity, with the specifications, and otherwise in the manner we request or require and in a timely fashion;
- our ability to manufacture our product candidates could be adversely affected by circumstances beyond our control, including natural disasters or adverse weather, or legal or regulatory issues we may experience that are unrelated to our activities;
- our ability to successfully renew the lease of our facility, which is set to expire in July 2032, on reasonable terms or at all; and
- our ability to establish and maintain certain licenses or permits necessary to continue our manufacturing activities for our clinical trials and, if any of our product candidates are approved, for commercialization.

We rely on highly specialized third-party suppliers and automation platforms for critical aspects of our manufacturing process, and any disruption, failure, or inability to scale these systems could adversely affect our ability to produce our product candidates in a timely and cost-effective manner.

Our manufacturing processes for sasineprocel incorporate highly specialized automated systems supplied by third parties, including the Cell X platform, also known as the Celligent system, potentially used across all stages of production and scale-up, and the Mytos device used during differentiation in stage 3 of our production process. These systems integrate robotics, liquid handling, optical machine vision and proprietary algorithms to evaluate and process patient-derived cells. We also depend on Cell X and other third parties for instruments and consumables under supply and license arrangements, and our Cell X and The Cleveland Clinic Foundation (CCF) licenses require milestone payments upon achievement of specified development and regulatory milestones. Any delay, disruption, quality or performance issue affecting these third-party platforms or supplies—including equipment malfunction, software or algorithm errors, supplier capacity constraints, delivery delays, component shortages, discontinuations, business interruptions or financial distress—could delay or halt manufacturing runs, increase our costs, reduce yields, or result in product quality issues, which could delay our preclinical and clinical development, regulatory submissions and, if approved, commercialization.

Because our automation initiatives are ongoing and certain steps remain manual in our current GMP process, we may not complete or scale automation as planned, our automated processes may not perform as expected, and we may be required to revert to less automated workflows. If we need to change or replace suppliers, platforms, or materials, we could be required to conduct additional qualification, validation, technology transfer and regulatory comparability studies, which are time-consuming, costly and uncertain. Our reliance on third parties also exposes us to risks related to single- or limited-source suppliers, export controls and logistics, and the need to identify, audit and qualify alternate vendors, any of which could adversely affect our ability to meet timelines or scale production.

In addition, failures in our automated data capture, analytics and in-process controls, or errors in the machine-vision or algorithmic selection of cells, could lead to batch failures, inconsistent product quality, loss of patient-specific material, patient segregation issues or regulatory non-compliance. If we are unable to secure, maintain or scale access to the Cell X platform, Mytos devices, or other critical systems on commercially reasonable terms, or if these systems do not operate as intended within our modular manufacturing template, we may be unable to achieve the throughput, costs or consistency necessary to support later-stage development or potential commercialization. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

Changes in methods of the manufacturing or formulation of sasineprocel or other product candidates may result in additional costs or delay.

As sasineprocel and any of our other current or future product candidates progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results, or address intellectual property considerations. There can be no assurance that any future manufacturing or formulation changes we may make will achieve their intended objectives, and such changes may also cause sasineprocel or any future product candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results or changes in the CMOs we use to manufacture components and consumables for sasineprocel or other product candidates could delay initiation or completion of clinical trials, require the conduct of bridging studies or additional clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval and jeopardize our ability to commercialize sasineprocel or other product candidates, if approved, and generate revenue.

Certain of our product candidates require specific shipping, storage, handling and administration, which in some cases, may require cold-chain logistics and subject our product candidates to risk of loss or damage if failures occur.

Certain of our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to

use. The handling and administration of our product candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates. In addition, because it is necessary to ship our product candidates and other materials globally from manufacturing sites to clinical sites, our product candidates will need to be frozen using specialized equipment and maintained following specific procedures in order to be shipped and stored without damage in a cost-efficient manner and without degradation. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product candidates, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product candidates within the specified period post-thaw could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of our clinical supply.

If any of our product candidates are approved, we will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third-parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for our commercial supply, if approved. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we are able to manufacture and distribute the products, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, our product development programs and our ability to seek or obtain regulatory approval for or commercialize our products may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs, and consultants to conduct our preclinical studies and clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators, and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with Good Laboratory Practice (GLP) requirements for certain preclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials of all of our product candidates. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with products produced in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators, or other third parties will devote adequate time and resources to such trials or studies 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, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

Table of Contents

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional CROs, investigators, and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We rely on third parties for certain manufacturing systems, materials and components for our product candidates and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not be able to manufacture sufficient quantities of our products or such quantities at an acceptable cost, which could delay, prevent, or impair, our development or commercialization efforts.

We rely on certain third-party suppliers and manufacturing partners for systems, components and consumables for manufacturing sasineprocel and other product candidates. For example, with respect to sasineprocel, we have a collaboration agreement with Cell X for the development of a GMP capable cell processing system, a services agreement with Mytos for the supply of the iDEM platform, and a supply agreement and master development agreement with ClearPoint Neuro for its SmartFlow cannula used as part of the drug delivery system. A third party's failure to execute on our supply requirements on commercially reasonable terms, in a timely manner and in compliance with regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our products on a reasonable timeframe.

We do not have long-term commitments with most of our third-party suppliers. Although there have not been recent disruptions or terminations of relationships with our key suppliers or manufacturing partners and we expect such agreements to be renewed on existing terms, we may face potential termination of such agreements or renewal on terms that are unacceptable to us, if at all, increasing the risk of failing to timely manufacture sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to renew agreements or establish long-term commitments with third-party suppliers or manufacturing partners, reliance on such third parties entails additional risks, including:

- failure of third-party suppliers to comply with regulatory requirements and maintain quality assurance;
- breach of the supply agreement by the third party;
- failure to obtain adequate raw materials and other materials required for manufacturing;
- failure to manufacture our product according to our schedule or at all;
- failure to successfully scale up manufacturing capacity, if required;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

A performance failure on the part of our existing or future suppliers could delay clinical development or regulatory approval, and related remedial measures may be costly or time consuming to implement. For example, we previously experienced a material delay in patient dosing during our Phase 1/2a ASPIRO trial due to issues with syringe design. We worked with the supplier to design and validate a new syringe design. We do not currently have arrangements in place for redundant supply or a second source for all required materials and components used in the manufacture of our product candidates. If our existing or future third-party suppliers or manufacturing partners cannot

perform as agreed, we may be required to replace such suppliers or partners and we may be unable to replace them on a timely basis or at all.

We rely on third-party suppliers for critical raw materials, reagents, and manufacturing platforms, and any disruption, delay, quality issue, capacity constraint, price increase, or termination of these supply or license relationships could materially and adversely affect our development timelines, manufacturing plans, and commercial prospects.

Our manufacturing processes depend on specialized raw materials, reagents, consumables, and equipment, some of which we currently obtain from sole or single sources. While we procure a number of cell culture reagents from multiple vendors, including Bio-Techne, Thermo Fisher, StemCell Technologies, Akron Biotech and ClearPoint Neuro, some of these materials may require supplier-specific specifications, release testing, and process compatibility, and not all items, such as the Sendai virus supplied by Thermo Fisher, are readily substitutable on short notice. In addition, in some circumstances we rely on sole source suppliers, including for iPSC reprogramming kits and for certain automated manufacturing systems, such as the Cell X and Mytos systems. Our use of such technology is licensed directly from a sole source and our supplier's ability to supply these kits is subject to its own upstream license arrangements. We also rely on sole-sourced manufacturing platforms.

Because our product candidates and processes are highly specialized, qualifying additional or alternative suppliers is time-consuming, costly, and uncertain. Even where technically feasible, we may need to undertake bridging studies, comparability analyses, new stability programs, and process validations to support the use of a new source. For clinical-stage product candidates such as sasineprocel, changes to our suppliers, components, or equipment may require prior regulatory notification or approval, additional CMC updates, or amended investigational submissions, and regulators may not agree that data generated using materials from an alternate supplier are comparable.

Our reliance on sole source suppliers for the iPSC reprogramming kit and key manufacturing platforms heightens these risks. If any of these parties elects to cease supplying us, fails to perform its obligations, experiences shortages, allocates supply to other customers, increases prices, encounters quality or compliance issues, becomes insolvent, experiences labor disputes or geopolitical or logistics disruptions, or otherwise cannot or will not meet our requirements, we may be unable to obtain sufficient quantities of critical inputs on a timely basis, on acceptable terms, or at all. We may also be unable to source functionally equivalent materials or equipment without significant development work or license rights we do not currently possess. If we are required to switch to a new supplier or platform, we could face substantial delays to our ongoing and planned clinical trials, including our planned Phase 3 activities, increased costs, and a need to resubmit CMC information, conduct additional preclinical testing or clinical bridging, or repeat manufacturing validations. These outcomes could delay, prevent, or limit regulatory approval and, if approved, impair our ability to commercialize our product candidates.

Our licenses and supply or service agreements may be subject to termination or non-renewal under various circumstances, including our breach, insolvency events, or at-will termination after notice periods. While we intend to qualify additional suppliers for certain critical reagents during our Phase 3 preparations, we may not be successful in doing so on our anticipated timelines, if at all. Any inability to secure, maintain, or expand our license rights or supply arrangements on commercially reasonable terms could force us to modify our manufacturing processes or product specifications, which may require extensive analytical work, new regulatory submissions, or additional clinical studies.

Further, our dependence on single or sole sources concentrates quality and compliance risk. If a supplier fails to comply with applicable cGMP standards or experiences an adverse regulatory inspection outcome, we could be forced to quarantine or discard materials, suspend manufacturing runs, or delay clinical dosing while issues are remediated or an alternative source is qualified. Even if a compliant alternative source exists, supply chain transitions can lead to variability in critical quality attributes, process performance, or yields, which could necessitate further

development work or regulatory engagement. Any of these events could materially harm our business, financial condition, results of operations, and prospects.

If any of the foregoing risks materialize, our clinical development could be significantly delayed or halted, our regulatory submissions could be delayed or denied, and, if our product candidates are approved, our ability to launch and commercialize any of our product candidates could be impaired, which would adversely affect our business and prospects.

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

Because we rely on certain third-party suppliers and other service providers, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements, or other similar agreements with our collaborators, advisors, employees, 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. 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 or other third parties, are intentionally or 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 and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may seek to enter into collaborations, licenses, and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses, and other similar arrangements for the development or commercialization of our product candidates, if approved, due to capital costs required to develop or commercialize the product candidates or manufacturing constraints. We may not be successful in our efforts to establish or maintain such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort, or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property, product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development or product candidates for our pipeline. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned, or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in

the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates, if approved, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools.

In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for our products 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 GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, adverse publicity requirements, or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions and the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay marketing authorization of any product candidate. We also cannot predict the likelihood, nature, or 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 be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as sasineprocel, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive regulatory 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 regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. These restrictions also apply to communications made prior to regulatory approval, meaning that we are prohibited from promoting or making claims about our product candidates before they receive marketing authorization. Any dissemination of information that could be viewed as promotional prior to approval may result in enforcement action, delay or denial of approval, or other regulatory consequences. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Any product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act (ACA), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (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 its product.

We believe that any of our product candidates, if 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 generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors.

The commercial success of sasineprocel and other product candidates will depend upon the degree of market acceptance of such product by physicians, patients, healthcare payors, and others in the medical community.

Our product candidates, including sasineprocel, may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians and other healthcare practitioners, patients, healthcare payors, or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more established products;
- the indications for which our product candidates are approved;

- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, (e.g., Medicare and Medicaid), private health insurers, and other third-party payors for our product candidates in addition to the surgical administration;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety, and efficacy of competitive drugs;
- the effectiveness of our or any potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate, including sasineprocel, is approved but does not achieve an adequate level of acceptance by physicians and other healthcare practitioners, hospitals, healthcare payors, or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs (*e.g.*, Medicare and Medicaid), private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, including sasineprocel, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our product candidates by third-party payors will have an effect on our ability to successfully commercialize those product candidates. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate, including for the surgical procedure required to administer sasineprocel or other product candidates. Even if we obtain coverage for a given product candidate by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and offer to reimburse patients only for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product candidate development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on product candidates that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs (which may be required for our products to be covered by Medicaid and Medicare), in certain circumstances, our product candidates would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such product candidate. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions, and fines should we be found to be in violation of any applicable obligations thereunder.

Obtaining and maintaining reimbursement status is time-consuming, costly, and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of managed care organizations on pricing and value-based care models, and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures, and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See the section titled "*Risk Factors—Risks Related to Our Business Operations and Industry—Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our product candidates and may adversely affect the prices we may set*" for additional related information.

Table of Contents

We face significant competition from entities that have developed or may develop product candidates for PD, including companies developing novel treatments and technology platforms. If our competitors develop and commercialize their product candidates more rapidly than we do, or their technologies or their product candidates are more effective, safer, or less expensive than our products, our business and our ability to develop and successfully commercialize product candidates may be adversely affected.

The biotechnological industry is characterized by rapid technological advancement, intense competition, and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing, or may develop products, product candidates, and processes competitive with our product candidates. Any product candidate that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of PD. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, among others. We anticipate that we will continue to face increasing competition as new therapies, technologies and data emerge within the field of neurodegenerative disease and, more specifically, for the treatment of PD.

We expect to compete with commercially available advanced therapies used in patients with motor fluctuations despite optimization of L-dopa, including DBS devices such as Infinity and Liberta RC (both marketed by Abbott), Vercise (marketed by Boston Scientific), and Percept (marketed by Medtronic), as well as Focused Ultrasound (FUS) technologies such as Exablate Neuro (marketed by Insightec). We anticipate that there will continue to be improvements in DBS and FUS technologies. We are aware of cell and gene therapy candidates in clinical development that target sporadic, genetic, or all forms of PD. This includes autologous cell therapies in development by Hope Bio, Oryon, and others; allogeneic therapies from BlueRock Therapeutics (BlueRock)/Bayer, Sumitomo (AMCHEPRY, approved in Japan), Cellular Intelligence, Kenai Therapeutics, iRegene, S.Biomedics, Xellsmart and others; and gene therapies from AskBio/Bayer, MeiraGTx, Prevail Therapeutics, and other earlier-stage competitors. We are also developing autologous microglia cell replacement therapies for a number of leukodystrophies. In this area, we expect to compete with commercially available therapies such as bone marrow transplant and Skysona (Genetix Biotherapeutics). We are also aware of small molecules, antibodies, and advanced therapies that are in development for leukodystrophies including a PPARg agonist in development by Minoryx Therapeutics, a thyroid receptor-b agonist in development by Viking Therapeutics, and an AMPK activator and a deuterium-modified thiazolidinedione both in development by Poxel SA and other earlier-stage competitors.

Many of our current or potential competitors, either alone or with their collaboration partners, have greater financial, technical, manufacturing, supply, marketing and sales, and resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biotechnological and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that have fewer or less severe side effects, are more potent, are more convenient, are less expensive or are sold more effectively than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory authority approval for their product candidates 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. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of established products, such as DBS. If our product candidates are approved, we expect that they will be priced at a significant premium over existing products. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any product candidate we may develop, if approved, could be adversely affected.

Table of Contents

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need 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 our products, we may not be able to generate product revenue.

We have no internal sales, marketing, or distribution capabilities, nor have we ever commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company with the marketing, sale, or distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities would adversely impact the commercialization of these products. 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 revenue from our product candidates 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 any product candidate that we develop 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 our product candidates effectively. If we are not successful in commercializing our product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future revenue from product candidates and we would incur significant additional losses.

Even if we obtain FDA approval of any of our product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions; however, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not guarantee regulatory approval in any other country.

We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates.

To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing, and distribution of our product candidates. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Approval procedures may be more onerous than those in the United States and may require that we conduct additional preclinical studies or clinical trials.

Table of Contents

If we obtain regulatory approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

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

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our product candidates, which may change from time to time, including the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

  coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop, or commercialize additional product candidates and technologies;
- the level of demand for any approved product candidates, which may vary significantly and be difficult to predict;
- our ability to establish and maintain collaborations, licensing, or other arrangements;

- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and amount of any milestone, royalty, or other payments payable by us or due to us under any collaboration, licensing, or other similar agreement.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel.

Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon the management, clinical, research and development, manufacturing, regulatory, financial and business development expertise of our senior management, particularly Damien McDevitt, Ph.D., our President and Chief Executive Officer, Lisa Johnson-Pratt, M.D., our Sasineprocel Development Lead and Chief Commercial Officer, and Kim Raineri, our Chief Technology Officer, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and preclinical studies, regulatory approvals, or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We will need to expand and effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology, and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are unable to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth and expanding our operations successfully.

As of June 30, 2026, we had 120 full-time employees and three part-time employees. As we continue development and pursue the potential commercialization of our product candidates, as well as transition to functioning as a public company, we will need to expand our financial, development, regulatory, manufacturing, information technology, marketing, and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers, and other third parties, and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are subject to various U.S. federal, state, and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers expose us to broadly applicable foreign, federal, and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert 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 civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to direct and indirect payments and other "transfers of value" made by such manufacturers to physicians (defined to include doctors, dentists,

optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants, and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members in such manufacturers; and

- analogous state and foreign laws and regulations, such as state anti-kickback, patient brokering, and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or paid by patients out-of-pocket; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements involving investment or financial arrangements with physicians may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, suspension or debarment from federal contracts, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize our product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidate for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, the ACA was enacted in the United States in 2010. Among the provisions of the ACA of importance to our potential product candidates, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Table of Contents

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, in the absence of legislation, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through fiscal year 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several 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. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

There has been heightened governmental scrutiny in the U.S. on pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; requires manufacturers to pay rebates to HHS if certain Medicare Part B- and Medicare Part D-covered drugs have price increases that outpace an allowable rate of inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and for the subsequent 15 drugs, which will first be effective in 2027, as well as the next 15 drugs that will be subject to price negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

More recently, the One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

In 2026, the U.S. government launched TrumpRx, a federal initiative to enable patients to gain access to certain prescription drugs at reduced costs based on pricing available in other countries (i.e., most-favored-nation pricing). In addition, the Trump administration is pursuing a two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. Subsequently, in April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. On the other hand, the Trump administration is also pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on international reference pricing for the drugs from economically comparable

countries. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries and bulk purchasing. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our product candidates, if approved. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms and initiatives may prevent us from being able to generate revenue, attain profitability, or commercialize our products, if approved.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay, or cease commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates, if approved. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability, and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering, or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay, or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to market;
- decreased demand for our product candidates;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by U.S. and foreign regulators;
- significant time and costs to defend the related litigation;
- a diversion of our management’s time and our resources;

Table of Contents

- substantial monetary awards to trial participants or product recipients;
- product recalls, withdrawals, or labeling, marketing, or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and protect us from only some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, products/clinical trial liability, cyber liability, clinical trials, and directors' and officers', and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and our service providers may be subject to a variety of data protection, privacy, and security obligations, including laws, regulations, standards, and contractual provisions, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations could subject us to potentially significant liability, fines, or penalties and otherwise harm our business.

We and our service providers maintain a large quantity of personal information, including sensitive personal information, such as confidential business and patient health information, in connection with our business operations and notably our clinical trials, and we are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in non-U.S. jurisdictions. These laws and regulations may be subject to differing interpretations by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our service providers, strategic partners, and future customers. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state, or foreign laws or regulations, our internal policies and procedures, or our contracts governing our processing of personal information, could result in negative publicity, government investigations and enforcement actions, claims by third parties (including class actions), and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the United States, numerous federal and state laws and regulations, including information privacy and security laws, data breach notification laws, and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection, and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. 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 HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant liabilities if our practices are non-compliant with applicable privacy and consumer protection laws.

In addition, certain state laws govern the privacy and security of health-related and other personal information, many of which may differ from each other and from HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act, as amended (the CCPA), gives California residents individual privacy rights related to how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. It also imposes additional data protection obligations on covered businesses, such as additional consumer rights processes, limitations on data uses, new risk assessment requirements for higher risk data, and opt outs for certain uses of sensitive data. The CCPA also created a California privacy protection agency authorized to issue substantive regulations and has resulted in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Approximately one-third of states have passed laws similar to the CCPA, and additional states are proposing similar laws, reflecting a trend toward more stringent privacy legislation in the United States. The scope and application of these laws varies by jurisdiction, and we may be subject to such laws either directly or through a customer. Several states also have adopted laws that govern the privacy of consumer health information, such as Washington's My Health My Data Act, which also creates rights for consumers and imposes obligations on companies to implement these laws. If we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

There are also privacy laws in other countries that may impact our operations, now or in the future. For example, in Europe, the General Data Protection Regulation (GDPR) imposes stringent requirements regarding the collection, use, disclosure, storage, transfer, or other processing of personal data of individuals, notably but not exclusively those within the European Economic Area (EEA) or in the context of an establishment in the EEA, including requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the documentation we must retain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. The GDPR also confers a private right of action in some circumstances on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), and/or civil claims (including class actions).

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States (in some circumstances), and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis.

We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Table of Contents

Further, following the withdrawal of the United Kingdom from the European Union and the end of the transition period, from January 1, 2021, companies could also be subject to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, as amended (collectively, the UK GDPR). The UK GDPR mirrors the fines under the GDPR and has the ability to fine up to the greater of €20 million/£17 million or 4% of annual global revenue. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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, store, use, transfer, disclose, and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers 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 such 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, could result in adverse publicity, and adversely affect our business, financial condition, results of operations, and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our product candidates' 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.

In the ordinary course of business, we collect, store, and transmit confidential information including but not limited to intellectual property, clinical trial data, proprietary and confidential business information, and personal information of our employees, contractors, service providers and strategic partners (collectively, Confidential Information). Our information technology systems and those of our third-party service providers, strategic partners, and other contractors or consultants are vulnerable to attack, damage, and interruption from computer viruses and malware (e.g., ransomware), "phishing" attacks, malicious code, misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, and sophisticated nation-state and nation-state-supported actors.

In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, as well as through artificial intelligence. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', or consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. If any such event, whether actual or perceived, were to occur, it could affect our reputation and/or operations, subject us to lawsuits (including class actions), cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and potential regulator enforcement and significantly increase our costs to recover or reproduce the data. We also rely on a third party to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption

or security incident affects our systems (or those of our third-party service providers, strategic partners, contractors or consultants) or were to result in a loss of or accidental, unlawful, or unauthorized access to, use of, release of, or other processing of Confidential Information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We have also outsourced elements of our information technology infrastructure and, as a result, a number of third-party service providers may or could have access to our Confidential Information. If our third-party service providers fail to protect their information technology systems and our Confidential Information, we may be vulnerable to disruptions in service and unauthorized access to our Confidential Information and we could incur liability and reputational damage. If the information technology systems of our third-party service providers and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state, and foreign government requirements include obligations of companies to notify individuals and, in some cases, government agencies and enforcement authorities of security breaches involving particular categories of personally identifiable information or personal data, which could result from incidents experienced by us or by our third-party service providers, strategic partners, contractors or consultants. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, or settlements. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). However, we may not detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Our business may be affected by the evolving regulatory framework for AI Technologies.

The regulatory framework for artificial intelligence (AI), machine learning, and automated decision-making technologies (collectively, AI Technologies) is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Our business could be affected by litigation, government investigations, and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry, and we could be subject to litigation, government investigation, and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, security, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and

criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations, and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, suspension or debarment from federal contracts, injunctive relief, product recalls, reputational damage, and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees and independent contractors, including principal investigators, CROs, consultants, and vendors may be improperly classified or may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We endeavor to properly classify our employees as exempt or non-exempt with respect to wage and hour laws, including for purposes of minimum wage, overtime and applicable meal and rest periods, and we monitor and evaluate such classifications. Although there are no current, pending or threatened claims or investigations against us asserting that any employees have been incorrectly classified as exempt, the possibility nevertheless exists that certain job roles could be deemed to have been incorrectly classified as exempt. In addition, we endeavor to classify our workforce properly, and we monitor and evaluate such classifications. Although there are no current, pending or threatened claims or investigations against us asserting that any independent contractors have been incorrectly classified, the possibility nevertheless exists that certain contractors could be deemed to be employees.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless, and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete, and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iv) laws that require the true, complete, and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from non-compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, suspension or debarment from federal contracts, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with this offering or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and may never achieve profitability. As of December 31, 2025, we had net operating loss (NOL) carryforwards of approximately $161.5 million for federal income tax purposes and $194.5 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOL carryforwards generated after December 31, 2017, can be carried forward indefinitely but are limited to 80% utilization against taxable income beginning

January 1, 2021, which may require us to pay federal income taxes in future years despite having federal NOL carryforwards to utilize. Unless previously utilized, our state NOL carryforwards begin to expire in various amounts in 2038. Our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an "ownership change." For these purposes, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not determined the amount of the cumulative change in our ownership resulting from this offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with this offering. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Changes to U.S. tariff and import/export regulations may have a negative effect on us.

The United States has enacted, and continues to consider, a range of trade-related measures, including tariffs, export controls, and other policies. The President of the United States has directed agencies to reassess key aspects of U.S. trade policy, and there has been ongoing debate and uncertainty surrounding potential changes to trade agreements, tariff structures, and foreign investment regulations. Shifts in trade policy—whether through legislation, executive action, or international negotiation—have and could continue to alter the global trade landscape and affect supply chains, pricing, and demand for goods and services. These developments, or the perception that such changes may occur, have and could continue to have a material adverse effect on global economic conditions, contribute to volatility in financial markets, and disrupt international trade, including trade between the United States and its key partners. Any of these factors could depress economic activity and the development and commercialization of our product candidates, which could result in a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patent, trade secret, and trademark protection for our product candidates and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property protection in the United States and other countries with respect to our product candidates and other proprietary technologies we may develop. We generally seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our product candidates, manufacturing processes, delivery devices and methods of use. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties. For intellectual property we in-license, we may have limited control over prosecution, maintenance, and enforcement/defense and may depend on our licensors, which could adversely affect the scope or availability of protection. If we are unable to obtain, maintain, expand, enforce, and defend the scope of our intellectual property protection, our business, financial condition, results of operations, and prospects could be materially harmed.

Table of Contents

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend, or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our product candidates or technologies.

In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to invent the inventions claimed in any of our owned patents or pending patent applications, or that we or any future licensors were the first to file for patent protection of such inventions. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies or products. Further, even if these patents are granted, they may be difficult to enforce. For example, to the extent we rely on method-of-use patents, such patents may not prevent a competitor from marketing the same or a similar product for an indication outside the scope of the patented method, and physicians may prescribe competing products “off-label.” To the extent such conduct infringes our method-of-use claims, that infringement may be difficult to prevent or enforce against in practice.

Further, any issued patents that we own or may license in the future covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, or enforceability of our patents and/or other intellectual property. Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Further, if we encounter delays in our development and testing of our product candidates, clinical trials, or regulatory review and approval of our product candidates, the period of time during which we could market our product candidates under patent protection may be reduced (i.e., patents protecting the product candidates might expire before or shortly after such product candidates are commercialized). Thus, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents issuing from our owned and any future in-licensed patent applications

may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations, and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party post-issuance submission of prior art to the USPTO challenging the validity of one or more claims of our patents or patents we may license in the future. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application or patent application we may license in the future. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, post-grant proceedings, inter partes review, interference proceedings, or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize our product candidates and other proprietary technologies we may develop and compete directly with us.

Moreover, some of our patent rights may in the future be co-owned with third parties. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

Filing, prosecuting, maintaining, enforcing, and defending patents on our product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. 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 intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and 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 products, and our patents or patents we may license in the future or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may license in the future at risk of being invalidated or interpreted narrowly, could put our patent applications and any patent applications we may license in the future at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, public policy initiatives may seek to increase access to therapies, including by limiting or weakening patent protection in certain circumstances, which could diminish the value of our intellectual property. Further, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. In addition, geopolitical actions in the United States and in foreign countries (such as the wars between Russia and Ukraine and Israel and Hamas) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing product made using our inventions in and into Russia. This or any of the foregoing could increase uncertainties and costs for the maintenance, enforcement, or defense of our issued patents, which could impair our competitive intellectual property position.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some circumstances, we may be dependent on any future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India, and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner, and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We would also be dependent on any future licensors to take the necessary actions to comply with these requirements with respect to any intellectual property we may license in the future.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and product candidates.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and 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. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the U.S. Supreme Court held in *Amgen v. Sanofi (2023)* that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future.

In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. The UPC is an international court established by a subset of EU Member States, and not all EU Member States participate or have ratified the UPC Agreement; accordingly, the geographic scope of UPC jurisdiction and Unitary Patent coverage is limited to participating EU Member States that have ratified the UPC Agreement. As a result, European patents (including those issued prior to ratification of the EU Patent Package) validated in participating, ratifying EU Member States now by

default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patent, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations, and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. We may choose to opt out of UPC jurisdiction for current and future European Patents and decline to request unitary effect for future European Patent grants.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our patent rights may be subject to priority, validity, inventorship, ownership, and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated, or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter, or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

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

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. non-provisional or international patent application 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 has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with

sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected.

If we do not obtain patent term extension and equivalent extensions outside of the United States for our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA regulatory approval of any of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for 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, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, collaborators, or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co-inventor, or owner of trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets, or other 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 the right to use intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. In addition, individuals named as inventors on our patents and patent applications may in the future become involved with competitors or otherwise take actions that could result in the development of products or processes designed to compete with or design around our intellectual property. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third-party collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We also use physical and technological security measures to protect our confidential and proprietary information; however, these measures may be breached or otherwise become ineffective.

Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. 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. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. 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. 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. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. In addition, we may need to share our proprietary information, including trade secrets, with current or future business partners, collaborators, contractors, and other third parties, including those located in jurisdictions that may present a heightened risk of misappropriation, including through direct intrusion by private parties, foreign actors or those affiliate with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property in the United States and abroad.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants, or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our product candidates and other proprietary technologies we may develop. 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 our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 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 or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until 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. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, 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 patent 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 patent application will issue with claims of relevant scope. Even if we believe we are free to operate based on our analyses, competitors may obtain issued claims, including in patents we believe are not relevant, that could block our efforts or result in infringement.

Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our product candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating, and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our product candidates and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure that our product candidates and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our product candidates, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that

we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our product candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover product candidates or the use of our products. We are aware of certain third-party patents in the United States and elsewhere containing claims directed to methods of manufacturing dopaminergic neurons that may cover certain methods that we may use to manufacture sasineprocel. Based on our current development plans, we currently expect the identified patents to expire before any commercial launch of sasineprocel, if approved. We are also developing alternative manufacturing methods that do not use the methods claimed in the relevant patent claims. However, we cannot assure you that these alternative methods will be successfully developed, suitable for commercial manufacturing, or determined to not infringe those claims. Our expectation regarding patent expiration before commercial launch does not eliminate potential risks relating to manufacturing activities conducted before expiration. If we use a manufacturing method covered by a valid and enforceable claim of one of these patents while it remains in force, we could face infringement claims. If successfully asserted, such claims could require us to obtain a license, modify our manufacturing processes, pay damages, or delay affected activities. A license may not be available on commercially reasonable terms or at all. Developing and implementing alternative manufacturing methods could require additional time, expense, comparability studies or regulatory submissions, which could delay the development or commercialization of sasineprocel.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable, and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In addition, such claims may be asserted against our collaborators, licensees, or other business partners, and we may be required to indemnify certain of these parties, which could increase our costs and adversely affect our business. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such 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 conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. 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 price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, or results of operations.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such 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 conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our product candidates.

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

Third parties, such as a competitor, may infringe our patent rights. We may be unable to detect or police all such infringement, and detecting infringement may be particularly difficult for certain manufacturing processes or other activities that are not readily observable. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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 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 conduct such litigation or proceedings adequately. 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.

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing, misappropriating, or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged or determined to be infringing, misappropriating, or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. 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, which may not survive such proceedings. Moreover, any name we may propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for

confusion with other product names. If the FDA or a comparable foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate, or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect, or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution, or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to obtain, enforce, or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats.

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 products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or may license in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our or their inventions;
- we or our licensors may fail to comply with obligations to the U.S. government (including under the Bayh-Dole Act) with respect to patents and patent applications arising from U.S. government funding, which could result in the loss of rights or the grant of licenses to third parties;
- 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 and future patent applications that we own or may license will not lead to issued patents;
- any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors 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;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;

- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations, and prospects.

We partially depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent, in part, on patents, know-how and proprietary technology licensed from others, including Cell X, CCF, iPS Academia Japan and Sumitomo. In addition to the foregoing, we are a party to a number of other license agreements under which we are granted rights to intellectual property that are critical to our business, and we may enter into additional license agreements in the future with third parties. Our existing license agreements impose, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, or we may be subject to litigation for breach of these agreements.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors 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. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the agreements under which we license intellectual property or technology from third parties 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 patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- 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 licensing agreement;
- our right to sublicense patent and other rights to third parties under our license arrangements or collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

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 technology or product candidates. As a result, any termination of or disputes over our intellectual property licenses

could result in the loss of our ability to develop and commercialize our product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license, or use third-party intellectual property and proprietary rights. We also depend on intellectual property, know-how, trade secrets, and other proprietary rights that we license from third parties, and termination or expiration of any of these licenses could result in the loss of significant rights and could harm our ability to develop and commercialize our product candidates. For example, product candidates may require specific materials, components, or processes to work effectively and efficiently, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents.

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 or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate, or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. In addition, our existing and future license and collaboration agreements may impose diligence, milestone payment, royalty, insurance, and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate the applicable license. We may also enter into sublicense arrangements, and if our sublicensor fails to comply with its obligations under an upstream license, the upstream licensor may terminate the upstream license, which could terminate our sublicense and leave us without rights to the applicable intellectual property unless we can obtain a direct license, which may not be available on reasonable terms or at all.

Additionally, we may collaborate with academic institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we are able to obtain a license, it may be non-exclusive, and our competitors may also receive access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources, or 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. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations, and prospects could suffer.

Disputes may also arise between us and our licensors regarding licensed intellectual property, including the scope of rights granted, interpretation-related issues, diligence obligations, sublicense rights, ownership of improvements or jointly developed intellectual property, and the control of prosecution, maintenance, and enforcement. If such disputes prevent or impair our ability to maintain or enforce our licensed rights on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Risks Related to This Offering and Ownership of Our Common Stock

There has been no public market for our common stock. An active, liquid, and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your common stock at or above the initial public offering price or at all.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on the Nasdaq Global Select Market (Nasdaq) under the symbol "ASPE", an active trading market for our common stock may never develop or may not be sustained following this offering. We and the representatives of the underwriters have determined the initial public offering price of our common stock through negotiation. This price may not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock may be highly volatile, and purchasers of our common stock could lose all or part of their investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for stock of biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;

Table of Contents

- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license additional product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators, or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biotechnology and biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders, or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- general economic, industry, geopolitical, and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors, or key personnel;
- intellectual property, product liability, or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations, or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will have broad discretion in the use of proceeds from this offering and may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our

business. Pending their use, we may 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. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the closing of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately $7.66 per share, based on the initial public offering price of $15.00 per share. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

After this offering, our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

Following the completion of this offering, our executive officers, directors, and greater than 5% stockholders, in the aggregate, will own approximately 44% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options and without giving effect to any potential purchases by such persons in this offering). As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. Additionally, the concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We do not currently intend to pay dividends on our common stock, so any returns on your investment will be limited to the value of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

Based on shares of common stock outstanding as of June 30, 2026, upon the closing of this offering, we will have a total of 29,078,600 shares of common stock outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of these shares, only the 9,375,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase

additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and substantially all of our securityholders have entered into lock-up agreements with the representatives pursuant to which they may not, with limited exceptions and among other things, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Leerink Partners LLC, Piper Sandler & Co., Stifel, Nicolaus & Company, Incorporated and UBS Securities LLC. The underwriters may permit our officers, directors, and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See the section titled "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional 19,703,600 shares of common stock will be eligible for sale in the public market, of which 12,762,164 shares will be held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, in each case based on shares of our common stock outstanding as of June 30, 2026 and without giving effect to any potential purchases by such persons in this offering.

In addition, as of June 30, 2026, 3,043,497 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 18,956,358 shares of our outstanding common stock, or approximately 65.2% of our total outstanding common stock based on shares outstanding as of June 30, 2026, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See the section titled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- 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 pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley);

- 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, unless the U.S. Securities and Exchange Commission (SEC) determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year, and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect immediately prior to the closing of this offering will contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless otherwise required by law or determined by the board of directors, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least two-thirds of the shares entitled to vote to remove a director for cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting powers, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least two-thirds of the shares entitled to vote to adopt, amend, or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, the chairman of the board of directors, the chief executive officer or the executive chairman, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation that will be in effect immediately prior to the consummation of this offering will provide that unless we consent in writing to the selection of an alternative forum, 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 our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended or 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 or any other claim for which the federal courts have exclusive jurisdiction. 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 Exchange Act and any claims for which the federal courts have exclusive jurisdiction. 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, which may discourage such lawsuits against us and our directors, officers, and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 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 in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Table of Contents

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors, and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

General Risk Factors

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

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain 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 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.

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. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. 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, results of operations and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors, and other collaborators and partners, even if we do not explicitly authorize or have actual

knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

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.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

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

Our operations and the operations of our suppliers, CROs, CMOs, and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers to produce our product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition, and stock price.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine and in the Middle East, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce or abandon clinical development or future commercialization efforts or

grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers, and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in tax laws or regulations may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, or interpreted, changed, modified, or applied adversely to us, any of which could adversely affect our business operations and financial performance. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may materially and adversely affect our business, financial condition, results of operations and cash flow.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market, or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K.

However, as an "emerging growth company," our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Implementing any appropriate changes to our internal control over financial reporting may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in establishing and maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and materially and adversely affect our business, financial condition, results of operations and prospects.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our 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 periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us 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. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

We could be subject to securities class action litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. 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 biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs (including the cost to defend against and any potential adverse outcome resulting from any such proceeding), damage to our reputation and a diversion of our management's attention and resources from other business concerns, which could harm our business, financial condition, results of operations and prospects.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design, and conduct of our ongoing and planned clinical trials and preclinical studies for our product candidates, such as the advancement of sasineprocel through Phase 3 trials and the development of sasineprocel into genetic PD, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the pricing and reimbursement of our products, if approved, the potential to develop future product candidates and pursue automated manufacturing processes for such product candidates, the potential benefits of strategic collaborations and the potential to enter into any future strategic arrangements, the timing and likelihood of success, plans, and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential,” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties, and assumptions described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. You should review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

In addition, statements that “we believe” and similarly qualified 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 you are cautioned not to rely unduly upon them.

Table of Contents

MARKET AND INDUSTRY DATA

We obtained the industry, market, and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry, and general publications and surveys, governmental agencies, and publicly available information in addition to research, surveys, and studies conducted by third parties. The content of these third-party sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research, and our industry experience and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

In addition, while we are responsible for all of the disclosure contained in this prospectus and we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $125.8 million (or approximately $145.4 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $15.00 per share, and after deducting the 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 currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, as follows:

- approximately $8.0 million to continue funding the Phase 1/2a ASPIRO trial evaluating sasineprocel in patients with sporadic and genetic PD;
- approximately $110.0 million to initiate and fund a Phase 3 trial evaluating sasineprocel in patients with sporadic and genetic PD, with plans to initiate such Phase 3 trial prior to the completion of the Phase 1/2a ASPIRO trial;
- approximately $4.0 million to continue funding the development of our microglia programs, including initiating IND-enabling studies; and
- the remainder for working capital and other general corporate purposes.

We may also use a portion of the remaining net proceeds and our existing cash, cash equivalents and marketable securities to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments or obligations to do so.

Based on our current operating plans, we believe that the estimated net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the second half of 2028. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Additionally, our expected use of existing cash, cash equivalents and marketable securities and our net proceeds from this offering represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress and costs of our development activities, the status of and results from clinical trials and preclinical studies, as well as any collaborations that we may enter into with third parties for our products, and the amount of cash used in our operations and any unforeseen cash needs as well as other factors described in the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Special Note Regarding Forward-Looking Statements.”

The net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities will not be sufficient to complete the Phase 1/2a ASPIRO trial, the Phase 3 trial for sasineprocel, which we intend to initiate prior to the completion of the Phase 1/2a ASPIRO trial, or the development of sasineprocel or any other current or future product candidates. After this offering, we will require additional capital in order to advance our current and any future product candidates through clinical trials, regulatory approval, and commercialization. Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. Nevertheless, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all.

Pending the uses described above, we plan to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit, and direct or guaranteed obligations of the United States.

Table of Contents

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, current and anticipated capital requirements, business prospects, and other factors our board of directors deems relevant, and subject to applicable laws and the restrictions contained in any future financing instruments.

Table of Contents

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of June 30, 2026:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, (ii) the Note Forgiveness, including the treatment of 622,707 shares of common stock as outstanding, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 9,375,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of June 30, 2026		
(in thousands, except par value and share data)	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma as Adjusted (unaudited)
Cash, cash equivalents and marketable securities	$ 72,377	$ 72,377	$ 198,158
Convertible preferred stock (Series Seed, Series Seed-2, Series A-1, Series A-2, Series B, and Series C), $0.0001 par value; 177,602,470 shares authorized, 177,593,856 issued and outstanding, actual; no shares authorized, issued, and outstanding, pro forma, and pro forma as adjusted	$ 338,808	—	—
Stockholders' (deficit) equity:			
Preferred stock, $0.0001 par value; no shares authorized, issued or outstanding, actual (other than the convertible preferred stock set forth above), 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.0001 par value; 228,898,561 shares authorized; 1,732,276 shares issued; and 1,109,569 shares outstanding, actual; 500,000,000 shares authorized, 19,703,600 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 29,078,600 shares issued and outstanding, pro forma as adjusted	—	2	3
Additional paid-in capital	13,855	354,484	480,264
Accumulated other comprehensive loss	(42)	(42)	(42)
Accumulated deficit	(264,886)	(266,709)	(266,709)
Total stockholders' (deficit) equity	(251,073)	87,735	213,516
Total capitalization	$ 87,735	$ 87,735	$ 213,516

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above, is based on 19,703,600 shares of our common stock outstanding as of June 30, 2026 after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock immediately prior to the closing of this offering and (ii) the Note Forgiveness, including the treatment of 622,707 shares of common stock as outstanding. See Note 13 to our unaudited interim financial statements

included elsewhere in this prospectus for additional information related to the Note Forgiveness. The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above excludes:

- 3,043,497 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2026 under our 2018 Plan, with a weighted-average exercise price of $6.75 per share;
- 27,314 shares of common stock issuable upon exercise of stock options granted subsequent to June 30, 2026, with a weighted-average exercise price of $9.79 per share;
- 6,799,243 shares of our common stock reserved for future issuance under the general share reserve of our 2026 Equity Incentive Plan (which number includes 3,634,825 new shares plus up to a maximum of 3,164,418 shares subject to outstanding awards granted under the 2018 Plan which after the effective date of the 2026 Plan are subsequently forfeited, cancelled, withheld or reacquired), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 872,358 shares of our common stock reserved for future issuance under the Executive Chair Reserve of our 2026 Plan, which is available solely for the issuance of shares pursuant to awards granted to our Executive Chair, Faheem Hasnain, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 290,786 shares of our common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan, which became effective as of immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP, as more fully described under the terms of the ESPP as described in the section titled "Executive and Director Compensation—Employee Stock Plans"; and
- 17,778 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2026, at an exercise price of $7.71 per share.

Table of Contents

DILUTION

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

As of June 30, 2026, our historical net tangible book value (deficit) was $(251.1) million, or $(226.28) per share of our common stock, based on 1,732,276 shares of common stock issued and 1,109,569 shares of common stock outstanding as of such date. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of common stock outstanding at June 30, 2026.

On a pro forma basis, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering, and (ii) the Note Forgiveness, including the resulting treatment of 622,707 shares of common stock as outstanding, our pro forma net tangible book value as of June 30, 2026 would have been $87.7 million, or $4.45 per share of our common stock.

After giving further effect to the sale and issuance of 9,375,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2026 would have been approximately $213.5 million, or approximately $7.34 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately $2.89 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $7.66 per share to new investors purchasing shares of common stock 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 (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share		$ 15.00
Historical net tangible book value (deficit) per share as of June 30, 2026	$ (226.28)	
Pro forma increase in historical net tangible book value per share as of June 30, 2026 attributable to the pro forma adjustments described above	230.73	
Pro forma net tangible book value per share as of June 30, 2026	4.45	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.89	
Pro forma as adjusted net tangible book value per share after this offering		7.34
Dilution per share to new investors participating in this offering		$ 7.66

If the underwriters exercise their option to purchase 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 approximately $7.65 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be approximately $3.20 per share, and the dilution per share to investors in this offering would be $7.35 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of June 30, 2026, the differences between the number of shares purchased from us, the total consideration paid to us in cash, and the weighted-average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on the initial public offering price of $15.00

per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	19,703,600	68%	$ 345,017,618	71%	$ 17.51
New investors participating in this offering	9,375,000	32%	140,625,000	29%	$ 15.00
Total	29,078,600	100%	$ 485,642,618	100%	

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 65% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors participating in this offering will increase to 10,781,250, or approximately 35% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations above (other than the historical net tangible book value calculations) are based on 19,703,600 shares of our common stock outstanding as of June 30, 2026 after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock immediately prior to the closing of this offering, and (ii) the Note Forgiveness, including the treatment of 622,707 shares of common stock as outstanding. See Note 13 to our unaudited interim financial statements included elsewhere in this prospectus for additional information related to the Note Forgiveness. The number of shares of our common stock issued and outstanding as of June 30, 2026 in the foregoing tables and calculations above excludes:

- 3,043,497 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2026 under our 2018 Plan, with a weighted-average exercise price of $6.75 per share;
- 27,314 shares of common stock issuable upon exercise of stock options granted subsequent to June 30, 2026, with a weighted-average exercise price of $9.79 per share;
- 6,799,243 shares of our common stock reserved for future issuance under the general share reserve of our 2026 Equity Incentive Plan (which number includes 3,634,825 new shares plus up to a maximum of 3,164,418 shares subject to outstanding awards granted under the 2018 Plan which after the effective date of the 2026 Plan are subsequently forfeited, cancelled, withheld or reacquired), as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 872,358 shares of our common stock reserved for future issuance under the Executive Chair Reserve of our 2026 Plan, which is available solely for the issuance of shares pursuant to awards granted to our Executive Chair, Faheem Hasnain, as more fully described under the terms of the 2026 Plan described in the section titled "Executive and Director Compensation—Employee Stock Plans";
- 290,786 shares of our common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan, which became effective as of immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP, as more fully described under the terms of the ESPP as described in the section titled "Executive and Director Compensation—Employee Stock Plans"; and
- 17,778 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2026, at an exercise price of $7.71 per share.

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

Table of Contents

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Aspen Neuroscience, Inc. is a leading, clinical-stage regenerative medicine biotechnology company focused on developing autologous iPSC-derived therapies to address neurodegenerative diseases with high unmet medical need. Our lead product candidate, sasineprocel, is an investigational single-dose, autologous iPSC-based cell therapy being evaluated for the treatment of PD. We believe sasineprocel has the potential to be disease-modifying by primarily replacing a patient's lost DA neurons with DANPCs. We are headquartered in San Diego, California, and were originally incorporated in Delaware on May 18, 2018.

Since our inception in 2018, we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management, technical, and business development staff to support our operations. To date, we have funded our operations primarily through aggregate gross proceeds of approximately $340 million from the sales of our convertible preferred stock, including approximately $115.6 million from our Series C convertible preferred stock financing in 2025.

We have incurred significant net losses since inception and we expect to continue to incur substantial losses for the foreseeable future. Our net losses for the years ended December 31, 2025 and 2024 were $62.1 million and $48.6 million, respectively. Our net losses for the six months ended June 30, 2026 and 2025 were $36.5 million and $31.8 million, respectively. As of June 30, 2026, we had an accumulated deficit of $264.9 million.

We expect our operating expenses to significantly increase as we continue to develop, conduct clinical trials, and seek regulatory approvals for our product candidates, engage in other research and development activities to expand our pipeline of product candidates, expand our operations and headcount, maintain and expand our intellectual property portfolio, and, if we obtain approval for one or more of our product candidates, launch commercial activities. We also expect to incur additional operating expenses associated with operating as a public company upon the completion of this offering, including costs related to SEC reporting obligations, Sarbanes-Oxley compliance, director and officer liability insurance, investor relations, and additional finance and legal personnel. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing and scope of our clinical trials and our expenditures on other research and development activities.

We will not generate any revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution. We may also seek to generate revenue through collaboration agreements, licensing arrangements, or other strategic transactions prior to or in connection with any such approval.

As a result, we will require substantial additional funding to support our ongoing operations as we advance our product candidates through clinical development, seek regulatory approvals, and prepare for and, if any of our product candidates are approved, proceed to commercialization. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, or other strategic arrangements. However, we may be unable to raise additional funds or enter into such agreements when needed, on acceptable terms,

or at all. Our inability to obtain adequate funding could have a material adverse effect on our business, results of operations, and financial condition.

At this time, due to the inherently unpredictable nature of clinical development and the early stage of our product candidates, we cannot reasonably estimate the costs required or timelines needed to complete development, obtain marketing approval, and commercialize our current or any future product candidates, if at all. For the same reasons, we are unable to accurately predict the timing or magnitude of increased expenses or when, or if, we will achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase it on a quarterly or annual basis. Our ability to continue advancing our programs will depend on our ability to obtain additional funding. If we are unable to secure sufficient capital on acceptable terms, we may be forced to delay, reduce, or eliminate some or all of our research and development programs, product portfolio expansion efforts, or commercialization activities, which could adversely affect our business prospects. In such circumstances, we may also be required to substantially reduce or terminate operations.

In various closings from October 2025 to November 2025, we issued and sold to investors in private placements an aggregate of 76,173,492 shares of Series C convertible preferred stock at a per share purchase price of $1.5179, and we received gross proceeds of approximately $115.6 million. As of June 30, 2026, we had cash, cash equivalents and marketable securities of $72.4 million. Together with the estimated net proceeds from this offering, we believe our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditures into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, our expected use of existing cash, cash equivalents, marketable securities, and our net proceeds from this offering represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. See “Liquidity and Capital Resources—Funding Requirements” below.

Results of Operations

Components of Results of Operations and Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for each of the periods below (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 41,833	$ 35,593	$ 6,240
General and administrative	17,472	17,865	(393)
Total operating expenses	59,305	53,458	5,847
Loss from operations	(59,305)	(53,458)	(5,847)
Other (loss) income:			
Interest income	1,793	4,397	(2,604)
Other (loss) income, net	(4,544)	504	(5,048)
Total other (loss) income, net	(2,751)	4,901	(7,652)
Net loss	$ (62,056)	$ (48,557)	$ (13,499)

To date, we have not generated any revenue. We do not expect to generate any revenue unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we fail to complete clinical development or obtain regulatory approval for our product candidates, our ability to generate future revenues and our results of operations and financial position would be adversely affected.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred in connection with the research, development and manufacturing of our lead product candidate, sasineprocel. Our research and development expenses include:

- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in manufacturing, research and development functions;
- clinical research organization and investigator fees to support our clinical trial activities;
- costs of outside consultants, including their fees and travel expenses;
- the cost of manufacturing our product candidate, including costs for developing our manufacturing process, production materials and laboratory supplies;
- equipment and facility-related expenses, including direct depreciation costs and allocated expenses for rent and other operating costs; and
- expenses related to compliance with regulatory requirements.

We expense research and development costs in the period in which they are incurred. Research and development activities are central to our business model. We expect our research and development expenses to increase significantly over the near term as we advance sasineprocel through clinical development, including the commencement of a Phase 3 registrational trial.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Non-personnel:			
Cell-therapy development and production costs	$ 14,497	$ 11,485	$ 3,012
Equipment and facilities costs	6,332	5,781	551
Depreciation	1,481	1,066	415
Total non-personnel costs	22,310	18,332	3,978
Personnel:			
Salaries, bonuses and benefits	18,345	16,295	2,050
Stock-based compensation	1,178	966	212
Personnel costs	19,523	17,261	2,262
Total research and development expense	$ 41,833	$ 35,593	$ 6,240

Research and development expenses were $41.8 million for the year ended December 31, 2025, compared to $35.6 million for the year ended December 31, 2024. The increase of $6.2 million was due to an increase in non-personnel costs primarily associated with the development and production of sasineprocel of $3.0 million, increased personnel costs for salaries, bonuses and benefits of $2.1 million, increased facilities costs of $0.5 million, increased depreciation expense of $0.4 million, and increased stock-based compensation expense of $0.2 million. Substantially all of our non-personnel research and development expenses for the years ended December 31, 2025 and 2024 related to our lead product candidate, sasineprocel. Non-personnel research and development expenses related to other programs were immaterial for the years ended December 31, 2025 and 2024.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related costs, including salaries, bonuses, benefits, and stock-based compensation expenses for personnel in executive, finance, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees paid for auditing, tax and consulting services; insurance costs; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the near term as we expand our headcount to support increased research and development activities. We also expect to incur increased expenses associated with being a public company, including costs for directors and officers' insurance, legal, audit, regulatory, and tax-related services related to compliance with the rules and regulations of the SEC and Nasdaq listing standards, and investor relations costs.

The following table summarizes our general and administrative expenses for the periods indicated (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Non-personnel:			
Professional fees, consultants and external spend	$ 5,172	$ 5,008	$ 164
Facilities costs	2,108	2,145	(37)
Depreciation	399	482	(83)
Total non-personnel costs	7,679	7,635	44
Personnel:			
Salaries, bonuses and benefits	8,454	8,489	(35)
Stock-based compensation	1,339	1,741	(402)
Personnel costs	9,793	10,230	(437)
Total general and administrative expense	$ 17,472	$ 17,865	$ (393)

General and administrative expenses were $17.5 million for the year ended December 31, 2025, compared to $17.9 million for the year ended December 31, 2024. The decrease of $0.4 million was primarily due to decreases in personnel costs resulting from decreases in stock-based compensation as prior grants either fully vested or were forfeited.

Other (Loss) Income

Interest income

Interest income consists of interest earned on our cash equivalents and marketable securities. Interest income was $1.8 million for the year ended December 31, 2025, compared to $4.4 million for the year ended December 31, 2024. The decrease of $2.6 million was primarily due to the lower average balance of cash equivalents and marketable securities during the year ended December 31, 2025.

Other (loss) income, net

Other (loss) income, net, primarily reflects changes in the fair value of the Cell X Convertible Note (described below in "—Contractual Obligations and Commitments—Cell X A&R Collaboration and License Agreement"), which is accounted for under the fair value option, with changes in fair value recognized in other (loss) income. Other loss was $4.5 million for the year ended December 31, 2025, compared to other income of $0.5 million for the year ended December 31, 2024. The decrease of $5.0 million was primarily due to a reduction in the fair value of the Cell X Convertible Note (as described below) resulting from changes in our estimated expected future investment returns of the Cell X Convertible Note.

Table of Contents

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for each of the periods below (in thousands):

	Six Months Ended June 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 28,454	$ 20,812	$ 7,642
General and administrative	9,764	10,074	(310)
Total operating expenses	38,218	30,886	7,332
Loss from operations	(38,218)	(30,886)	(7,332)
Other income (loss):			
Interest income	1,670	858	812
Other income (loss), net	2	(1,731)	1,733
Total other income (loss), net	1,672	(873)	2,545
Net loss	$ (36,546)	$ (31,759)	$ (4,787)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Six Months Ended June 30,		
	2026	2025	Change
Non-personnel:			
Cell-therapy development and production costs	$ 11,706	$ 7,656	$ 4,050
Equipment and facilities costs	3,611	3,043	568
Depreciation	763	620	143
Total non-personnel costs	16,080	11,319	4,761
Personnel:			
Salaries, bonuses and benefits	11,123	8,957	2,166
Stock-based compensation	1,251	536	715
Personnel costs	12,374	9,493	2,881
Total research and development expense	$ 28,454	$ 20,812	$ 7,642

Research and development expenses were $28.5 million for the six months ended June 30, 2026, compared to $20.8 million for the six months ended June 30, 2025. The increase of $7.6 million was due to an increase in non-personnel costs primarily associated with the development and production of sasineprocel of $4.1 million, increased personnel costs for salaries, bonuses and benefits of $2.2 million, increased facilities and equipment costs of $0.6 million, increased stock-based compensation expense of $0.7 million, and increased depreciation expense of $0.1 million. Substantially all of our non-personnel research and development expenses for the six months ended June 30, 2026 and 2025 related to our lead product candidate, sasineprocel. Non-personnel research and development expenses related to other programs were immaterial for the six months ended June 30, 2026 and 2025.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated (in thousands):

	Six Months Ended June 30,		
	2026	2025	Change
Non-personnel:			
Professional fees, consultants and external spend	$ 2,739	$ 3,281	$ (542)
Facilities costs	1,135	1,204	(69)
Depreciation	118	184	(66)
Total non-personnel costs	3,992	4,669	(677)
Personnel:			
Salaries, bonuses and benefits	4,540	4,721	(181)
Stock-based compensation	1,232	684	548
Personnel costs	5,772	5,405	367
Total general and administrative expense	$ 9,764	$ 10,074	$ (310)

General and administrative expenses were $9.8 million for the six months ended June 30, 2026, compared to $10.1 million for the six months ended June 30, 2025. The decrease of $0.3 million was primarily due to decreases in professional, consultant and other external spend of $0.5 million, decreases in salaries, bonuses and benefits of $0.2 million, partially offset by increases in stock-based compensation of $0.5 million.

Other Income (Loss)

Interest income

Interest income consists of interest earned on our cash equivalents and marketable securities. Interest income was $1.7 million for the six months ended June 30, 2026, compared to $0.9 million for the six months ended June 30, 2025. The increase of $0.8 million was primarily due to the higher average balance of cash equivalents and marketable securities during the six months ended June 30, 2026.

Other income (loss), net

Other income (loss), net, primarily reflects changes in the fair value of the Cell X Convertible Note (described below in "—Contractual Obligations and Commitments—Cell X A&R Collaboration and License Agreement"), which is accounted for under the fair value option, with changes in fair value recognized in other income (loss). Other income was $2,000 for the six months ended June 30, 2026, compared to other loss of $1.7 million for the six months ended June 30, 2025. The increase of $1.7 million was primarily due to a reduction in the fair value of the Cell X Convertible Note (as described below) of $1.7 million during the six months ended June 30, 2025, compared to an increase of $2,000 of the fair value of the Cell X Convertible Note during the six months ended June 30, 2026, each resulting from changes in our estimated expected future investment returns of the Cell X Convertible Note.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. We expect to incur substantial expenditures as we advance our primary product candidate through clinical development, undergo the regulatory approval process, engage in other research and development activities to expand our pipeline of product candidates, expand our operations and headcount, and maintain and expand our intellectual property. Further, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

To date, we have funded our operations primarily through the sale of preferred stock. We have raised an aggregate of approximately $340 million in gross proceeds from the issuance of preferred stock, including $115.6

million in gross proceeds from the issuance and sale of our Series C preferred stock in the fourth quarter of 2025. As of June 30, 2026 and December 31, 2025, we had cash, cash equivalents and marketable securities of $72.4 million and $110.7 million, respectively.

Cash Flows

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2025	2024
Operating activities:		
Net loss	$ (62,056)	$ (48,557)
Non-cash charges	10,974	3,764
Changes in operating assets and liabilities	(1,765)	631
Net cash used in operating activities	(52,847)	(44,162)
Net cash provided by investing activities	4,197	20,631
Net cash provided by financing activities	115,526	457
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 66,876	$ (23,074)

Operating Activities

For the year ended December 31, 2025, net cash used in operating activities was $52.8 million, reflecting a net loss of $62.1 million and a net change in our operating assets and liabilities of $1.8 million, partially offset by non-cash charges of $11.0 million. Non-cash charges primarily consisted of the $4.5 million change in the fair value of the Cell X Convertible Note, stock-based compensation of $2.5 million, amortization of our right-of use lease assets of $2.3 million, and depreciation of $1.6 million.

For the year ended December 31, 2024, net cash used in operating activities was $44.2 million, reflecting a net loss of $48.6 million and a net change in our operating assets and liabilities of $0.6 million, partially offset by non-cash charges of $3.8 million. Non-cash charges primarily consisted of stock-based compensation of $2.7 million, amortization of our right-of-use lease assets of $2.2 million, and depreciation of $1.4 million, offset by the accretion of the discount on our marketable securities of $2.0 million.

Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities was $4.2 million, primarily consisting of maturities of marketable securities of $47.5 million, partially offset by the purchase of marketable securities of $33.6 million and purchases of property and equipment of $9.7 million.

For the year ended December 31, 2024, net cash provided by investing activities was $20.6 million, primarily consisting of maturities of marketable securities of $103.1 million, partially offset by purchase of marketable securities of $74.9 million, the purchase of the Cell X Convertible Note of $5.0 million, and purchases of property and equipment of $2.6 million.

Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities was $115.5 million, primarily consisting of net cash proceeds from the issuance of Series C preferred stock.

For the year ended December 31, 2024, net cash provided by financing activities was $0.5 million, primarily consisting of cash proceeds from stock option exercises by employees under the 2018 Plan.

Table of Contents

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table summarizes our cash flows for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2026	2025
Operating activities:		
Net loss	$ (36,546)	$ (31,759)
Non-cash charges	3,853	4,944
Changes in operating assets and liabilities	(1,812)	(3,804)
Net cash used in operating activities	(34,505)	(30,619)
Net cash (used in) provided by investing activities	(25,613)	24,756
Net cash (used in) provided by financing activities	(692)	50
Net decrease in cash, cash equivalents and restricted cash	$ (60,810)	$ (5,813)

Operating Activities

For the six months ended June 30, 2026, net cash used in operating activities was $34.5 million, reflecting a net loss of $36.5 million and a net change in our operating assets and liabilities of $1.8 million, offset by non-cash charges of $3.8 million. Non-cash charges primarily consisted of stock-based compensation of $2.5 million, amortization of our right-of-use lease assets of $1.2 million, and depreciation of $0.9 million, primarily offset by the accretion of discounts on short-term investments of $0.7 million.

For the six months ended June 30, 2025, net cash used in operating activities was $30.6 million, reflecting a net loss of $31.8 million and a net change in our operating assets and liabilities of $3.8 million, offset by non-cash charges of $4.9 million. Non-cash charges primarily consisted of a decrease in the fair value of the Cell X Convertible Note of $1.7 million, stock-based compensation of $1.2 million, amortization of our right-of-use lease assets of $1.1 million, and depreciation of $0.8 million.

Investing Activities

For the six months ended June 30, 2026, net cash used in investing activities was $25.6 million, consisting of purchases of marketable securities of $55.6 million, and purchases of property and equipment of $3.8 million, offset by maturities of marketable securities of $33.8 million.

For the six months ended June 30, 2025, net cash provided by investing activities was $24.8 million, consisting of maturities of marketable securities of $38.3 million, offset by purchases of marketable securities of $9.8 million, and purchases of property and equipment of $3.7 million.

Financing Activities

For the six months ended June 30, 2026, net cash used in financing activities was $0.7 million resulting from the payment of $0.8 million in deferred offering costs related to our planned initial public offering, offset by proceeds from the exercises of employee stock options of $0.1 million.

For the six months ended June 30, 2025, net cash provided by financing activities was $50,000, consisting of proceeds from the exercises of employee stock options.

Funding Requirements

As of June 30, 2026, we had cash, cash equivalents and marketable securities of $72.4 million. Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities as of June 30, 2026 will not be sufficient to fund our capital and operating expenditures for at least the twelve months following the date the unaudited financial statements were issued, and there is substantial doubt about our ability to continue as a

Table of Contents

going concern. Nevertheless, together with the estimated net proceeds from this offering, we believe our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditures into the second half of 2028. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risk and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we currently expect. Additionally, our expected use of existing cash, cash equivalents, marketable securities, and our net proceeds from this offering represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve.

We will need substantial additional capital to develop our lead program and fund operations for the foreseeable future. The net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities will not be sufficient to complete the Phase 1/2a ASPIRO trial, the Phase 3 trial for sasineprocel, which we intend to initiate prior to the completion of the Phase 1/2a ASPIRO trial, or the development of sasineprocel or any other current or future product candidates. Our future capital requirements are difficult to predict and will depend on many factors, including but not limited to:

- the scope, timing, rate of progress, and costs of our clinical trials for our current and any future product candidates;
- the number and scope of our clinical programs we decide to pursue;
- the cost, timing, and outcome of preparing for and undergoing regulatory review of our current and future product candidates;
- the cost and timing of manufacturing our product candidates, including the costs and timing of maintaining our own manufacturing facility, and commercial scale manufacturing if any product candidate is approved;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar agreements;
- the timing of any milestone and royalty payments to our existing or future suppliers, collaborators, or licensors;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the extent to which we acquire or in-license other product candidates and technologies;
- the extent to which we enter into licensing or collaboration agreements for any of our programs; and
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution of our product candidates, if they receive marketing approval.

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of public or private equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, or other strategic arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. In addition, debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional

funds through equity or debt financings or through commercial arrangements 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 our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Contractual Obligations and Commitments

During the normal course of our business, we enter into agreements for research and professional services, and for the purchase of lab supplies used in our research and clinical trial activities. These agreements are important to our operations but do not involve material financial commitments and generally provide for termination after a notice period, and, therefore, are cancelable contracts and not separately presented. For more information regarding our operational relationships, see the section titled "Business—Manufacturing."

Lease Agreements

In March 2019, we entered into a lease agreement for office, research and development, and laboratory space located in San Diego, California, which commenced in April 2019. We subsequently amended the lease to expand the premises to approximately 31,000 rentable square feet and extended the term through September 15, 2027. We are required to maintain a letter of credit in the amount of $0.2 million as security for our obligations under this lease, which is recorded as restricted cash.

In May 2021, we entered into a lease agreement for approximately 22,000 rentable square feet of office, research and development, laboratory, GMP manufacturing and warehouse space located in San Diego, California. This lease commenced on April 1, 2022, and has a term expiring on July 31, 2032, with one option to renew for an additional five-year term. We are required to maintain a letter of credit in the amount of $0.4 million as security for our obligations under this lease, which is recorded as restricted cash.

As of June 30, 2026, total future minimum lease payments under our operating lease agreements were $11.6 million.

In August 2026, we entered into a noncancelable operating lease agreement with HCP Life Science REIT, Inc. for approximately 48,696 rentable square feet of office, research and development, laboratory, storage and warehouse space located in La Jolla, California (the New Lease), which we intend to establish as our corporate headquarters after the lease for our existing corporate headquarters expires in September 2027. The New Lease has an initial term of 93 months commencing on July 1, 2027 and expiring on March 31, 2035. The New Lease includes a beneficial occupancy period beginning on execution of the agreement and continuing through June 30, 2027, allowing us to complete facility improvements, install equipment and furniture, and begin certain operations prior to the July 1, 2027 lease commencement date without payment of base rent. At execution, we were obligated to pay $0.3 million, representing the first month's base rent and estimated direct expenses. The New Lease provides for a 23-month rent abatement period, during which no base rent is due; as a result, our next base rent payment is not due until July 2029. Aggregate base rent is approximately $20.2 million, net of abatements, with refurbishment and other construction allowances of up to approximately $2.5 million and a special allowance of up to $2.0 million, and a required letter of credit of approximately $0.4 million.

TSRI License Agreement

In October 2018, we were assigned an exclusive license agreement effective July 2018 by Summit for Stem Cell Foundation with the Scripps Research Institute (TSRI, and the agreement, the TSRI License Agreement). Under the TSRI License Agreement, TSRI granted us an exclusive, worldwide, royalty-bearing license, with the right to sublicense through multiple tiers (subject to certain conditions), under certain intellectual property relating to certain methods for differentiating DA neurons from iPSCs and certain bioinformatics assays, and together with certain licensed biological materials, to make, have made, use, have used, sell, have sold, offer for sale and import licensed products, services and processes in all fields worldwide. The licensed intellectual property includes methods that are used in the manufacture of sasineprocel. TSRI reserved rights in the licensed intellectual property and/or licensed

biological materials for non-corporate sponsored internal research and educational purposes without obligation to further compensate us for such uses and further reserved the right to grant similar non-exclusive licenses to other nonprofit or academic institutions for similar internal research and educational purposes.

Under the TSRI License Agreement, we are obligated to use commercially reasonable efforts to develop and obtain regulatory approval for, and, if applicable, market and sell licensed products, services and processes in sufficient quantities to meet market demands. In addition, for each of the disclosed inventions and intellectual property described above that are the subject of our license, we are obligated to achieve certain development diligence benchmarks relating to intellectual property development and regulatory filings by specified anniversaries of the TSRI License Agreement's effective date. Such benchmarks may be extended by us up to two times for a certain number of months upon the payment of a fee. If we fail to achieve such development diligence benchmarks, TSRI has the right, at its option, to either terminate the TSRI License Agreement in its entirety, terminate our rights with respect to specific licensed products, services or processes, or convert the license granted to us to non-exclusive upon advance notice.

We paid TSRI a non-creditable, non-refundable license issue upfront fee of $1,000. We are further obligated to pay TSRI a running royalty of 1.0% on future net sales of licensed products, services and processes on a licensed product-by-licensed product and country-by-country basis. We are also obligated to pay TSRI the following percentage of non-royalty sublicensing revenues: (a) 15% if the sublicense is executed prior to the third anniversary of the effective date of the TSRI License Agreement, and (b) 5% if executed thereafter. Sublicense revenue fees paid by us in the first year after execution of the applicable sublicense shall be capped at $250,000. Payments related to the TSRI License Agreement are made in the period when the contingency is resolved, and the amounts become payable. Other than the non-creditable, non-refundable license issue upfront fee, no amounts have been payable under the TSRI License Agreement.

Unless terminated earlier, the TSRI License Agreement expires upon such time as no further royalties are due to TSRI, which lasts, on a country-by-country basis, until ten years after the date of first commercial sale of the first licensed product, licensed process, or licensed service sold in such country that was covered by the same invention disclosure among the disclosed intellectual property, but in any event no later than 20 years following the effective date of the TSRI License Agreement. We may terminate the TSRI License Agreement for convenience at any time upon advance notice to TSRI. TSRI may terminate the TSRI License Agreement for our material breach (subject to separate cure periods depending on whether our breach is payment-related or not), certain insolvency proceedings involving us, or if we commit a felony relating to the development, manufacture, use, marketing, distribution or sale of licensed products, services, processes or biological materials. Upon any early termination, the licenses granted to us terminate and such rights revert to TSRI.

AJ License Agreement

In September 2019, we entered into a non-exclusive license agreement with iPS Academia Japan, Inc. (the AJ License Agreement) pursuant to which iPS Academia Japan, Inc. (AJ) granted us a worldwide, limited, non-exclusive, non-transferable and royalty-bearing license, without the right to grant or authorize sublicenses, under certain patents relating to iPSCs licensed to AJ by Kyoto University for the development, manufacture, and sale of licensed products for therapeutic uses in humans (but excluding diagnostic and prophylactic purposes). We also received a limited, non-exclusive, non-transferable, royalty bearing license, without the right to grant sublicenses, under certain licensed cells to develop, make, have made and use licensed cells solely for the development and manufacture of licensed products. We utilize licensed technology under the AJ License Agreement in the manufacture of sasineprocel.

Pursuant to the AJ License Agreement, we have paid AJ aggregate upfront fees of $60,000 and are obligated to pay annual maintenance fees of $25,000 until and including the calendar year in which we obtain approval of a first new drug application of a licensed product in the territory. We have paid development milestones of $290,000 and are obligated to pay future milestones of up to $135,000 upon the successful achievement of development milestones, and up to $1.1 million in the aggregate when certain net sales thresholds of a licensed product are met. We are obligated to pay AJ a running royalty rate in the low single digits, of net sales of licensed products. Our running royalty obligations are determined on a country-by-country and product-by-product basis, and shall only be due with respect to licensed products in the applicable country in the territory so long as the development, manufacture, sale, import or export of the licensed products is covered by licensed patents in such country. Once all licensed patents are extinguished in a given country, whether by expiration, lapse, revocation, or otherwise, our obligation to pay running

royalties in that country ceases, except with respect to the applicable running royalties for the licensed patents used prior to the extinguishment in any such country. In addition, beginning in the calendar year following the first NDA approval of a licensed product in the territory and continuing through the expiration or termination of the AJ License Agreement, we must pay AJ a certain creditable annual minimum royalty in the mid-tens of thousands of dollars range, reduced by any running royalties paid during a certain number of preceding royalty reporting periods.

Under the AJ License Agreement, we are also required to grant AJ a non-exclusive, worldwide, royalty-free and fully paid-up license under any improvement patents we develop in the course of or as a result of exercising the license granted under the AJ License Agreement, with AJ having the right to sublicense such improvement patents to Kyoto University and other non-commercial academic institutions in Japan for academic research and educational purposes. The AJ License Agreement contains additional customary representations and warranties, covenants, indemnifications and insurance and confidentiality provisions for agreements of its type.

We are required to use commercially reasonable due diligence in developing and marketing licensed products worldwide. Unless earlier terminated in accordance with its terms, the AJ License Agreement continues until the expiration of the last to expire patent within the licensed patents worldwide. Each party may terminate the AJ License Agreement if the other party conducts any act that incurs incurable damage to the credibility, trust or reputation of the terminating party. AJ may terminate the AJ License Agreement upon written notice for uncured material breach by us (with a cure period for remedy), if we undergo an insolvency event, if we challenge, directly or indirectly, any licensed patent in any country, or if we undergo a change of control and fail to notify AJ or if our acquirer is then currently in any legal dispute or licensing conflict with AJ or the owner of the licensed patents. We may terminate the AJ License Agreement for convenience upon advance written notice.

In the event that AJ's upstream license agreement with Kyoto University (under which AJ obtained rights to the licensed patents licensed to us) is terminated, the AJ License Agreement shall automatically terminate on the date of termination of AJ's license with Kyoto University. In such case, AJ shall cause Kyoto University to negotiate with us the terms of a direct license between us and Kyoto University on similar terms and conditions to the AJ License Agreement, provided certain conditions are met. However, upon any termination of the AJ-Kyoto University upstream license, the licenses granted to us under the AJ License Agreement shall survive automatically for a set period of time as described in the AJ License Agreement, from the date of termination provided that certain conditions and obligations of ours are met.

Payments related to the AJ License Agreement are expensed in the period when the contingency is resolved, and the amounts become payable. We incurred expenses of $235,000 and $25,000 under this agreement during the years ended December 31, 2025 and 2024, respectively. We did not incur any expenses under this agreement during the six months ended June 30, 2026 and 2025.

Sumitomo License Agreement

In December 2023, we entered into a non-exclusive license agreement with Sumitomo Pharma Co., Ltd. (the Sumitomo License Agreement), pursuant to which Sumitomo Pharma Co., Ltd. (together with its successors and assigns under the Sumitomo License Agreement, including RACTHERA Co., Ltd. following the Organizational Split described below, Sumitomo) granted us a non-exclusive sublicense under certain patent rights originally licensed by ID Pharma Co., Ltd. (ID Pharma) to Sumitomo relating to technology for manufacturing iPSCs. Under the terms of the Sumitomo License Agreement, Sumitomo granted us a non-exclusive, non-transferable, and non-sublicensable license to manufacture iPS cells, and to use such iPS cells to develop, have developed, manufacture, have manufactured, import, distribute, and have distributed licensed products in the licensed territory (described below) in the field of autologous therapy for neurodegenerative disorders in the central nervous system and degenerative eye disorders. We utilize licensed technology under the Sumitomo License Agreement in the manufacture of sasineprocel. In connection with Sumitomo's reorganization of its regenerative medicine and cell therapy business, effected through an absorption-type company split and related share transfer under the Companies Act of Japan (the Organizational Split), Sumitomo's rights and obligations under the Sumitomo License Agreement were transferred to, assigned to and/or succeeded by RACTHERA Co., Ltd., with our prior consent.

The licensed territory under the Sumitomo License Agreement initially covers the region of the United States and Canada. We have the option to expand the licensed territory to include two other regions: (a) certain European countries upon additional payment to Sumitomo and (b) certain Asian countries upon a further additional payment to Sumitomo. If we wish to sublicense all or any portion of our rights in the licensed IP to a third party, Sumitomo has agreed to use reasonable efforts to negotiate and enter into a direct license with such third party on terms no less favorable than those in our agreement, except where such third party is a competitor of Sumitomo.

We retain ownership of any improvement, invention or discovery in relation to the licensed IP. However, we are required to grant Sumitomo an irrevocable, non-exclusive, non-transferable, perpetual, worldwide, royalty-free license, without a right to sublicense, to exploit all such improvements solely in connection with exploitation of the licensed IP.

We paid Sumitomo a non-refundable upfront payment ¥40.0 million in December 2023 and are required to pay non-refundable annual license fees of ¥6.0 million, creditable against royalties in the fiscal year of the first commercial sale of a licensed product and each year thereafter. Thus far, we have paid Sumitomo ¥25.0 million towards certain development milestones and are obligated to pay Sumitomo future development milestone payments of up to ¥125.0 million per licensed product per region for each of the three regions in the licensed territory upon the successful achievement of each development milestone, and up to ¥1.85 billion per licensed product when certain net sales thresholds of a licensed product are met. We are also required to pay Sumitomo a running royalty in the low single digits of annual net sales of each licensed product on a country-by-country basis during the royalty term, which lasts until the later of 1) the lapse, expiry or abandonment of the last valid claim covering the licensed intellectual property or 2) the tenth anniversary of the first commercial sale of a licensed product in the licensed territory. The royalty rate may be reduced pursuant to a customary reduction for certain intellectual property license payments in favor of third parties, subject to a low single-digit royalty rate floor. We incurred expenses of ¥6.0 million and ¥6.0 million under the Sumitomo License Agreement during the years ended December 31, 2025 and 2024, respectively. We incurred expenses of ¥3.0 million and ¥3.0 million under the Sumitomo License Agreement during the six months ended June 30, 2026 and 2025, respectively.

The Sumitomo License Agreement continues on a licensed product-by-licensed product and country-by-country basis until the expiration of all royalty terms. Upon expiration (but not early termination), our license under the Sumitomo License Agreement becomes fully paid and irrevocable. Either party may terminate the Sumitomo License Agreement for the other party's material breach (subject to differing applicable cure periods if the breach is payment-related or not) and if the other party enters into insolvency proceedings. Sumitomo may terminate the agreement if we initiate any action to challenge the validity, enforceability or scope of the licensed IP. In the event the original license agreement between Sumitomo and ID Pharma is terminated, the Sumitomo License Agreement automatically terminates, and Sumitomo is required to reasonably cooperate in assisting us in entering into a direct license with ID Pharma. We may terminate the Sumitomo License Agreement in its entirety or on a licensed product-by-licensed product and region-by-region basis at any time for convenience upon advance written notice.

Cell X A&R Collaboration and License Agreement

In January 2024, we entered into a Collaboration and License Agreement (the Prior Cell X Agreement) with Cell X Technologies, Inc. (Cell X), which was amended and restated in August 2026 (as amended and restated, the A&R Cell X Agreement), pursuant to which we license systems and methods for automated detection, analysis, isolation, and harvesting of biological objects, including iPSCs, as well as related image analysis technologies (the Cell X Platform Technology). We hold (a) an exclusive, worldwide, sublicensable license under the Cell X Platform Technology to develop, practice, make, have made, use, sell, offer to sell, import and commercialize cellular therapeutic products made using the Cell X Platform Technology (Licensed Products) for the diagnosis, treatment, or prevention of PD and leukodystrophies using autologous or allogeneic iPSCs and cells derived from iPSCs (the Exclusive License), (b) a perpetual, irrevocable, fully paid-up, non-exclusive, worldwide, sublicensable license under the Cell X Platform Technology to develop, practice, make, have made, use, sell, offer to sell, import and commercialize Licensed Products for the treatment or prevention all other indications using autologous iPSCs and cells derived from iPSCs, and (c) an exclusive, worldwide, sublicensable license under the Cell X Platform Technology for PD and leukodystrophies, or non-exclusive, worldwide, sublicensable license under the Cell X Platform Technology for other autologous indications, to develop, practice, have practiced, make, have made and use automated cell processing systems (Licensed Instruments) incorporating the Cell X Platform Technology solely to the

extent the Licensed Instruments are used as research, manufacturing, processing or analytical tools to enable autologous or allogeneic iPSCs or cells derived from iPSCs for the diagnosis, treatment, and prevention of PD or leukodystrophies and the treatment or prevention all other indications (the Instrument License). The A&R Cell X Agreement does not require us to pay royalties on Licensed Products. We utilize the Cell X Platform Technology in connection with our manufacturing process for sasineprocel.

Under the A&R Cell X Agreement, the parties' prior collaboration program was replaced with a technology transfer and support framework. Pursuant to this framework, Cell X is required to transfer specified licensed know-how and documentation to us and provide certain consultation and technical assistance. Pursuant to the A&R Cell X Agreement, we entered into a master services agreement with Cell X under which Cell X may perform services pursuant to statements of work entered into from time to time. We paid Cell X an upfront fee of $250,000 in 2024 under the Prior Cell X Agreement, which was included as a component of research and development expenses in the statement of operations. Under the A&R Cell X Agreement, we are obligated to pay future development and regulatory milestone payments of up to approximately $8.8 million in the aggregate, consisting of up to $6.0 million for up to two licensed products for PD and up to $2.8 million for one licensed product for leukodystrophies. We may also be required to reimburse Cell X for approved technical and regulatory support in excess of specified no-cost support hours. We paid Cell X a total of $2.8 million and $6.0 million during the years ended December 31, 2024 and 2025, respectively, which included those expenses incurred under the Prior Cell X Agreement. Unless terminated earlier, the A&R Cell X Agreement continues on a Licensed Product-by-Licensed Product, exclusive indication-by-exclusive indication and country-by-country basis until the expiration of the last-to-expire valid claim of the licensed patent rights in such country. Upon expiration, our Exclusive License converts to an irrevocable, perpetual, exclusive, and sublicensable license and our Instrument License converts to an irrevocable, perpetual, fully paid-up, and sublicensable license. We may terminate the A&R Cell X Agreement in its entirety, or on a Licensed Product-by-Licensed Product, exclusive indication-by-exclusive indication, or country-by-country basis, at any time after the first anniversary of the effective date of the A&R Cell X Agreement, upon 90 days' prior written notice to Cell X. Either party may terminate the A&R Cell X Agreement for the other party's material breach, subject to customary cure periods, or upon a bankruptcy event of the other party. Cell X may also terminate if we challenge the validity, enforceability or scope of the licensed rights. Upon an early termination, all licenses granted to us other than the non-exclusive licenses terminate; provided, however, that upon termination by us for Cell X's material breach, and upon our written election, our Exclusive License becomes irrevocable and perpetual, provided we continue to make milestone payments as set forth in the A&R Cell X Agreement. Qualifying sublicenses granted by us survive termination as direct licenses from Cell X, subject to specified conditions.

Cell X Secured Convertible Promissory Note

In January 2024, we entered into a Secured Convertible Promissory Note Purchase Agreement with Cell X pursuant to which we purchased a secured convertible promissory note (the Cell X Convertible Note) with an original principal amount of $5.0 million bearing 8% simple interest per annum. The Cell X Convertible Note is secured by a first priority security interest in substantially all of Cell X's assets, including its intellectual property. The outstanding principal and interest shall automatically convert into shares of Cell X's preferred stock upon a qualified financing in Cell X. We have optional conversion rights upon a non-qualified equity financing and upon maturity of the Cell X Convertible Note. The principal and accrued interest are due and payable upon the earliest to occur of (i) the maturity date, (ii) a sale of Cell X (whether to us or to a third party), or (iii) the occurrence of an Event of Default, as defined in the Cell X Convertible Note. Following the Cell X Side Letter (as defined below), in the event we acquire Cell X or in the event of a third-party sale of Cell X, we are entitled to receive the entire outstanding amount of the Cell X Convertible Note. The fair value of the Cell X Convertible Note was $0.9 million and $5.5 million as of December 31, 2025 and December 31, 2024, respectively, which is included in other noncurrent assets on the balance sheet. The fair value of the Cell X Convertible Note was $0.9 million as of June 30, 2026.

In January 2026, we entered into a First Amendment to the Cell X Convertible Note, which extended the original maturity date of January 22, 2026 to February 22, 2026. Subsequently, we entered into a series of additional amendments to further extend the maturity date. In August 2026, we entered into a Side Letter agreement with Cell X (the Cell X Side Letter), pursuant to which, upon the satisfaction of certain conditions, the maturity date will be extended to March 31, 2028 and all security related to the Cell X Convertible Note will be released.

CCF Exclusive License Agreement

In August 2026, we entered into an Exclusive License Agreement (the CCF Agreement) with The Cleveland Clinic Foundation (CCF), pursuant to which CCF granted us direct licenses under certain patents, software and know-how underlying the Cell X Platform Technology (the CCF Licensed Technology). We hold (a) an exclusive, worldwide, sublicensable license under the CCF Licensed Technology to develop, practice, have practiced, make, have made, use, sell, offer to sell, import and commercialize cellular therapeutic products for the diagnosis, treatment and prevention of PD and leukodystrophies using autologous or allogeneic iPSCs and cells derived from iPSCs, (b) a non-exclusive, worldwide, sublicensable license under the CCF Licensed Technology to develop, practice, have practiced, make, have made, use, sell, offer to sell, import and commercialize cellular therapeutic products for the treatment or prevention of all other indications using autologous iPSCs and cells derived from iPSCs, and (c) an exclusive, worldwide sublicensable license under the CCF Licensed Technology for PD and leukodystrophies and non-exclusive, worldwide, sublicensable license under the CCF Licensed Technology for all other indications to develop, practice, have practiced, make, have made and automated cell processing systems (Licensed Instruments) incorporating the CCF Licensed Technology solely to the extent the Licensed Instruments are used as research, manufacturing, processing or analytical tools in connection with such cellular therapeutic products (and not as standalone commercial products) for the diagnosis, treatment, and prevention of PD or leukodystrophies and the treatment or prevention all other indications. We may elect, at any time before December 31, 2031, to convert leukodystrophies from an exclusive indication to a non-exclusive indication. We are required to use commercially reasonable efforts to develop and commercialize the licensed products worldwide. The CCF Agreement does not require us to pay running royalties based on a percentage of net sales of licensed products; however, we are obligated to pay fixed minimum annual payments and milestone payments as described below.

Under the CCF Agreement, we are obligated to pay CCF an upfront fee in the low five figures and a fixed, minimum annual royalty payment of $140,000 for 2026 and each calendar year thereafter during the term. We may also be obligated to pay milestone payments of up to approximately $6.1 million in the aggregate, consisting of up to approximately $3.1 million in development and commercialization milestone payments and up to $3.0 million in sales milestone payments. We are also obligated to reimburse CCF for our pro rata share of patent prosecution costs and expenses incurred by CCF after the effective date, calculated based on the total number of direct licensees of such patents at the time such costs are incurred.

Unless terminated earlier, the CCF Agreement continues on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire valid claim covering the applicable licensed product in such country. Upon expiration, the licenses granted under the CCF Agreement become fully paid-up, irrevocable and perpetual on a country-by-country and licensed product-by-licensed product basis. We may terminate the CCF Agreement for CCF's uncured material breach upon 60 days' notice, or for any other reason upon 60 days' notice and payment of a termination fee and any other amounts then due or owing. CCF may terminate the CCF Agreement upon specified events relating to our insolvency or for an uncured failure to pay amounts due, a materially false or misleading representation or statement, or an uncured failure to perform a material covenant. CCF may also terminate the CCF Agreement if we challenge specified licensed patents, subject to certain exceptions and a cure period. If CCF does not terminate the CCF Agreement following such a challenge, the fixed minimum annual royalty payment and certain milestone payments associated with the challenged patents may be increased. Upon termination, our rights to the CCF Licensed Technology terminate and revert to CCF. Qualifying sublicenses granted by us survive termination as direct licenses from CCF, subject to specified conditions.

California Institute for Regenerative Medicine Award

In March 2024, CIRM issued an $8.0 million award to us to co-sponsor a Phase 1/2a dose escalation study of our lead product candidate, sasineprocel, in sporadic PD (the Award). We are eligible to receive seven disbursements in varying amounts, with one disbursement receivable upon the execution of the Award, and six disbursements receivable upon the completion of certain milestones throughout the project period of the Award, which is estimated to be from April 2024 to September 2026 (the Award Period).

Following the conclusion of the Award Period, we have, in our sole discretion, the option to treat the Award either as a loan or as a grant. If we do not elect to treat the Award as a loan within 10 years of the award date, the Award will be considered a grant, and we will be obligated to pay CIRM, on a quarterly basis, a low single-digit

royalty on commercial sales of sasineprocel until such aggregate royalty payments equal nine times the total amount awarded to us under the award. If we elect to treat the Award as a loan, we would be obligated to repay the loan within ten business days of making the election at an amount based on a specified percentage of the Award (ranging from 80% to 100%, plus, in certain cases, interest up to an annual percentage rate of 10% plus LIBOR), with the applicable amounts based on the phase of development of sasineprocel at the time the election is made.

We have elected for accounting purposes to treat the Award as a direct research and development arrangement in accordance with ASC 730-20, *Research and Development—Research and Development Arrangements*, as we do not intend to repay the Award other than by way of royalty payments on potential future sales of sasineprocel. The Award is recognized as an offset to research and development expenses as costs related to the project are incurred as we have concluded that the research and development risk is substantive and it is not yet probable that development will be successful. A deferred liability is recorded when the cash disbursements under the Award exceed the related research and development expenses incurred through such date.

During the year ended December 31, 2025, we received two cash disbursements under the Award totaling $1.7 million. During the year ended December 31, 2025, $2.8 million was recognized as an offset to research and development expense, and $0.4 million was deferred and recorded in other current liabilities as of December 31, 2025. During the year ended December 31, 2024, we received three cash disbursements under the award totaling $5.7 million. During the year ended December 31, 2024, $4.2 million was recognized as an offset to research and development expense, and $1.5 million was deferred and recorded in other current liabilities as of December 31, 2024.

During the six months ended June 30, 2026 and 2025, we did not receive any cash disbursements under the Award. We recognized $0.9 million and $1.0 million as an offset to research and development expense for the six months ended June 30, 2026 and 2025, respectively. We recorded no deferred liability for the Award as of June 30, 2026.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements included elsewhere in this prospectus, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 1 to our audited financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

We are required to estimate our accrued 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 associated preclinical study or clinical trial as measured by the timing of various aspects of the trial 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 trial, we adjust our rate of expense recognition if actual results differ from our estimates.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. 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 equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, 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. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 6 to our financial statements included elsewhere in this prospectus for information concerning 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 years ended December 31, 2025 and 2024 and during the six months ended June 30, 2026 and 2025.

We recorded stock-based compensation expense of $2.5 million and $2.7 million for the years ended December 31, 2025 and 2024, respectively. We recorded stock-based compensation expense of $2.5 million and $1.2 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, there was $12.0 million of total unrecognized stock-based compensation expense related to unvested stock options and early-exercised stock options, which we expect to recognize over a remaining weighted-average period of 3.2 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Common Stock Valuation

In the absence of an active market for our common stock, the fair value of our common stock was determined by our Board of Directors in accordance with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the Practice Aid). In doing so, our Board of Directors determined the best estimate of fair value of our common stock, exercising reasonable judgment and considering numerous objective and subjective factors, including:

- valuations of our common stock performed by independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our products, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences sector, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;

- the prices of our preferred stock sold to investors in arm's-length transactions, including the valuation implied in the sales of Series C convertible preferred stock in the fourth quarter of 2025, and the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In accordance with the Practice Aid, we considered the following methods:

- *Current Value Method*. Under the current value method, once the fair value of the enterprise is established, the value is allocated to the various series of preferred and common stock based on their respective seniority, liquidation preferences or conversion values, whichever is greatest.
- *Option Pricing Method (OPM)*. Under the 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 estimated fair values of the convertible preferred stock and common stock are inferred by analyzing these options. This method is appropriate to use when the range of possible future outcomes is so difficult to predict that estimates would be highly speculative, and dissolution or liquidation is not imminent.
- *Probability-Weighted Expected Return Method (PWERM)*. The PWERM is a scenario-based analysis that estimates 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.

Based on our early stage of development, the difficulty in predicting the range of specific outcomes (and their likelihood), and other relevant factors, the OPM allocation method was considered most appropriate for valuations prior to November 30, 2025. For valuations prepared after November 30, 2025, a hybrid method between the PWERM and OPM was used, where the equity value was probability-weighted across multiple scenarios, including an initial public offering (IPO) scenario and a stay-private scenario, and then probability weighted the resulting per share values based on management's assessment of the likelihood of each outcome. Under the IPO scenario, we applied a fully diluted precedent transaction (backsolve) approach that uses the most recent preferred stock financing as a reference point for value on a fully diluted basis. Under the stay private scenario, we inferred total equity value using a backsolve method anchored to our most recent preferred financing (adjusted for market movement) and allocated that value across our company's share classes using an OPM. Because our common stock is not publicly traded, we also considered the illiquidity of our common stock and reflected a discount for lack of marketability based on an expected time to liquidity. The resulting scenario weighted value represents an estimate of the fair value of our common stock on a minority, nonmarketable basis.

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 complete an initial public offering or other liquidity event, and the determination of the appropriate valuation methods.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our Board of Directors to estimate the fair value of our common stock in connection with our accounting for granted stock options or for any other such awards we may grant, as the fair value of our common stock will be determined based on the closing price of our common stock as reported on the date of grant on the stock exchange on which our common stock is traded.

Table of Contents

Off–Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off–balance sheet arrangements as defined under SEC rules.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 1 to our financial statements appearing elsewhere in this prospectus.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This period allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash, cash equivalents and marketable securities consist of cash held in readily available checking and money market accounts, as well as short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. 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 or results of operations.

Foreign Currency

We contract with vendors in foreign countries, including countries in Europe and the Asia Pacific. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Table of Contents

Net realized and unrealized gains and losses from foreign currency transactions are reported in other income (expense), net, in the statements of operations and comprehensive loss. The impact of foreign currency costs on our operations have been negligible for all periods presented.

Inflation Risk

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

Table of Contents

BUSINESS

Aspen Neuroscience, Inc. is a leading, clinical-stage regenerative medicine biotechnology company focused on developing autologous iPSC-derived therapies to address neurodegenerative diseases with high unmet medical need. Our lead product candidate, sasineprocel, is an investigational single-dose, autologous iPSC-based cell therapy being evaluated for the treatment of PD. We believe sasineprocel has the potential to be disease-modifying by replacing a patient's lost DA neurons with DANPCs, capable of integrating and reestablishing functional connections. In an ongoing Phase 1/2a ASPIRO clinical trial of sasineprocel in mid-stage to moderately advanced sporadic PD, patients have experienced, what we believe to be, sustained and clinically meaningful improvements in motor, quality of life, and non-motor symptoms as measured by comparison to clinically meaningful change benchmarks. Based on these findings, we believe sasineprocel has the potential to improve upon the current standard of care in PD and address the significant unmet need for a disease-modifying therapy that may slow or halt the progression of this devastating disease. These benchmarks are reviewed on an ongoing basis during the trial and reflect management's belief based on a review of published literature, regulatory agency guidelines and precedent in PD clinical research, and discussions with key opinion leaders in the field. The benchmarks have not been discussed with the FDA or any other government regulatory authority, and have not been independently validated by any third parties.

PD is a progressive neurodegenerative disease primarily characterized by the loss of DA neurons as well as impaired DA neurotransmission that results in the progressive deterioration of motor and non-motor neurological function. It is the second most common neurodegenerative disorder, estimated to affect more than one million people in the United States and more than 10 million people globally. The prevalence has doubled globally over the past 25 years, making it one of the fastest growing CNS diseases. PD patients suffer from characteristic motor symptoms, including movement, coordination and speech impairments, as well as non-motor symptoms, including loss of sense of smell, sleep behavior disorders, difficulty swallowing, urinary symptoms, constipation, orthostatic hypotension, depression, psychosis, dementia and cognitive impairment. These symptoms can severely impact a patient's quality of life, contribute to progressive disability and loss of independence, and are associated with increased morbidity and mortality over time.

The current standard of care is palliative DRT, including levodopa and dopamine agonists, which addresses motor symptoms but does not replace lost DA neurons, nor does it slow continued neuronal degeneration. DRT inadequately addresses non-motor symptoms, decreases in effectiveness over time, and is associated with side effects that can significantly impact patient quality of life. As DRT loses its effectiveness or as its side effects become intolerable, advanced therapies, such as DBS, are considered. While DBS can be effective in addressing certain motor symptoms of PD, it has not been shown to slow disease progression in mid-stage to moderately advanced PD patients and can potentially worsen cognition, gait, speech and other axial symptoms. DBS has other drawbacks as well, including long delays in access and optimization, multiple invasive surgeries with permanent implanted hardware and risks such as hemorrhage, infection, and device failure. In contrast to DRT and DBS, cell replacement therapy holds significant promise as an approach to restore and replace lost dopamine neurons and neural circuitry necessary for normal motor and non-motor function. Our cell replacement approach represents a promising therapy that could provide long-term benefits from a single administration without the need for permanently implanted hardware.

Allogeneic approaches in development for PD can require one year or more of immunosuppressive therapy post-treatment, which is associated with increased risks of infection, organ toxicity, and metabolic complications. In contrast, autologous cell therapies are derived from a patient's own cells which reduces the risk of immune rejection after transplantation. Our clinical trial of sasineprocel has not required any immunosuppression post-administration and is designed to support the formation of functional synaptic connections and neural circuitry without the need for immune suppression. In third-party NHP models of PD, autologous DA progenitor cell transplantation survived without immunosuppression and integrated more robustly and produced more sustained motor improvements than allogeneic transplants. Moreover, our autologous iPSC approach is designed to require minimal cell expansion, which may reduce the opportunity for genomic abnormalities to arise and for cells harboring growth-promoting abnormalities to become selectively enriched during extended culture. While this is designed to be a one-time therapy, the autologous nature of the product could allow for redosing, if valuable over a patient's multi-year course. We believe our autologous cell replacement strategy presents a significant advantage over both current standard-of-care therapies and

Table of Contents

allogeneic cell therapies in development for PD, and has the potential to deliver a tolerable, disease-modifying treatment with durable, long-term effectiveness.

Sasineprocel and our end-to-end autologous iPSC platform are based on advances in cellular reprogramming, including the Nobel Prize–winning discovery by Shinya Yamanaka and John B. Gurdon, which demonstrated that mature, specialized cells can be reprogrammed into iPSCs through the introduction of defined transcription factors (commonly referred to as Yamanaka factors). We combine these foundational reprogramming methods with our stem cell biology expertise, the latest artificial intelligence, ML and genomic approaches to optimize cell identity, purity and functional potential and to enable a scalable, reproducible, standardized, and data-driven manufacturing process for autologous cell therapy. Sasineprocel, our proprietary autologous iPSC-derived composition of DANPCs, CNS progenitors, and glial progenitors, is designed to establish a biologically active cellular microenvironment that supports cell engraftment, survival, and functional integration of transplanted cells with the goal of restoring functional dopamine signaling in PD patients. We believe the sustained benefit observed in patients treated with sasineprocel provides evidence of neural circuitry reconstruction and is further supported by preclinical studies, in which we observed that DANPCs transplanted into PD animal models differentiated into DA neurons that integrated into the brain and restored dopamine signaling. We hypothesize that sasineprocel's combination of cells beyond DANPCs may play a key role in supporting neural synapse formation and general microenvironmental health to enable a broad and profound treatment effect in PD patients, including improvement in non-motor symptoms.

We are currently conducting the open-label Phase 1/2a ASPIRO trial evaluating sasineprocel in patients with sporadic PD and have begun enrolling genetic PD patients. The trial consists of sequential dose cohorts with sasineprocel administered as a single bilateral intracranial injection into the post-commissural putamen, an area of the brain that participates in motor control, using well-understood, standard stereotactic neurosurgical techniques. The study's primary objective is to assess safety and tolerability. The study's secondary and exploratory objectives are to evaluate the potential efficacy of sasineprocel, measured by changes from baseline in multiple patient- and clinician-reported PD-specific outcomes. These include changes in MDS-UPDRS Parts I-IV, which measures the severity and progression of PD, including motor and non-motor symptoms; Hauser diary (to measure "Good On" time, defined as time without troublesome dyskinesia); and quality of life measures including PDQ-39. ^{18}FDOPA PET imaging is being used to evaluate the engraftment of cells. Certain of the secondary endpoints used in this trial are validated endpoints used in previous PD registrational clinical trials.

As of August 18, 2026, the data cutoff date, 15 patients had been dosed, with seven participants receiving a low dose and eight participants receiving a high dose. Sasineprocel was observed to be generally well-tolerated with the majority of reported adverse events being mild to moderate. Among the patients dosed, 72 TEAEs were reported. There was no evidence of graft-induced dyskinesias or graft rejection, and no clinically significant hemorrhages were observed post-operatively. As sasineprocel is autologous, with no requirement for immunosuppression, there were no immunosuppression-related events. Only one TEAE, myoclonus (sudden, uncontrollable muscle movement), was considered possibly related to sasineprocel, with sertraline, a selective serotonin reuptake inhibitor, identified as a co-suspect medication. One participant had two serious adverse events related to the surgical procedure (neck swelling and dysphagia due to intubation in the prone position and ischemic stroke (cerebral infarction) due to pre-operative interruption of anticoagulants that the patient was taking for a history of deep venous thrombosis). The most commonly reported TEAEs, defined as occurring in 10% or more of patients, were related to the surgery, including incision site pain, swollen tongue, headache, infusion site pain, glossodynia, hypoesthesia, and oropharyngeal pain. Two patients had intracranial hemorrhages not requiring any surgical treatment. Of these two patients, one patient had no associated symptoms and the other, who had a history of migraine, experienced a headache which resolved, with levetiracetam identified as a co-suspect medication. As of the data cutoff date, all 12 patients from the first three cohorts had at least one six-month or later follow up evaluation.

We assessed clinical efficacy outcomes every six months after administration of sasineprocel. We observed improvements across several secondary and exploratory endpoints, including changes in Good On Time (On time without troublesome dyskinesia normalized to 16 hours of the day), Off time, MDS-UPDRS Part III OFF, MDS-UPDRS Part II ON, and PDQ-39 scores, as summarized below. Certain of the secondary endpoints used in this trial, including Good On Time and MDS-UPDRS Part III OFF, are validated registrational endpoints used in previous PD registrational clinical trials. The mean improvements at 18 months in both cohorts and 24 months in the low dose cohort for Good On Time and MDS-UPDRS Part III OFF scores were above clinically meaningful change benchmarks. The mean PDQ-39 and MDS-UPDRS Part II ON scores improved above clinically meaningful change

Table of Contents

benchmarks in the low dose cohort at 18 and 24 months and were stable in the high dose cohort at 18 months. ^{18}FDOPA PET imaging is also being used to evaluate the engraftment of cells. ^{18}FDOPA PET imaging showed elevated ^{18}FDOPA uptake values at six, 12, and 18 months following sasineprocel administration compared to baseline, which is evidence of the survival, viability, and integration of transplanted iPSCs. Clinically meaningful change benchmarks are reviewed on an ongoing basis during the trial and reflect management's belief based on a review of published literature, regulatory agency guidelines and precedent in PD clinical research, and discussions with key opinion leaders in the field. The benchmarks have not been discussed with the FDA or any other government regulatory authority, and have not been independently validated by any third parties.

Additionally, the ASPIRO trial is exploring changes in DA medication as measured by LEDD, a standardized calculation that converts all DA medications a patient is taking into a single equivalent dose of levodopa, providing a measure of total daily DA medication burden using established methodology. A reduction in LEDD suggests that a patient requires less DA medication to manage their motor symptoms. As of the data cutoff date, in the low dose cohort, two, three, three and three patients showed a reduction in LEDD at six, 12, 18 and 24 months, respectively, and one patient experienced an LEDD increase at 18 and 24 months. In the high dose cohort, at six months, three out of eight patients showed an LEDD reduction and one patient showed an LEDD increase; at 12 months, two out of four patients showed an LEDD reduction and one patient showed an LEDD increase; at 18 months, three out of four patients showed an LEDD reduction and one showed an LEDD increase.

	Low Dose n=4					High Dose n=8			
Month	Baseline (n=4)	6 (n=4)	12 (n=4)	18 (n=4)	24 (n=4)	Baseline (n=8)*	6 (n=8)	12 (n=4)	18 (n=4)
Mean Change in Good On Time (hrs) Hauser Diary (MCID > 1 hrs)	11.6 (2.21)	+1.6 (1.46)	+2.1 (1.46)	+2.2 (2.75)	+2.6 (1.78)	9.8 (2.48)	+2.3 (2.59)	+2.4 (1.26)	+2.7 (2.08)
Mean Change in OFF Time (hrs) Hauser Diary (MCID < 1 hrs)	4.1 (1.87)	-2.1 (1.70)	-2.0 (1.50)	-1.9 (2.46)	-2.3 (1.50)	5.5 (1.67)	-1.9 (2.31)	-2.4 (1.26)	-2.7 (2.08)
Mean Change in MDS-UPDRS part III OFF score (points) (MCID 4-5 points)	42.3 (5.32)	-17.5 (5.20)	-15.5 (9.61)	-13.0 (4.40)	-15.8 (7.54)	44.5 (9.75)	-9.6 (4.78)	-13.5 (13.87)	-19.3 (6.40)
Mean Change in MDS-UPDRS part II ON score (points) (MCID 2-4 points)	14.0 (3.46)	-7.0 (5.00)	-5.3 (5.44)	-6.0 (6.27)	-6.8 (7.14)	10.9 (7.41)	-1.4 (2.83)	-2.3 (3.30)	0.0 (3.16)
Mean Change in PDQ-39 (points) (MCID 4-5 points)	13.8 (4.21)	-5.7 (3.65)	-7.6 (7.41)	-5.0 (9.09)	-5.0 (6.30)	15.5 (12.40)	-3.1 (6.30)	-6.2 (6.88)	-3.9 (6.83)
Number of patients with LEDD reduction		2	3	3	3		3	2	3

Figure 1. Sustained improvements observed across multiple validated PD endpoints. Data summarized above is as of August 18, 2026. A decrease (negative number) compared to baseline is an improvement for MDS-UPDRS scores and PDQ-39. The numbers in parentheses represent standard deviations. Mean changes in data summarized above are driven by totality of data across patients and not driven by a limited number of patients exhibiting significantly better-than-average improvements. *For the four high dose patients for whom data was available at the 12-month and 18-month assessments, the baseline values for Good On Time (hours) Hauser Diary, Off Time (hours) Hauser Diary, MDS-UPDRS Part III OFF score, MDS-UPDRS Part II ON score, and PDQ-39 were: 11.7 (0.9), 4.3 (0.9), 44.0 (4.2), 9.5 (9.3), 16.1 (15.6), respectively. For the three low dose patients in Cohort 4, no data is yet available because six months have not elapsed since dosing for all three patients.

We expect to report further long-term data from the ASPIRO trial in the first half of 2028. In addition, we plan to dose a single cohort of approximately three to six patients with genetic PD in the ASPIRO trial. We anticipate initiating biopsy collection for the Phase 3 trial by the end of 2026. Following feedback from the FDA, we anticipate dosing patients in the Phase 3 trial in the second half of 2027.

Our History, Team and Investors

We were founded in 2018 based on more than two decades of research conducted by Jeanne F. Loring, Ph.D., Professor Emerita at the Scripps Research Institute and founding Director of the Center for Regenerative Medicine. Dr. Loring's laboratory developed foundational methods for reprogramming adult human cells into iPSCs and subsequently differentiating them into dopamine-producing neurons. This scientific work, built upon Nobel Prize-winning discoveries demonstrating cellular reprogramming to pluripotency, forms the basis of our autologous iPSC platform and our lead product candidate, sasineprocel.

Since our inception, we have focused on translating this academic innovation into a clinically scalable, regulatory-compliant therapeutics platform. Our management team was intentionally assembled to integrate deep expertise in neuroscience research with extensive experience in drug discovery and development, regulatory strategy, commercialization and manufacturing. This combination of capabilities has been critical to advancing our platform from foundational research through current Good Manufacturing Practice requirements (cGMP) manufacturing, comprehensive preclinical validation, and ongoing clinical evaluation.

Damien McDevitt, Ph.D., our Chief Executive Officer, previously served as Chief Executive Officer of Akcea Therapeutics, a rare diseases company, prior to its acquisition by Ionis Pharmaceuticals in 2020, and held several leadership roles at Ionis Pharmaceuticals, Acadia Pharmaceuticals, and GlaxoSmithKline Pharmaceuticals. Dr. McDevitt was involved in the commercialization, late-stage development or in-licensing of the following approved products: TEGSEDI (inotersen) for hereditary transthyretin-mediated amyloidosis, WAYLIVRA (volanesorsen) for familial chylomicronemia syndrome (approved in the European Union) and DAYBUE (trofinetide) for Rett syndrome. Lisa Johnson-Pratt, M.D., our Sasineprocel Development Lead and Chief Commercial Officer, has successfully led programs across the entire product life cycle with leadership roles in medical affairs, clinical development, product development, portfolio planning and new product strategy. Dr. Johnson-Pratt was involved in the launch of GARDASIL (human papillomavirus 9-valent vaccine, recombinant), IMITREX (sumatriptan) and MAXALT (rizatriptan benzoate), and new indication launches of SINGULAIR (montelukast sodium) and COZAAR (losartan potassium), and led new product strategy for BLENREP (belantamab mafodotin-blmf), WAINUA (eplontersen), and TRYNGOLZA (olezarsen).

The Executive Chairman of our Board of Directors, Faheem Hasnain, is the Co-Founder, Chairman and Chief Executive Officer of Gossamer Bio. Mr. Hasnain previously served as President, Chief Executive Officer and Director of Receptos, which was acquired by Celgene in 2015. He is joined by a distinguished group of Board members who bring additional operational, scientific, financial and strategic expertise.

Since our inception, we have raised approximately $347 million from a syndicate of leading life sciences investors and organizations, including OrbiMed, ARCH Venture Partners, Frazier Life Sciences, Medical Excellence Capital, and Kite, a Gilead Company, as well as a grant from CIRM. These investors have extensive experience supporting the development and commercialization of innovative biotechnology platforms and therapeutics. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Our Manufacturing Platform and Scientific Approach

We have developed an integrated, end-to-end autologous iPSC platform designed to generate autologous cell therapies for the treatment of neurodegenerative diseases (our platform). iPSCs are stem cells created by reprogramming mature, specialized (somatic) cells—such as skin cells—back into a pluripotent state. In this state, they behave similarly to embryonic stem cells in so far as they can self-renew indefinitely and differentiate into virtually any cell type in the body, such as DANPCs and other CNS neurons, which we believe makes them the ideal starting point for an autologous therapy for PD. Our platform combines proprietary cell reprogramming methods, automated and scalable manufacturing processes, and comprehensive quality control (QC) systems, including advanced genomics and bioinformatics, to manufacture iPSCs from fibroblasts with the aim to produce DANPCs designed to have high fidelity, reproducibility, and functional performance.

Table of Contents

Our manufacturing process is performed in three stages.

Stage 1 (Skin to Fibroblasts): Dermal fibroblast cells are isolated from a PD patient's skin punch biopsy (3mm) using a minimally invasive procedure, expanded in culture, tested for correct cell type identity by visual morphology assessment, harvested, formulated, and cryopreserved. These fibroblasts are released as starting materials for Stage 2 following QC testing for sterility, viability, genetic identity, and genomic integrity.

Stage 2 (Fibroblasts to iPSCs): The fibroblasts are converted into iPSCs through a process known as *cellular reprogramming*, in which a defined set of transcription factors, classically Oct3/4, Sox2, Klf4, and L-Myc, collectively referred to as the Yamanaka factors, are introduced to reset the cells' gene expression and epigenetic profiles, thereby reverting them from a differentiated somatic state back to a pluripotent, embryonic-like state. We utilize Yamanaka factors and viral vectors encoding Yamanaka factors licensed from third parties including iPS Academia Japan, Inc. and Sumitomo Pharma Co. Ltd. See "Licensing and Collaboration Agreements" below for additional information. These iPSCs are advanced to Stage 3 following characterization and QC testing for sterility, identity, purity and pluripotency (using our proprietary PluriTest).

Stage 3 (iPSCs to DANPCs): The iPSCs derived from PD patients are first expanded to establish a stable, high-quality, iPSC population of appropriate cell number. Using our robust and proprietary differentiation iPSC platform, these cells are then efficiently and consistently differentiated into DANPCs.

Our iPSCs are differentiated into DANPCs by recapitulating key stages of midbrain development *in vitro* using defined culture conditions and signaling cues. The process begins with neural induction, where iPSCs are directed away from pluripotency toward a neural fate. This is achieved through dual SMAD inhibition, which blocks BMP and TGF-β signaling, producing neuroectodermal cells resembling early neural progenitors. Next, these neural progenitors are patterned toward a ventral midbrain identity, the developmental origin of dopaminergic neurons. This step involves activating Sonic Hedgehog (SHH) signaling to induce ventral characteristics and WNT/β-catenin signaling (via GSK3β inhibitors) to specify midbrain fate. Finally, under continued exposure to these cues and supportive growth factors combined with Notch signaling inhibition through a gamma secretase inhibitor to promote neuronal maturation, cells differentiate into dopaminergic precursors, characterized by expression of markers such as FOXA2 and OTX2. These precursor cells are designed to further mature into functional, dopamine-producing neurons upon a differentiation and after transplantation. Overall, our approach uses a stepwise, developmentally informed process designed to control signaling pathways and efficiently and reproducibly generate dopaminergic precursors from iPSCs for therapeutic application.

At the end of Stage 3, the DANPCs are harvested, filled and finished, and then cryopreserved. These DANPCs are designed to have high cell lineage fidelity and predictable functional performance, including maturity, engraftment and dopamine release. The DANPC drug product released at Stage 3 is dependent on QC testing for strength (cell concentration), purity, identity, and potency. The final product is not a homogenous cell population, and other non-DA cells are present in the final product at low percentages, including astrocyte progenitors and progenitors for

Table of Contents

cholinergic and glutamatergic neurons. Prior to patient administration, the DANPCs are shipped to the site as a sterile, cryopreserved product.

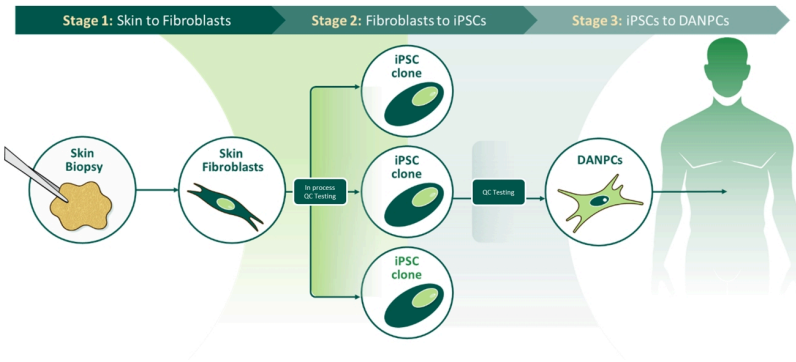


Figure 2. The three stages of sasineprocel cell manufacturing.

Our platform is designed to address key challenges associated with autologous cell therapies, including inter-patient variability, genomic instability, and inconsistent cellular differentiation. To mitigate these risks, we use multiple assays and proprietary datasets to assess genetic identity, genomic integrity, lineage specification, purity, and to assess functional performance prior to clinical administration. We have combined our data with work started in 2012, before the company was founded, by our scientific founders at the Scripps Research Institute to create proprietary data that integrates whole-genome sequencing, RNA sequencing, and transcriptomic analytics. Certain assays are currently used for product characterization and release, while additional RNA sequencing-based machine learning models continue to be refined as part of our broader potency assurance framework. A series of rigorous release assays are performed on the final manufactured product to assess product quality attributes. These include RNA-sequencing-based tests to assess identity and maturity (NeuriTest), engraftment potential (GraftTest), and dopamine release (DopaTest). These bioinformatics-based assessments are informed by preclinical *in vitro* and *in vivo* studies testing different lots from individual PD patient cells, with lots from multiple PD donors evaluated. In addition, an *in vitro* bioassay, the DOPA decarboxylase (DDC) activity assay, is performed to measure conversion of levodopa (L-dopa) to dopamine to test cellular functionality and stability of DANPCs after cryopreservation.

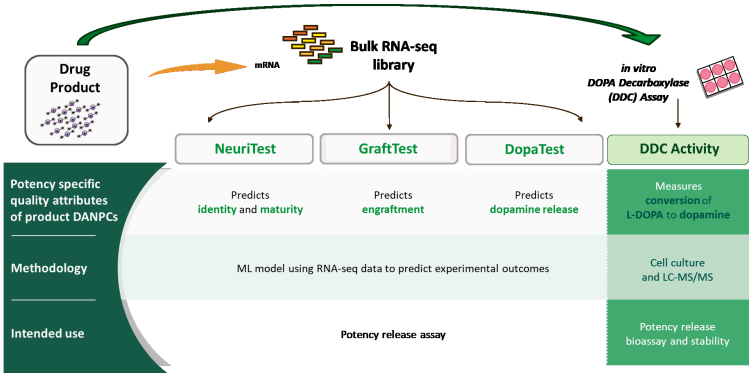


Figure 3. Overview of expected potency assays (ML models and bioassays) used to assess sasineprocel performance. Four independent tests are performed: NeuriTest, GraftTest, DopaTest, and DDC activity.

We are developing an automated, robust, modular manufacturing process for sasineprocel that we believe could reduce the manual labor required by more than 90% while still maintaining GMP requirements. Our manufacturing system incorporates two principal automated systems. The first is the Cell X platform, which can be used in Stage 1, Stage 2, and the iPSC scale-up portion of Stage 3. The Cell X platform integrates incubation within an isolation chamber, robotics, liquid handling, and optical machine vision, along with proprietary ML algorithms to evaluate fibroblast cell culture and iPSC clones for quality and to identify the most promising cells for advancement through the manufacturing process. The Cell X platform automates all standard cell culture steps for derivation of iPSCs including cell selection, reprogramming, cell removal, expansion, and harvest. We expect that the Cell X platform will be capable of autonomous (self-driving) manufacturing to support manufacturing capacity for hundreds of patients on an annual basis. The second system, the Mytos device, is used in Stage 3, during which iPSC clones are differentiated into DANPCs in a closed system process. This system automates the feeding, expansion, passaging, and harvest of the iPSC into DANPCs. The Cell X platform and the Mytos devices are supplied by third party technology solution providers and are purchased and owned by Aspen. We expect the automated manufacturing process to be ready for use in early 2027, but will be required to submit an IND amendment to the FDA prior to utilizing the automated manufacturing process in our clinical trials.

We have designed a modular automation template that combines these automated platforms within a small cleanroom footprint (approximately 5,000 square feet) intended to achieve manufacturing capacity for hundreds of patients annually. We expect that this automation template can be replicated and scaled up through module replication for manufacturing to meet potential future demand.

Our Strategy

We are committed to developing and delivering novel autologous iPSC-derived cell replacement therapies for patients with significant unmet medical need, beginning with PD. Our strategy to achieve this mission includes the following key elements:

- **Advance sasineprocel, our personalized potentially disease-modifying product candidate for PD patients, through Phase 3 trials for sporadic PD.** We are continuing to advance our lead product candidate, sasineprocel, in PD, following encouraging interim results in our Phase 1/2a ASPIRO trial, including sustained improvement in PD patients' motor and non-motor symptoms, and quality of life measures. We believe sasineprocel has the potential to slow or halt the progression of PD, which would transform the lives of PD patients. Following feedback from the FDA, we plan to commence a Phase 3 study in patients with PD by the end of 2026. The initial phase of the study will involve collecting details of disease and natural history of PD and obtaining skin biopsies in order to manufacture sasineprocel, with the goal of dosing patients in the second half of 2027. After assessment of efficacy and safety at 18 and 24 months post dose, we plan to collect long-term safety follow-up data for a total of 15 years post dose, based on current FDA guidelines for cell and gene therapy products.
- **Expand development of sasineprocel into genetic PD and maximize the therapeutic potential of sasineprocel across PD patients.** Based on preclinical evaluation and support for the potential for autologous iPSC-derived cells from genetically defined (GBA) PD patients, we are planning to expand our Phase 1/2a ASPIRO trial of sasineprocel to include a cohort of patients with genetically-defined PD, including patients with LRRK2 and GBA1 mutations, to enable broad patient access to sasineprocel. We have begun enrolling genetic PD patients. Pending the results of this cohort, we intend to include patients with genetic PD in our Phase 3 program to support a broad label for sasineprocel, if approved.
- **Build scalable, automated autologous cell manufacturing to support potential commercialization in North America (United States and Canada) with plans in the future to expand globally.** We plan to continue to invest in automating our cell manufacturing process to decrease costs and maintain product consistency, while preparing for commercial scale with a focus on continuing to improve automation and implementing our plan to scale capacity to meet anticipated demand. Our end-to-end platform and modular automation template is designed to allow for capital-efficient scaling of our manufacturing system to enable the potential treatment of hundreds of patients annually per module.

- **Maximize the commercial opportunity of sasineprocel and opportunistically engage in strategic collaborations.** We plan to build a fully integrated biotechnology company capable of executing registrational trials and obtaining regulatory approvals. As we advance sasineprocel toward potential approval, we intend to build a commercial infrastructure to support the sale and distribution of any of our product candidates, if approved. In certain instances, however, we may seek to partner with third parties that can serve to broaden the reach and access to sasineprocel. Our decision to potentially partner sasineprocel or any of our programs will be determined by an assessment of the potential benefits of doing so and our ability through such partnerships to access additional resources, capabilities and expertise for our programs.
- **Expand our pipeline by leveraging our platform to identify and develop additional product candidates in CNS indications where cell replacement therapy offers meaningful therapeutic potential.** We have significant expertise in the discovery and development of autologous iPSCs to treat patients with CNS diseases. We have demonstrated the potential for our technology across additional neuronal cell types in preclinical proof-of-concept studies. We believe our ability to reestablish neural circuitry through the administration of neuronal cells designed with high fidelity, reproducibility, and functional potency may extend beyond DA neurons. Using our platform, we are advancing a second program targeting microglial cells for the treatment of pediatric rare indications, such as inherited leukodystrophies. Additionally, we have discovery programs focused on deriving non-neuronal cell types with potential for application outside the CNS.

Our Pipeline

We are leveraging our proprietary platform to build a diversified pipeline of autologous iPSC-based therapies for the treatment of multiple CNS diseases, with an initial focus on sporadic and genetic PD. Our goal is to maximize the value of our clinical translation, manufacturing, and QC capabilities to expand into additional CNS indications, starting with our microglia program. We have worldwide commercial rights to all our programs and have summarized our clinical and preclinical programs below.

After assessment of efficacy and safety at 18 and 24 months post dose, we plan to collect long-term safety follow-up data for a total of 15 years post dose, based on current FDA guidelines for cell and gene therapy products.

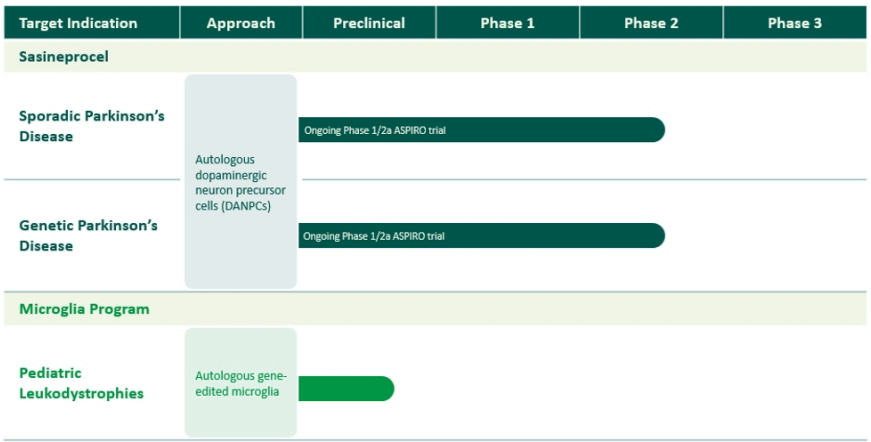


Table of Contents

Lead Program: Sasineprocel for PD

Sasineprocel for Sporadic PD

We are developing sasineprocel, a single-dose, autologous iPSC-based therapeutic candidate for PD that is designed to replace a patient's lost dopamine neurons. We are currently conducting the open-label Phase 1/2a ASPIRO trial of a single dose of sasineprocel in mid-stage to moderately advanced PD patients. The trial consists of four cohorts at two dose levels, both of which were anticipated to be biologically active, with sasineprocel administered as a single bilateral intracranial injection into the post-commissural putamen using well-understood, standard stereotactic neurosurgical techniques. As of the data cutoff date, 15 patients had been dosed, with seven participants receiving a low dose and eight participants receiving a high dose. As of the data cutoff date, all 12 patients from the first three cohorts had at least one six-month or later follow up evaluation. We assessed clinical outcomes every six months after administration of sasineprocel. Sasineprocel has been granted RMAT designation from the FDA for the treatment of levodopa-responsive PD and Fast Track designation from the FDA for the treatment of PD to improve motor function. A biological product candidate is eligible for RMAT designation if it meets the definition of a regenerative medicine therapy, which the FDA defines as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exception, if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it has the potential to address unmet medical needs for such disease or condition. A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. However, RMAT or Fast Track designation may not result in a faster development process, review, or approval compared to conventional FDA procedures, and does not increase the likelihood that sasineprocel will receive regulatory approval. In addition, because sasineprocel is designed to be administered through drug delivery devices, we anticipate that sasineprocel would be regulated as a combination product by the FDA, which requires coordination between the FDA's Center for Biologics Evaluation and Research and the FDA's Center for Devices and Radiological Health for review. For additional information, see the section titled "Risk Factors – Additional time may be required to obtain marketing authorizations for any of our product candidates that we develop as combination products."

Sasineprocel Genetic PD

We have begun enrolling patients and are preparing to initiate dosing a new cohort in the Phase 1/2a ASPIRO trial to evaluate sasineprocel in patients with genetically defined PD, leveraging our existing autologous DANPC manufacturing process. For the new cohort, we also plan to utilize additional standard of care stereotactic neurosurgical techniques including CT and MRI imaging guidance and robot assisted neurosurgery and an infusion pump to deliver sasineprocel. Pending the results of this cohort, we intend to include patients with genetic PD in our Phase 3 program to support a broad label for sasineprocel, if approved. Approximately 15%, or 150,000 of U.S. and 1.5 million of global PD patients have a genetic component of the condition. The most common PD-associated mutations are in the GBA1 and LRRK2 genes and are associated with increased susceptibility to PD, driving earlier disease onset. However, these mutations do not confer a developmental defect in neuronal function and the majority of people with these mutations will not develop PD. Although these mutations contribute to disease pathogenesis, preclinical studies have shown that iPSC reprogramming resets markers of cellular aging, mitochondrial dysfunction, and epigenetic abnormalities, and potentially winds back the epigenetic clock to a pre-disease state. Further, preclinical studies evaluating iPSC-derived DA neurons carrying GBA1 mutations have not demonstrated consistent or material differences in key cellular characteristics compared to wild type iPSC-derived DA neurons under the conditions tested. Therefore, we believe functional DA neurons can be efficiently derived from autologous iPSCs, even in the presence of late onset disease-associated mutations, supporting the use of sasineprocel as a potential treatment for genetically defined PD.

Microglia Replacement Program

Microglia replacement represents the second cell replacement program generated from our platform. Microglia are the resident immune cells of the CNS and play critical roles in immune surveillance, lipid metabolism, synaptic remodeling, and maintenance of neural tissue homeostasis. Impaired microglial function has been implicated in a range of neurological diseases, including genetic leukodystrophies and neurodegenerative disorders, including frontotemporal dementia and Alzheimer's.

Our lead microglia program initially targets pediatric leukodystrophies, a group of rare, genetically defined neurological disorders that primarily affect the white matter of the CNS. Our approach is designed to generate autologous, gene-corrected microglia precursor cells derived from patient-derived iPSCs. We utilize targeted genome editing approaches to address disease-associated genetic variants. These gene-corrected cells are then differentiated into microglia precursor cells intended for administration to the CNS, where they are designed to engraft and replace dysfunctional microglia and support the restoration of key microglial functions within the CNS. Subject to the successful completion of ongoing preclinical and development activities, we expect to initiate IND-enabling studies in the second half of 2027.

Parkinson's Disease Background and Current Limitations

Unmet Medical Need for PD

PD is a progressive neurodegenerative disease primarily characterized by the loss of DA neurons in the nigrostriatal pathway resulting in the severe, progressive deterioration of motor and non-motor neurological function. It is the second most common neurodegenerative condition (after Alzheimer's disease). At the time of diagnosis, patients often have lost more than 50% of their DA neurons. Motor symptoms include the "Classic Parkinson's triad" of bradykinesia (absent or decreased movement, gait difficulty), muscle rigidity, and resting tremor, as well as painful dystonia (abnormal muscle tone resulting in muscular spasm and abnormal posture). Over time, these symptoms will often become severe, leading to falls, the inability to work or perform self-care, and increased mortality over time. Patients also suffer from a range of non-motor symptoms, including anosmia (loss of sense of smell), autonomic dysfunction (dysfunction of the autonomic nervous system that controls heart rate, body temperature, breathing rate, digestion, and sensation), difficulty swallowing, urinary symptoms, constipation, sleep behavior disorders, orthostatic hypotension (dizziness or lightheadedness when standing after sitting or lying down), depression, psychosis, dementia and cognitive impairment. These symptoms can severely impact a patient's quality of life, contribute to progressive disability and loss of independence, and are associated with increased morbidity and mortality over time. Current standard of care is limited to DRT, which inadequately addresses non-motor symptoms, decreases in effectiveness over time, and is associated with side effects that can significantly impact patient quality of life.

PD affects an estimated more than one million people in the United States with 90,000 new patients diagnosed each year. Globally, an estimated more than 10 million people are living with PD. 25.2 million people are projected to be living with PD worldwide by 2050, representing a 112% increase from 2021. Approximately 1.3 million PD patients are projected to be living in the United States by 2036. The prevalence has doubled globally in the past 25 years, driven by an aging global population and improved diagnosis through expanded access to movement disorder specialists (MDS). The economic burden in the United States has surpassed the $79 billion previously projected for 2037, with total annual costs reaching $82.2 billion in 2024 and expected to exceed $112 billion by 2045. Disability income is approximately $4.8 billion and, as most already-diagnosed patients are over the age of 65, Medicare bears the largest share of U.S. medical costs. Additionally, incidence of young-onset PD has increased globally. Overall, the disease can exert a significant impact on patients, their families, their caregivers and community, the healthcare system, payors, and society.

Current Standard of Care

DRT (e.g., levodopa-based regimens) represents the current standard-of-care for treatment of PD. DRT can help manage motor symptoms, but PD symptoms inevitably progress despite optimized pharmacologic therapy. Side effects of DRT include nausea, orthostatic hypotension, impulse control and neuropsychiatric disorders and the development of motor fluctuations and dyskinesia with long-term use. Continuous DA infusions can be used as alternative therapies for patients with intolerable motor fluctuations, though their use is limited by managing delivery devices and the same side effects that limit use of their oral formulations.

The benefits of DRT can be tracked by capturing "Good On" and "Off" times (the times when medications are working well and not working, respectively). As PD progresses, Good On Time at a given dose typically diminishes as Off Time increases. Escalation of DRT is typically limited by side effects - namely peak dose dyskinesia - which can become intolerable to patients. It is at this time when advanced therapies, namely DBS, are considered.

Table of Contents

DBS is effective at reducing Off Time and managing tremor. It also often helps patients reduce doses of DRT, thus reducing peak-dose dyskinesia. However, it has some significant limitations. Due to the shortage of DBS-trained MDS, referrals to physicians capable of managing DBS patients can take many months. Further, only 10-15% of PD patients eligible for DBS are referred for treatment and <2% of patients elect to undergo the DBS placement procedure. Many patients are resistant to permanent placement of foreign hardware devices into their brains and elsewhere in their bodies (DBS extension wires are placed in the neck which connect the brain leads to batteries that are generally placed in the chest). Further, the hardware may limit use of diagnostic magnetic resonance imaging (MRI) scans and cause interference with electrocardiograms (ECGs) and other potentially needed emergency diagnostic studies. Additionally, it can take up to six months after an MDS referral to schedule DBS lead placement surgery (which is associated with a small risk of symptomatic hemorrhage), and a second surgery for battery placement is commonly performed separately. Then it can take many months working with a DBS neurologist to optimize device settings to maximize benefit and minimize stimulation-induced side effects. Moreover, the batteries for the system need to be periodically replaced. The DBS hardware may fail or become infected, often necessitating additional surgeries or removal of the hardware and sometimes long courses of antibiotics. DBS has not been shown to slow disease progression in mid-stage to moderately advanced PD patients and can potentially worsen cognition, gait, speech and other axial symptoms.

The benefits of each of these treatments diminish over time and we believe no existing treatment adequately addresses non-motor symptoms, such as autonomic dysfunction, neuropsychiatric symptoms, dementia and cognitive impairment, which increase as the disease progresses and leads to severe morbidity and mortality.

Rationale for Cell Therapy in PD

There is an urgent need to develop disease-modifying therapies that sustain dopamine production and have an impact on both motor and non-motor symptoms, but current approved therapies are focused on improving motor symptoms. Longer acting forms of DRT will likely have the same challenges for chronic PD patients as current L-dopa therapy. Maintenance or replacement of DA neurons and supporting cell types may represent a more promising approach for a true disease-modifying treatment with long-term effectiveness. Cell replacement therapy represents a promising option for a therapy that can provide long-term benefit from a single administration. Of the estimated more than one million people in the United States affected by PD, we believe that approximately 300,000 of such patients are refractory to DRT and that approximately half of those patients would be eligible for a cell replacement therapy surgery. Previous studies have demonstrated that transplantation of human fetal, ventral-mesencephalic tissue containing DA neurons can lead to long-lasting (greater than 10 years) engraftment of DA neurons and improvements in the motor symptoms of PD. These findings provide historical support for the concept of DA cell replacement and therapeutic strategy. Current cell replacement strategies under investigation for PD include transplantation of allogeneic and autologous stem cell-derived DA neuron precursors.

Allogeneic Cell Therapy in PD and its Challenges

Current studies in allogeneic therapies provide some early evidence for success, feasibility, and safety of stem cell transplantation, cell survival, and engraftment. Allogeneic approaches use a cell line derived from an individual other than the patient, while autologous therapies use the patient's own cells. The allogeneic, embryonic stem cell-derived, dopamine-producing neuronal product, bemdaneprocel, from BlueRock Therapeutics LP, a clinical-stage cell therapy company and wholly owned subsidiary of Bayer AG, demonstrated favorable safety results at 36 months in Phase 1 trial participants, which we believe validates the potential of a cell replacement approach for PD. However, bemdaneprocel and certain other allogeneic products can require systemic immunosuppression, with drugs like tacrolimus and prednisone, for one year or more following surgery. These immunosuppressants carry significant clinical risks and side effects, especially tacrolimus, which has a narrow therapeutic index and requires therapeutic drug monitoring and adds to the cost of treatment. The drawbacks of immunosuppression with tacrolimus and prednisone include:

- High adverse event burden, including risk of organ toxicity (renal, hepatic, GI bleeding) that prompt the need for many other medications as well as major medical interventions (e.g., dialysis, surgery)
- Exacerbation of comorbid conditions (e.g., diabetes and hypertension)

Table of Contents

- Recurrence of previous infections (e.g., cytomegalovirus) as well as an increased risk of opportunistic viral or fungal infections, which have led to reported patient deaths. Patients have had to take prophylactic anti-infectives and adapt their lifestyles to avoid exposure to infection
- Drug-monitoring requirements and dosing contraindications

These drawbacks can preclude patient eligibility, especially for older PD patients with common comorbidities. Further, this requires physician monitoring and vigilance not usually seen in MDS practices and increases costs. All these factors can lead to noncompliance, which can lead to insufficient immunosuppression and can decrease the efficacy of the allogeneic therapy.

In addition, large-scale expansion of allogeneic cell lines requires extensive cell banking and manufacturing scale-up, which may increase the risk of genome instability over time. For example, scale up of iPSCs can select for mutations which provide a proliferation advantage, such as mutations in the *TP53* gene, similar to mutations commonly found in human cancers. Redosing with the same allogeneic product may also be limited by the development of immune sensitization.

The burden and deleterious effects of immunosuppression—alongside the ethical and regulatory complexities associated with embryonic stem cells—make autologous iPSC-derived therapies a highly attractive alternative. We believe an autologous iPSC-derived product has the potential to create autologous dopamine-producing cells for PD patients while eliminating the need for immunosuppression. In addition, we believe primate experimental data support the absence of an ongoing neuroinflammatory immune response as typically seen in allogeneic therapies, which can better facilitate optimal graft integration and improved synaptic circuit formation. Moreover, autologous manufacturing uses the patient's own cells, so there is no large-scale master cell bank expansion, thereby potentially reducing the risk of accumulating genomic abnormalities, including those that could lead to malignant transformation. Further, an autologous product is not expected to trigger immune rejection responses that are commonly associated with donor-derived allogeneic cell therapies, such as organ toxicity. As a result, autologous approaches may allow greater flexibility in dosing at a higher level unlike allogeneic therapies, where higher dosing may increase the risk of immune-mediated rejection or require intensive immunosuppressive regimens.

Autologous and Allogeneic in NHPs

A third-party preclinical study was conducted by the University of Wisconsin-Madison (Tao et al., Nature Medicine, 2021) comparing autologous to allogeneic iPSC-derived DA neuronal cell transplantation in NHP models of PD over a two-year period, without immunosuppression, to evaluate motor function, graft survival and integration, among other things. This study demonstrated improvements in motor behavior following transplantation of DA progenitor cells, with autologous grafts associated with approximately 40% to 60% improvement in motor function, sustained over a 24-month post-transplant period, compared with allogeneic grafts in the absence of immunosuppression (Figure 4 below). In addition, histological analyses showed that autologous grafts differentiated into tyrosine hydroxylase (TH)-positive DA neurons and exhibited extensive neurite and axonal outgrowth extending from graft sites into surrounding host tissue, consistent with reconstruction of DA neural circuitry. In contrast, allogeneic grafts in the same model demonstrated more limited neurite outgrowth and reduced integration in the absence of immunosuppression. These findings suggest that autologous DA progenitor transplantation may support more robust neural integration and restoration of DA signaling compared with donor-derived cells when immunosuppression is not administered. However, allogeneic cell therapies in clinical settings are generally administered with immunosuppression, and the results of this study may not be predictive of patient outcomes under conditions in which immunosuppression is used. To our knowledge, there are no published preclinical studies directly

Table of Contents

comparing autologous to allogeneic dopaminergic precursor cell transplantation under immunosuppression in comparable non-human primate models of Parkinson's disease.

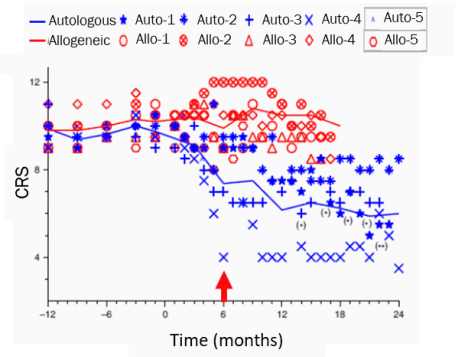


Figure 4. Monthly clinical rating score (CRS) of the monkeys receiving allogeneic or autologous transplantation from 12 months before transplantation to 24 months after transplantation. The transplantation occurred at month 0. Lines show mean values for every three months from the allogeneic group or the autologous group. Significance was assessed by Friedman test (non-parametric statistical test); * $p < 0.05$, ** $p < 0.01$.

Our Solution – Sasineprocel Overview

We are developing sasineprocel, an investigational single-dose "one and done," autologous iPSC-based product candidate for PD that is designed to replace a patient's lost dopamine neurons with DANPCs. We believe sasineprocel, our personalized and proprietary composition of neural precursors for each patient, has the potential to recapitulate and restore neural circuitry in PD patients and, if approved, become the first FDA-approved disease-modifying therapy for PD with potential to address motor and non-motor symptoms. There are several characteristics of sasineprocel that differentiate it from standard of care and/or allogeneic therapies in development and position it as a potentially transformative treatment for PD patients:

- **Personalized approach:** Sasineprocel is an autologous product candidate designed to minimize the risk of immune rejection and eliminate the need for long-term immunosuppression and its associated risks. In addition, based on market research, we believe patients prefer the personalized approach of autologous cell therapy as compared to gene or allogeneic therapies.
- **Proprietary cell composition:** Sasineprocel's proprietary composition of DANPCs, together with supportive CNS and glial progenitors and other neuronal cells, is designed to create a biologically active microenvironment that may support restoration of neural circuitry and synapse formation. We believe this differentiated cellular composition may contribute to the meaningful and sustained improvements observed in PD patients in the ASPIRO trial.
- **Precise and streamlined delivery:** Sasineprocel is administered through a minimally invasive procedure using well-understood standard of care stereotactic neurosurgical techniques, which key opinion leaders reported being amenable to. The product is thawed at the time of surgery for immediate administration and does not require on-site cell processing or testing capabilities. Following administration, sasineprocel requires no device maintenance, programming, or ongoing optimization, differentiating it from device-based therapies such as DBS.
- **Advanced cell characterization:** We leverage ML-enabled bioinformatics to characterize key attributes of sasineprocel, including quality, purity, maturity, engraftment potential, and dopamine production, with the goal of ensuring consistent cellular differentiation.

- **Broad applicability:** Sasineprocel is designed to address a broad population of PD patients, including those who may not tolerate immunosuppressive regimens, who are reluctant to undergo implantation of permanent hardware in the brain, or whose disease is associated with a genetic driver.

We are currently conducting the open-label Phase 1/2a ASPIRO trial of a single dose of sasineprocel in patients with PD. Promising interim clinical data from both the high and low dose cohorts suggests that the administration of sasineprocel could potentially lead to significant long-term clinical benefit for PD patients across both motor and non-motor symptoms and potentially slow or halt the progression of the disease. We plan to dose approximately a single cohort of three to six patients with genetic PD in the ASPIRO trial. We anticipate initiating biopsy collection for the Phase 3 trial by the end of 2026. Following feedback from the FDA, we anticipate dosing patients in the Phase 3 trial in the second half of 2027.

Proposed Mechanism of Action

Sasineprocel is a proprietary composition consisting primarily of dopamine neural precursors, DANPCs, along with supportive CNS and glial progenitors, designed to replace lost DA neurons and restore motor and non-motor function in patients with PD. The loss of these DA neurons in the substantia nigra pars compacta leads to a concentrated loss of dopamine within the striatum, specifically the post-commissural putamen, which is where sasineprocel is precisely administered. Placing sasineprocel into the putamen, an area where there is significant DA neuronal loss associated with PD pathology, is optimal for restoring the lost dopamine signaling and neurocircuitry. Following transplantation, DANPCs are intended to engraft and mature into dopamine-producing neurons. As these grafted DA neurons mature, they are designed to form synaptic connections with existing neurons and achieve integration with a patient's existing neural circuitry promoting functional recovery. Our hypothesis is that this functional recovery can re-establish the brain's ability to release dopamine on demand in a physiological manner. Consistent with this proposed mechanism, our preclinical studies have demonstrated that sasineprocel differentiated into post-mitotic DA neurons following transplantation, established synaptic connectivity, and restored dopamine signaling in established animal models of PD. In addition to DANPCs, sasineprocel contains low percentages of supportive neural and glial progenitor cell populations, including astrocyte progenitors and progenitors capable of giving rise to other neuronal cell types. Based on ongoing preclinical studies and the known biological functions of these cell types, DANPCs, along with other neural and glial progenitors, may help establish a biologically active microenvironment that promotes cell engraftment, survival, and functional integration.

Phase 1/2a ASPIRO Trial Design

We are conducting a first-in-human, multi-center, open-label Phase 1/2a ASPIRO trial evaluating the safety, tolerability, and efficacy of the intracranial injection of sasineprocel in patients with mid-stage to moderately advanced PD. The study's primary objective is to assess the safety and tolerability of bilateral administration of sasineprocel into the post-commissural putamen. The study's secondary and other exploratory objectives are to evaluate the potential efficacy of sasineprocel, measured by changes from baseline in multiple patient- and clinician-reported PD-specific outcomes. These include changes in MDS-UPDRS Parts I-IV, Hauser diary (to measure "Good On" time, defined as time without troublesome dyskinesia), and quality of life measures including PDQ-39. These secondary endpoints are validated endpoints used in previous PD registrational clinical trials for drugs such as RYTARY approved in 2015 and VYALEV (foscarbidopa/foslevodopa) approved in 2024.

We plan to evaluate the outcomes of these patients every six months for the first two years and yearly thereafter and intend to perform long-term safety follow-up extending through 15 years. Secondary endpoints include the evaluation of putaminal Fluorodopa uptake using Fluorodopa PET, which is specialized brain imaging technique that uses a radioactive tracer called ^{18}FDOPA to visualize DA nerve terminals in the striatum, the brain region most affected in PD. Additionally, we evaluated movement, function, sleep, and medication using two forms of digital health technologies (DHT), one for use at home and a wearable device for use both at home and outside the home.

We enrolled 15 patients in the ASPIRO trial of which 12 patients from the first three cohorts have available data for secondary and other exploratory objectives. Key patient enrollment criteria included age 50 to 70, at least four years post-PD diagnosis and responsiveness to L-dopa. Patients who had prior brain intervention (including DBS and FUS), were cognitively impaired or had medical or surgical risk factors for trial participation were excluded.

We use a streamlined, precise and minimally invasive process for sasineprocel administration that may generally allow patients to be discharged the next day. Prior to administration, the drug product arrives as cryopreserved cells in a vial, which is warmed at bedside one hour before surgery. The product is delivered using well-understood, standard stereotactic neurosurgical techniques. The administration is performed through a single approximately 5mm burr hole per hemisphere with bilateral cell deposition into the putamen over a duration of approximately 90 minutes.

Patients were treated in four cohorts differentiated by formulation and dose level. In the dose-preparation formulation cohorts, four patients received 10 million cells (Cohort 1 low dose) and four patients received 15-20 million cells (Cohort 2 – high dose). In the thaw-and-inject cohorts, four patients received 20 million cells (Cohort 3 – high dose) and three patients received 10 million cells (Cohort 4 – low dose). Our thaw-and-inject formulation eliminates the need for a dose preparation process and extensive testing, allowing for a short (approximately 25 minutes) procedure to thaw the product and load the delivery device for surgery. This thaw and inject formulation is designed to enable surgical scale-out to institutions that do not have cell processing and testing capabilities.

IND clearance was delayed from January to August 2023 due to a clinical hold imposed by FDA related to insufficient information in the IND regarding the syringe used as part of our drug delivery system. During the course of the ASPIRO trial, we also experienced a delay in patient dosing due to issues with the design of the syringe. We worked with the supplier to design and validate a new syringe configuration, which has been implemented for subsequent dosing. We do not currently have arrangements in place for redundant supply or a second source for all required materials and components, including the delivery device, used in our clinical trials. See “Risk Factors—Risks Related to Our Reliance on Third Parties” for additional information.

ASPIRO Trial Design

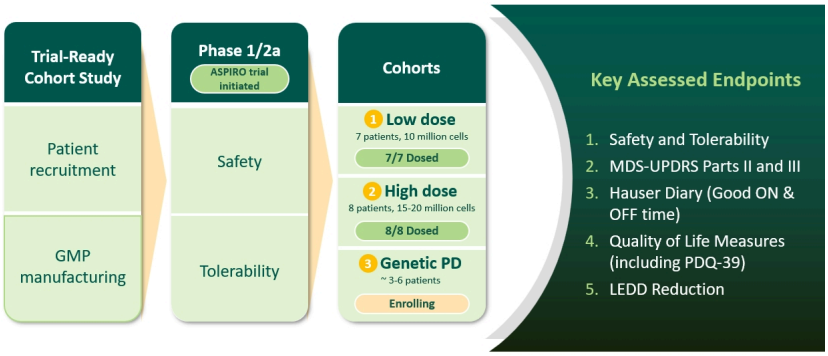


Figure 5. Schematic representation of Aspen’s Phase 1/2a ASPIRO trial with endpoints.

As of August 18, 2026, the data cutoff date, sasineprocel was generally well tolerated with a majority of reported adverse events being mild to moderate. As of the data cutoff date, 15 patients had been dosed, with seven participants receiving a low dose and eight participants receiving a high dose. Among the patients dosed, 72 TEAEs were reported. There was no evidence of graft-induced dyskinesias or graft rejection, and no clinically significant hemorrhages were observed post-operatively. As sasineprocel is autologous, with no requirement for immunosuppression, there were no immunosuppression-related events. Only one TEAE, myoclonus (sudden, uncontrollable muscle movement), was considered possibly related to sasineprocel, with sertraline, a selective serotonin reuptake inhibitor, identified as a co-suspect medication. One participant had two serious adverse events related to the surgical procedure (neck swelling and dysphagia due to intubation in the prone position and ischemic stroke (cerebral infarction) due to pre-operative interruption of anticoagulants that the patient was taking for a history of deep venous thrombosis). The most commonly reported TEAEs, defined as occurring in 10% or more of patients, were related to the surgery, including incision site

Table of Contents

pain, swollen tongue, headache, infusion site pain, glossodynia, hypoesthesia, and oropharyngeal pain. As of the data cutoff date, all 12 patients from the first three cohorts had at least one six-month or later follow up evaluation. Two patients had intracranial hemorrhages not requiring any surgical treatment. Of these two patients, one patient had no associated symptoms and the other, who had a history of migraine, had a headache that resolved, with levetiracetam identified as a co-suspect medication.

We are assessing clinical outcomes every six months after administration of sasineprocel. As of the data cutoff date, we observed improvements across several secondary and exploratory endpoints, including changes in Good On Time (On time without troublesome dyskinesia normalized to 16 hours of awake time), MDS-UPDRS Part III OFF. Consistent with these motor improvements, we also observed improvements in activities of daily living and quality of life measures assessed by MDS-UPDRS Part II ON and PDQ-39 scores, as summarized below. Certain of the secondary endpoints used in this trial, including Good On Time and MDS-UPDRS Part III OFF, are validated registrational endpoints used in previous PD registrational clinical trials. The mean improvements at 18 months in both cohorts and 24 months for the low dose cohort for Good On Time and MDS-UPDRS Part III OFF scores in both cohorts were above clinically meaningful change benchmarks. The mean PDQ-39 and MDS-UPDRS Part II ON scores improved above clinically meaningful change benchmarks in the low dose cohort at 18 and 24 months and were stable in the high dose cohort at 18 months. ^{18}FDOPA PET imaging is also being used to evaluate the engraftment of cells. ^{18}FDOPA PET imaging showed elevated ^{18}FDOPA uptake values at six, 12, and 18 months following sasineprocel administration compared to baseline, which is evidence of the survival, viability, and integration of transplanted iPSCs. Clinically meaningful change benchmarks are reviewed on an ongoing basis during the trial and reflect management's belief based on a review of published literature, regulatory agency guidelines and precedent in PD clinical research, and discussions with key opinion leaders in the field. The benchmarks have not been discussed with the FDA or any other government regulatory authority, and have not been independently validated by any third parties.

Additionally, the ASPIRO trial is exploring changes in DA medication as measured by LEDD, a standardized metric that converts all DA medications a patient is taking into a single equivalent dose of levodopa, providing a measure of total daily DA medication burden. A reduction in LEDD suggests that a patient requires less DA medication to manage their motor symptoms. As of the data cutoff date, in the low dose cohort, two, three, three and three patients showed a reduction in LEDD at six, 12, 18 and 24 months, respectively, and one patient experienced an LEDD increase at 18 and 24 months. In the high dose cohort, at six months, three out of eight patients showed an LEDD reduction and one patient showed an LEDD increase; at 12 months, two out of four patients showed an LEDD reduction and one patient showed an LEDD increase; at 18 months, three out of four patients showed an LEDD reduction and one showed an LEDD increase.

	Low Dose n=4					High Dose n=8			
Month	Baseline (n=4)	6 (n=4)	12 (n=4)	18 (n=4)	24 (n=4)	Baseline (n=8)*	6 (n=8)	12 (n=4)	18 (n=4)
Mean Change in Good On Time (hrs) Hauser Diary (MCID > 1 hrs)	11.6 (2.21)	+1.6 (1.46)	+2.1 (1.46)	+2.2 (2.75)	+2.6 (1.78)	9.8 (2.48)	+2.3 (2.59)	+2.4 (1.26)	+2.7 (2.08)
Mean Change in OFF Time (hrs) Hauser Diary (MCID < 1 hrs)	4.1 (1.87)	-2.1 (1.70)	-2.0 (1.50)	-1.9 (2.46)	-2.3 (1.50)	5.5 (1.67)	-1.9 (2.31)	-2.4 (1.26)	-2.7 (2.08)
Mean Change in MDS-UPDRS part III OFF score (points) (MCID 4-5 points)	42.3 (5.32)	-17.5 (5.20)	-15.5 (9.61)	-13.0 (4.40)	-15.8 (7.54)	44.5 (9.75)	-9.6 (4.78)	-13.5 (13.87)	-19.3 (6.40)
Mean Change in MDS-UPDRS part II ON score (points) (MCID 2-4 points)	14.0 (3.46)	-7.0 (5.00)	-5.3 (5.44)	-6.0 (6.27)	-6.8 (7.14)	10.9 (7.41)	-1.4 (2.83)	-2.3 (3.30)	0.0 (3.16)
Mean Change in PDQ-39 (points) (MCID 4-5 points)	13.8 (4.21)	-5.7 (3.65)	-7.6 (7.41)	-5.0 (9.09)	-5.0 (6.30)	15.5 (12.40)	-3.1 (6.30)	-6.2 (6.88)	-3.9 (6.83)
Number of patients with LEDD reduction		2	3	3	3		3	2	3

Figure 6. Sustained improvements observed across multiple validated PD endpoints. Data summarized above is as of August 18, 2026. A decrease (negative number) compared to baseline is an improvement for MDS-UPDRS scores and PDQ-39. The numbers in parentheses represent standard deviations. Mean changes in data summarized above are driven by totality of data across patients and not driven by a limited number of patients exhibiting

Table of Contents

significantly better-than-average improvements. *For the four high dose patients for whom data was available at the 12-month and 18-month assessments, the baseline values for Good On Time (hours) Hauser Diary, Off Time (hours) Hauser Diary, MDS-UPDRS Part III OFF score, MDS-UPDRS Part II ON score, and PDQ-39 were: 11.7 (0.9), 4.3 (0.9), 44.0 (4.2), 9.5 (9.3), 16.1 (15.6), respectively. For the three low dose patients in Cohort 4, no data is yet available because six months have not elapsed since dosing for all three patients.

Beyond these changes being what we believe to be clinically meaningful from baseline, third-party natural history studies suggest patients with PD worsen across all these measures. Parkinson's Progression Markers Initiative, or PPMI, is a large, internationally used research data set designed to collect standardized clinical data over time to better understand how PD starts and progresses. These PPMI data suggest progressive worsening of approximately two points per year on the MDS-UPDRS Part III OFF scale. In contrast, sasineprocel, including eight patients (low dose; n=4, high dose; n=4), shows a mean decrease, or improvement, at six, 12, and 18 months of 14.6, 14.5, and 16.1 points, respectively, and, including four patients (low dose; n=4), shows a mean decrease, or improvement, at 24 months of 15.8 points. Figure 7 below presents the mean change from baseline in MDS-UPDRS Part III OFF scores for each patient at the six-month, 12-month, 18-month and 24-month assessments together with the mean change from baseline observed in natural history study patients, reflecting the progressive worsening expected in PD patients over time.

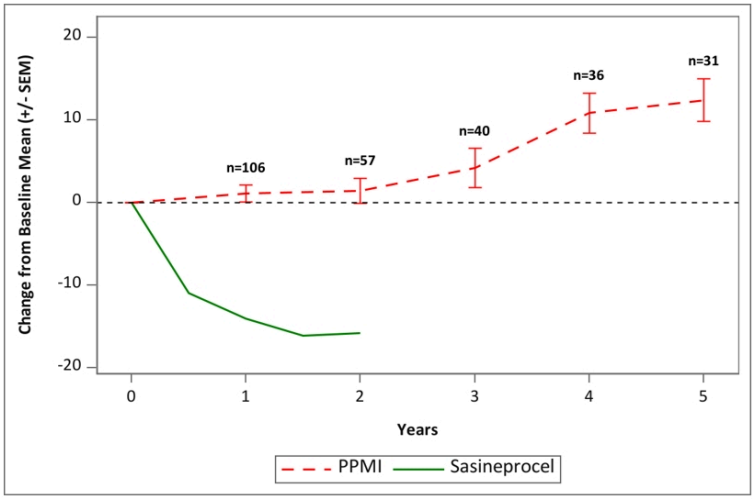


Figure 7.

Figure 8 below presents the Good On Time for each patient at each available assessment, as measured using the Hauser diary, together with the mean Good On Time hours for the low dose and high dose cohorts at each assessment, in each case as of the August 18, 2026 efficacy data cutoff. The mean Good On Time hours for each cohort at each assessment, as shown in Figure 8 below, reflect the average of the individual patient Good On Time hours at such assessment. As measured by mean change from baseline per patient, the low dose cohort showed a mean increase of 2.2 hours at 18 months and 2.6 hours at 24 months, and the high dose cohort showed a mean increase of 2.7 hours at 18 months. For the low dose cohort, there were four patients in each of the assessments shown. For the high dose cohort, there were eight patients for the baseline and Day 180 assessments. Day 365, and 18-month assessments had

Table of Contents

four patients; the mean baseline and standard deviation for the four patients shown at Day 365, and 18 months was 11.7 (0.9).

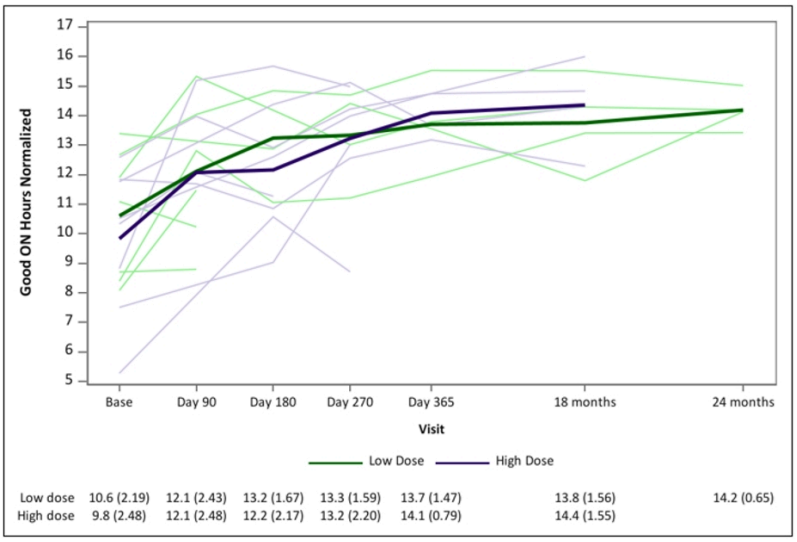


Figure 8.

Quality of Life Assessments

In addition to preliminary safety and motor function data, we observed improvements in quality of life symptoms following the administration of sasineprocel.

Quality of life improvements are being assessed using PDQ-39, a 39-item, patient reported questionnaire used to measure health related quality of life in people with PD. PDQ-39 is the most widely used disease specific quality of life measure for PD. The questionnaire asks patients how often, over the past month, they have experienced difficulties related to PD across eight domains, including mobility, activities in daily living, emotional well-being, stigma associated with disease, social support, cognition, communication, and bodily discomfort. Each domain is scored on a standard scale ranging from 0–100 and the total score is the mean of the eight subdomains, with higher values indicating greater disease burden. As of the data cutoff date, patients in the first cohort (low dose; n=4) and the second cohort (high dose; n=4), treatment with sasineprocel resulted in a reduction in total PDQ-39 score of 5.0 at each of 18 months and 24 months for the low dose cohort and 3.9 at 18 months for the high dose cohort demonstrating meaningful improvements in quality of life. As of August 18, 2026, the data cutoff date, the total PDQ-39 score at 18 months improved (decreased) in three out of eight patients, with a mean 29% reduction from baseline, remained stable in four patients, and worsened in one patient. As of the data cutoff date, the total PDQ-39 score at 24 months improved (decreased) in three out of four patients, with a mean 36% reduction from baseline, and worsened in one patient.

Exploratory Endpoints

We have explored endpoints across the Scales for Outcomes in Parkinson's Disease – Autonomic (SCOPA-AUT) measurements, a validated, patient-reported questionnaire specifically designed to assess autonomic nervous system symptoms in people with Parkinson's disease, and the Montreal Cognitive Assessment (MoCA) measurements, the most widely used brief cognitive screening tool for detecting mild cognitive impairment (PD-MCI)

Table of Contents

and Parkinson's disease dementia (PDD). At 18 months, out of eight patients (low dose; n=4, high dose; n=4), we saw directional improvements in SCOPA-AUT in three patients, stability in four patients, and worsening in one patient. At 24 months, out of four patients (low dose; n=4), we saw directional improvements in SCOPA-AUT in two patients, stability in one patient, and worsening in one patient. At 18 months, out of eight patients (low dose; n=4, high dose; n=4), we observed stability in MoCA in all eight patients, and at 24 months, out of four patients (low dose; n=4), we observed stability in MoCA in all four patients. For purposes of evaluating clinical trends in SCOPA-AUT scores, management defined "improvement" as a greater than 20% decrease from baseline, "stable" as a change between a 20% decrease and a 20% increase from baseline, and "worsening" as a greater than 20% increase from baseline.

The gait axial subscore, a clinical metric derived from MDS-UPDRS Part III, improved in seven out of eight patients at 18 months, with a mean 46% reduction, and improved in all four patients at 24 months, with a mean 45% reduction, as shown in Figure 9 below. Notably, all eight patients demonstrated improved gait axial subscores compared to baseline as of their most recent follow-up. Low gait axial subscores are associated with reduced fall risk. DRT typically has little effect on the axial symptoms of PD, suggesting the consistent improvement is potentially the result of neural circuitry reconstruction following the administration of sasineprocel.

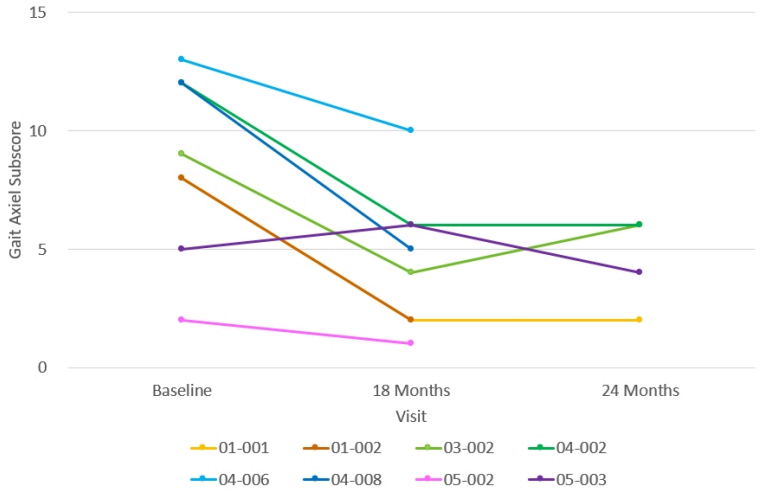


Figure 9.

We evaluated ^{18}FDOPA PET imaging to assess DA activity in the putamen following administration of sasineprocel. ^{18}FDOPA PET is a specialized neuroimaging technique that uses a radiolabeled dopamine precursor to assess DA activity in the striatum, including the putamen, a brain region significantly affected in PD. ^{18}FDOPA PET showed increased ^{18}FDOPA uptake at six, 12 and 18 months following sasineprocel administration compared to baseline, including a mean approximately 17% increase of ^{18}FDOPA uptake was reported in the eight patients with 18-month data as of the data cutoff date. These data, including the ^{18}FDOPA PET data from the eight patients that have reached 18 months, are supportive of engraftment and survival of transplanted cells and support continued clinical evaluation of sasineprocel as a cell replacement therapy for PD.

Table of Contents

Preclinical Data

We have conducted a comprehensive nonclinical program to inform activity, engraftment, dosing, and safety to support the clinical development of sasineprocel.

In our preclinical studies, we have observed that sasineprocel when transplanted into an established 6-OHDA PD rodent model differentiated into post-mitotic DA neurons, established synaptic connectivity, and restored dopamine signaling. Across multiple donor-derived cell lines, in a preclinical study of rats, sasineprocel demonstrated sustained engraftment and sustained functional recovery over the longest allowable observation periods. Additional safety studies confirmed the ability to precisely deliver cells within the striatum and no evidence of tumor formation.

Sasineprocel In Vivo Engraftment and Maturation

Our preclinical studies have demonstrated successful engraftment and maturation following intracerebral transplantation of DANPCs and subsequent recovery of DA signaling deficits in a rodent 6-OHDA model of PD. Transplantation of DANPCs from four different PD donors into the denervated striatum resulted in behavioral recovery (decrease in amphetamine-induced rotations) over a 28-week rodent study (Figure 10A below). Histological analyses showed survival of transplanted cells within the target region and differentiation into TH-positive DA neurons. These cells exhibited robust neurite and axonal outgrowth extending into the surrounding host tissue, consistent with integration into existing neural circuitry (Figure 10B below).

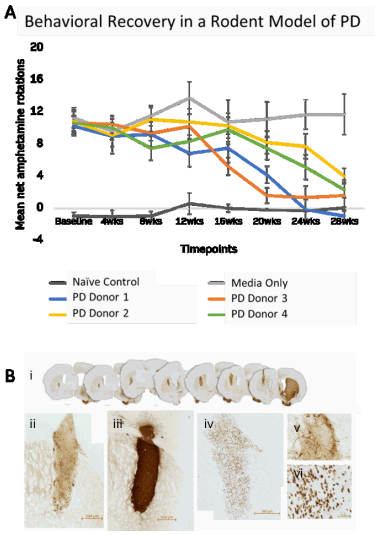


Figure 10. (A) Mean net amphetamine-induced rotations per minute, from Baseline (pre-dosing) until 28-weeks post-dosing. (B) Representative histological images of a series sections from a rodent brain stained for TH (i), magnified image of the striatum stained for TH (ii), human cytoplasm indicating presence of human cells (iii), human nuclei indicating presence of human cells (iv), increased magnification of the grafted cells stained for TH (v) and human cytoplasm (v).

Table of Contents

Preclinical Delivery and GLP Safety Data

Prior to initiating our Phase 1/2a ASPIRO trial, we designed and validated a targeted stereotactic intracerebral delivery approach for sasineprocel to localize cells to the striatum, the primary site of DA neuron loss in PD. In rodent and NHP models using delivery methods intended to replicate the planned clinical procedure, we observed sasineprocel administration was well tolerated and resulted in accurate localization to the intended target region without evidence of procedure-related neurological deficits, off-target biodistribution, or persistent adverse findings, supporting the feasibility and potential safety of the delivery method for sasineprocel in clinical settings.

Across our toxicology, tumorigenicity, and biodistribution studies in rodent and NHP models at clinically relevant and supra-clinical doses, sasineprocel demonstrated no evidence of teratoma, tumor formation, abnormal proliferation, ectopic tissue formation, or off-target biodistribution. We believe these findings are consistent with and supportive of a potential low tumorigenic risk profile expected of sasineprocel.

Sasineprocel for Genetic PD

We are preparing to expand our Phase 1/2a ASPIRO trial evaluating sasineprocel to include a cohort of patients with genetically defined PD and have begun enrolling genetic PD patients. Approximately 15%, or 150,000 of U.S. and 1.5 million of global PD patients have a genetic component of the condition. Mutations in genes such as GBA1, LRRK2, and PINK1 are associated with increased susceptibility to PD, drive earlier disease onset, and accelerated disease progression. Although these mutations contribute to disease pathogenesis, preclinical studies have shown that iPSC reprogramming can reset cellular aging markers, mitochondrial dysfunction, and epigenetic abnormalities.

In vitro studies showed that GBA1-derived iPSC lines successfully differentiated into DA neurons that exhibit characteristic morphology and expression of key DA markers.

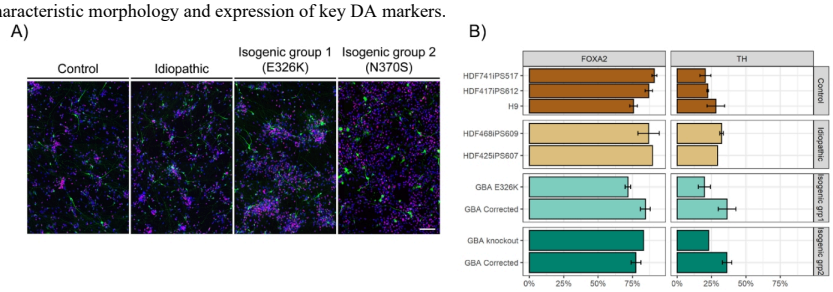


Figure 11. A) Immunocytochemistry for DAN markers FOXA2 and TH at Day 40 post differentiation. Scale bar=100 µm. The four different lines show similar morphologies of TH+ neurons and a similar abundance of FOXA2+ cells. B) Quantification of FOXA2+ and TH+ cells normalized to total DAPI+ cells at Day 40 (n=3 lines/group).

Our preclinical studies also showed there were no consistent differences in response to α-synuclein pre-formed fibril treatment between GBA1-DANs and isogenic controls. Our preclinical studies give us conviction that functional DA neurons can be efficiently derived from autologous iPSCs, even in the presence of disease-associated mutations, supporting the use of sasineprocel as a potential treatment for genetically defined PD.

We have strategically expanded our ongoing Phase 1/2a ASPIRO trial beyond sporadic PD into genetically defined subpopulations. By leveraging our existing reprogramming and manufacturing process, we aim to expand sasineprocel into genetic PD without the additional technical, regulatory, and manufacturing complexity associated with gene editing technologies. Pursuing both sporadic and genetically defined PD populations may support a potential broad label for sasineprocel across PD, if approved.

Planned Transition to Phase 3 Development

Based on the safety results observed to date and interim clinical data from the ongoing Phase 1/2a ASPIRO trial, we plan to advance sasineprocel into a Phase 3 trial, subject to continued data maturation and regulatory feedback.

The planned Phase 3 trial is intended to evaluate the safety and efficacy of sasineprocel in a larger patient population and to support a potential Biologics License Application (BLA). The Phase 3 trial is expected to include a control group, prespecified primary and secondary efficacy endpoints, exploratory endpoints and longer-term assessments designed to evaluate durability of clinical effects.

Aspen intends to leverage insights from the Phase 1/2a ASPIRO trial—including dose selection, neurosurgical techniques, sasineprocel delivery procedures utilizing an infusion pump and measures of clinical activity—to inform the design of the Phase 3 trial. Based on preliminary discussions with FDA, we anticipate conducting a single Phase 3 registrational study that includes a sham-controlled trial design and an 18-month primary endpoint. We plan to further engage with regulatory authorities to obtain feedback on key details of the Phase 3 program, including endpoint selection, statistical considerations, and trial design features. We also plan to meet with regulatory authorities to align on our CMC plan to support the manufacturing process for the Phase 3 study and potential future commercialization.

Microglia Replacement Program

Microglia replacement represents the second program generated from our platform. Microglia are the resident immune cells of the CNS and play critical roles in immune surveillance, lipid metabolism, synaptic remodeling, and maintenance of neural tissue homeostasis. Impaired microglial function has been implicated in a range of neurological diseases, including genetic leukodystrophies and neurodegenerative disorders. Our lead program targets pediatric leukodystrophies, a group of rare, genetically defined neurological disorders that primarily affect the white matter of the CNS. Our approach is designed to generate autologous, gene-corrected microglia precursor cells derived from patient-derived iPSCs. We utilize targeted genome editing approaches to address disease-associated genetic variants. These gene-corrected cells are then differentiated into microglia precursor cells intended for administration to the CNS, where they are designed to engraft and replace dysfunctional microglia and support the restoration of key microglial functions within the CNS.

This program builds on the same core platform technologies used to generate sasineprocel, including autologous iPSC reprogramming, iPSC clonal selection, and directed differentiation. Our microglia programs also leverage the manufacturing infrastructure, analytical assays, and QC systems developed for sasineprocel. This shared platform may enable efficient development and potential scalability of microglia replacement therapies across multiple CNS indications where microglial dysfunction contributes to disease pathology. Subject to the successful completion of ongoing preclinical and development activities, we expect to initiate IND-enabling studies in the second half of 2027.

In addition to pediatric leukodystrophies, this approach may provide a modular “plug-and-play” framework in which different disease-causing genes could potentially be corrected or replaced in patient-derived cells using the same underlying cell engineering and manufacturing platform. This strategy may enable the development of microglia replacement therapies for other monogenic disorders involving microglial dysfunction, sometimes referred to as microgliopathies, by combining a standardized cell platform with targeted gene correction tailored to the underlying genetic defect.

Manufacturing

Manufacturing of autologous cell therapies requires multiple steps. We aim to innovate and continually enhance our manufacturing platform through automation, ML, and other technology operation solutions in order to reduce costs and manufacturing time and provide patients with access to our personalized regenerative therapies, if approved.

While the autologous cell therapy field has advanced tremendously in the past decade, historical challenges have included the high cost of manufacturing and batch-to-batch variabilities. We are developing an automated, robust, modular manufacturing process designed to meet potential future demand of our product candidates. We use the Cell X platform and the Mytos device, which each has the potential to automate a significant part of our manufacturing process. Combined with our in-house bioinformatics capabilities and other enabling technologies, we aim to develop a manufacturing process template that can be replicated to scale out manufacturing to meet potential future demand.

We currently manufacture in-house and contract with Cell X under a Supply Agreement to purchase instruments and with other third parties for consumables.

Mytos Agreement

In September 2024, we entered into a Main Services Agreement and related order forms and schedules (the Mytos Agreement) with Mytos. Under the Mytos Agreement, Mytos supplies us with automated cell culture devices, along with related software licensing and associated services. We use the Mytos iDEM Triple device and the iDEM platform in Stage 3 of our manufacturing process for sasineprocel to automate key cell culture steps during the differentiation process. Mytos provides cloud-based software to operate the device, installation services, and additional development services to validate the device for compatibility with our manufacturing requirements.

Under our order form with Mytos, we may purchase Mytos iDEM Triple devices at a purchase price in the low hundreds of thousands of dollars, per device. The Mytos Agreement also contemplates various installation fees in a range of tens of thousands of dollars, depending on the number of devices. The Mytos Agreement further provides us with a license to the basic tier software required to operate the device, which is provided at no additional charge for so long as we own the device.

We retain all right, title, and interest in and to all data, protocols, and outputs arising from our use of the Mytos iDEM Triple device and related software. Mytos retains all intellectual property rights in the device, software, and services, including any improvements arising from our use thereof. We have granted Mytos a limited license to use our data and outputs for the purpose of providing the goods, software, and services to us in accordance with the Mytos Agreement and for developing improvements to the Mytos iDEM Triple device and/or software during the term of the agreement.

The Mytos Agreement has an initial term of two years from the effective date and automatically renews for successive one-year periods unless terminated. We may terminate the agreement for convenience upon 30 days' prior written notice, subject to payment of any authorized costs and expenses incurred and de-installation fees. Either party may also terminate the agreement for (i) material breach (subject to a 30-day cure period for remediable breaches), (ii) non-payment that remains outstanding more than 30 days after written notice, or (iii) if the other party suspends or ceases its business or suffers an insolvency event. In addition, Mytos may terminate the agreement immediately if there is a change of control of the Company that results in us being held by a direct competitor of Mytos as defined in the Mytos Agreement.

We are responsible for all risk and liability arising from reliance on the outputs of the device. We may not sell the device to any third party without Mytos' prior written consent. We paid Mytos $1.5 million and $0.2 million during the years ended December 31, 2025 and 2024, respectively. We paid Mytos $1.3 million and $0.7 million during the six months ended June 30, 2026 and 2025, respectively.

We rely on third parties for certain materials and components for sasineprocel and other product candidates.

ClearPoint MSA

In January 2022, we entered into a Master Supply Agreement (the ClearPoint MSA) with ClearPoint Neuro, Inc. (ClearPoint). Under the ClearPoint MSA, ClearPoint manufactures and supplies us with specialized neurosurgical products, including its SmartFlow ventricular cannulas. We use the ClearPoint SmartFlow cannula as part of our drug delivery system for the administration of sasineprocel.

The ClearPoint MSA sets forth the purchase price for the products. ClearPoint invoices us in accordance with the invoice schedule set forth in the applicable purchase order or SOW. The initial term of the ClearPoint MSA ends in January 2027 and will automatically renew for successive one-year periods unless either party provides at least 180 days' written notice of its intent not to renew prior to the expiration of the then-current term. In addition, either party may terminate the ClearPoint MSA for material breach of the agreement, subject to a 30-day cure period. The ClearPoint MSA does not provide either party with a right to terminate for convenience during the term. If the ClearPoint MSA is terminated for any reason other than ClearPoint's material breach, we are responsible for any non-cancelable costs or expenses incurred by ClearPoint in connection with third-party obligations under outstanding purchase orders or statements of work.

We are solely responsible for obtaining all regulatory approvals relating to our therapies incorporating ClearPoint products, including the ClearPoint SmartFlow cannula. ClearPoint retains all right, title, and interest in and to the products sold to us pursuant to the ClearPoint MSA and all intellectual property rights related thereto, including sole ownership of any improvements, additions, or variations to the products, whether or not made at our request, except to the extent otherwise set forth in a development agreement with respect to custom products that have been enhanced, improved, or customized by ClearPoint solely for our use. ClearPoint further has the right to sell, offer, license, or otherwise commercialize the products and services covered by the ClearPoint MSA to third-party customers. We paid ClearPoint $0.3 million during each of the years ended December 31, 2025 and 2024. We paid ClearPoint $0.3 million and $0.1 million during the six months ended June 30, 2026 and 2025, respectively.

Manufacturing Stages for iPSCs and Sasineprocel Drug Product

As described above, our production process is performed in three stages. Stage 1 (skin to fibroblast) has a manufacturing duration of approximately three weeks. Stage 2 (fibroblasts to iPSCs) has a duration of approximately eight weeks. Stage 3 (iPSCs to DANPCs) has a duration of approximately five weeks. Following each stage, we complete QC testing which typically takes a total of four to five weeks. Intermediate products (that is, products following Stage 1 and Stage 2) can be conditionally released during QC testing in approximately one to two weeks, which could speed up the overall manufacturing process.

A series of rigorous release assays are performed on the final drug product to assess product quality attributes. These include RNA sequencing based tests to assess identity and maturity (NeuriTest™), engraftment potential (GraftTest), and dopamine release (DopaTest). These bioinformatics-based assessments are informed by preclinical *in vitro* and *in vivo* studies testing different lots from individual PD patient cells, with lots from multiple PD donors evaluated. In addition, an *in vitro* bioassay, DDC activity assay, is performed to measure conversion of L-dopa to dopamine to test cellular functionality and stability of DANPCs after cryopreservation.

Manufacturing Formulations

In our Phase 1/2a ASPIRO trial, we have used two manufactured formulations. In the first two cohorts, PD patients received our dose prep formulation which required processing at a cell processing laboratory, located at or near the dosing site. The dose preparation process was a three to four hour activity and the final formulated product underwent testing for cell count/viability, gram stain, and endotoxin to perform provisional release and enable product administration, while final sterility testing was reported post-surgery. In Cohort 3, four patients received the high dose using our thaw-and-inject formulation, reducing time and cost associated with cell processing and testing steps at the surgical facility. Our thaw-and-inject formulation is designed to eliminate the need for timely processing and testing, allowing for a short (approximately 25 minutes) procedure to thaw the product and load the delivery device for surgery. We developed the thaw-and-inject formulation, which we expect to be our commercial formulation, to enable surgical institutions that do not have cell processing and testing capabilities to use our product candidates, if approved.

The overall manufacturing process for the dose prep formulation and the thaw-and-inject formulation are the same with the exception of the post harvest downstream volume reduction step, the formulation step, the excipients utilized, the fill step, and the final product container. For dose prep formulation, the final cell concentration is 6.7 x 10^6 cells/mL filled at 1.5 mL in a 2mL cryovial whereas for the thaw-and-inject formulation, the final cell concentration is 1.0 x 10^8 cells/mL filled at 0.5mL in a 2mL CellSeal vial.

Table of Contents

The thaw-and-inject formulation of sasineprocel (ANPD001 Suspension) was evaluated in a series of nonclinical studies designed to assess location, engraftment, and safety following direct intracerebral administration. In rodents, a non-GLP engraftment study and a pivotal single-dose GLP toxicity study demonstrated that ANPD001 Suspension was well tolerated and resulted in persistent engraftment of human cells with comparable average graft size and number of mature dopaminergic neurons after three-month in life maturation in a side-by-side evaluation with dose prep formulation (ANPD001 Injectable Suspension) and human cells appeared to remain localized to the target striatal region, with no morphological evidence of migration outside the brain. No adverse effects on clinical observations, body weights, functional assessments, clinical pathology, or macroscopic or microscopic pathology were observed. These studies support the safety of the thaw-and-inject formulation and its suitability for clinical administration without additional dose preparation steps.

Manufacturing Automation

We are developing an automated, robust, modular manufacturing process for sasineprocel that we believe could reduce the manual labor required by more than 90% while still maintaining GMP requirements. Our manufacturing process incorporates automated systems across key steps of cell selection, reprogramming, expansion, differentiation, harvest, and fill and finish.

Automation is intended to reduce manual handling, improve process safety and consistency, and enable parallel processing of multiple patient-specific manufacturing runs within a controlled footprint. We also use automated data capture and analytical tools to support in-process monitoring, quality assessments, and manufacturing decision-making.

We continue to invest in process development and automation to support later-stage clinical development and commercialization. These efforts are designed to improve operational efficiency and scalability while maintaining product quality and regulatory compliance. We have successfully moved from an R&D stage process to a GMP, manual process for the Phase 1/2a ASPIRO trial and are in the process of automating significant portions of the manufacturing process for the planned Phase 3 trial. Prior to the start of manufacturing for our Phase 3 study, we plan to meet with regulatory authorities to align on our CMC plan to support the manufacturing process for the Phase 3 study and potential future commercialization. We expect our automation initiatives, if successful, can be used to scale up manufacturing to meet potential future demand.

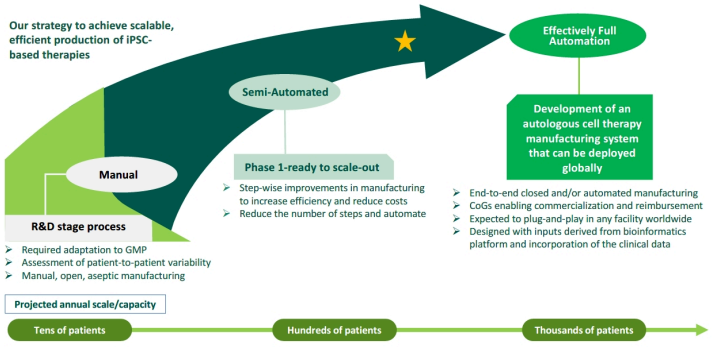


Figure 12. A summary of our plans for autonomous, automated cell manufacturing to support potential future demand.

Sales and Marketing

We are a clinical-stage company and have not yet established a full commercial organization or distribution capabilities. As we advance our product candidates toward potential approval, we intend to build a commercial infrastructure to support the product launch, sale, reimbursement and distribution of any approved products. We will continue to evaluate opportunities to work with strategic partners to enhance our development and commercialization capabilities with respect to sasineprocel and our other product candidates. In addition, we intend to commercialize our product candidates, if approved, in key markets in the United States, the European Union, and Asia Pacific, either alone or with partners to maximize the worldwide commercial potential of our programs.

Competition

The biotechnology industry is characterized by rapid technological advancement, intense competition and a strong emphasis on proprietary and novel products and product candidates. While we believe that our platform, our lead product candidate, sasineprocel, and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including larger and better-funded biotechnology, pharmaceutical, biopharmaceutical, and therapeutics companies. In many cases, companies with competing programs will have access to greater financial, technical, manufacturing, supply, marketing and sales resources, and may be more advanced in those programs. Moreover, we may also compete with universities and other research institutions that may be or will become active in research in our target indications. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Key competitive factors affecting the success of our product candidates, if approved, are likely to be efficacy, safety, convenience, presentation, price and the availability of reimbursement from government and third-party payors. Our competitors 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. We anticipate that we will continue to face increasing competition as new therapies, technologies and data emerge within the field of neurodegenerative disease and, more specifically, for the treatment of PD.

We are developing sasineprocel for the treatment of PD. We expect to compete with commercially available advanced therapies used in patients with motor fluctuations despite optimization of L-dopa, including DBS devices such as Infinity and Liberta RC (both marketed by Abbott), Vercise (marketed by Boston Scientific), and Percept (marketed by Medtronic), as well as Focused Ultrasound (FUS) technologies such as Exablate Neuro (marketed by Insightec). We anticipate that there will continue to be improvements in DBS and FUS technologies.

We are aware of cell and gene therapy candidates in clinical development that target sporadic, genetic, or all forms of PD. This includes autologous cell therapies in development by Hope Bio, Oryon, and others; allogeneic therapies from BlueRock/Bayer, Sumitomo (AMCHEPRY, approved in Japan), Cellular Intelligence, Kenai Therapeutics, iRegene, S.Biomedics, Xellsmart and others; and gene therapies from AskBio/Bayer, MeiraGTx, Prevail Therapeutics, and other earlier-stage competitors.

We are also developing autologous microglia cell replacement therapies for a number of leukodystrophies. In this area, we expect to compete with commercially available therapies such as bone marrow transplant and Skysona (Genetix Biotherapeutics). We are also aware of small molecules, antibodies, and advanced therapies that are in development for leukodystrophies including a PPARg agonist in development by Minoryx Therapeutics, a thyroid receptor-b agonist in development by Viking Therapeutics, and an AMPK activator and a deuterium-modified thiazolidinedione both in development by Poxel SA and other earlier-stage competitors.

Intellectual Property

We strive to protect the intellectual property and proprietary technology that we consider important to our business through a variety of methods. We seek to obtain domestic and international patent protection and endeavor to file patent applications for new commercially valuable inventions as they arise to expand our intellectual property

portfolio. We also rely on proprietary know-how and trade secrets to protect certain innovations that may be important to our business and to benefit from their confidential status.

As of October 2026, our patent portfolio included five granted U.S. patents, 15 granted international patents, and approximately 69 pending patent applications across 16 patent families, including the seven families identified in more detail below. Our granted international patents are held in the following jurisdictions: the United Arab Emirates, Australia, the European Patent Convention (validated in Switzerland, Spain, Great Britain, Ireland, Turkey, and the Unitary Patent territory), Hong Kong, Israel, Japan, Mexico, and Saudi Arabia. We also have pending international patent applications in the United Arab Emirates, Australia, the European Patent Convention, Hong Kong, Israel, Japan, Mexico, Saudi Arabia, Brazil, Canada, China, India, Singapore, South Korea, and before the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty. Our patent applications, if granted, are designed to provide protection for sasineprocel and our platform technologies, including:

- Claims relating to DANPCs and cell compositions comprising such cells
- Methods for differentiating DANPCs from stem cells
- Assays and analytical methods for identifying and characterizing iPSCs and neuronal progenitor cells
- Potency assays and other functional assays for assessing functional characteristics of cell therapy products
- Automated manufacturing systems and methods
- Delivery devices for stereotactic implantation of cell suspensions
- Methods for treating genetically-linked PD

DANPC Manufacturing, Differentiation and Resulting Compositions, Including Sasineprocel

We own four patent families relating to manufacturing processes for producing DANPCs from stem cells, including computer-implemented methods and systems for identifying and isolating iPSCs and automated methods of manufacturing DANPCs from stem cells, DANPC compositions produced by the methods, DANPC compositions characterized by specific attributes, and methods of using the DANPCs to treat disease.

These patent families include granted patents in the United States and foreign jurisdictions. These patent families also include pending Patent Cooperation Treaty (PCT) applications, pending United States patent applications, and pending patent applications in foreign jurisdictions. One of these patents will expire in 2030. The other patents, and if issued these patent applications, will expire from 2041-2046, without taking into account any possible patent term adjustment or extension and assuming payment of all applicable maintenance, renewal, annuity or other governmental fees.

In addition to patent protection, we also rely in part on trade secret protection and confidentiality agreements to protect certain proprietary know-how and other aspects of our manufacturing processes, including process parameters and methods that may not be suitable for patent protection. We seek to protect these trade secrets and proprietary information, in part, through confidentiality provisions in agreements with employees, consultants, contractors and other third parties, as well as through other internal security measures. However, trade secrets may be difficult to protect, and we may not be able to prevent the unauthorized disclosure or use of our proprietary information.

Quality Control and Potency Assays

We have developed a suite of assays designed to identify and characterize cells at various stages of our manufacturing process and to assess functional characteristics of the final cell product. These assays are intended to support in-process monitoring and/or release testing for our product candidates, including sasineprocel.

Our assay suite includes:

- **GraftTest:** An assay for predicting engraftment capability of differentiated neuronal cell products (covered by issued patents and pending applications)
- **NeuriTest:** Gene expression-based assays for identifying neuronal progenitor cells, including methods for classifying differentiation state (patent applications pending in the United States and internationally)
- **DopaTest:** An assay for predicting dopamine production capability of differentiated neuronal cells (covered by issued patents and pending applications)
- **DDC Potency Assay:** An assay measuring L-dopa decarboxylase activity and related potency assessment frameworks (covered by pending applications)

Regulatory authorities, including the FDA, generally expect developers of cell therapy products to establish potency assays and other analytical methods that are relevant to the product's biological activity. We believe these assays and related quality control measures are important to support development and, if approved, commercial manufacturing of our product candidates.

Patent Coverage for Quality Control and Potency Assays. Certain of the patent families described below include claims that may support one or more of the assays described above, among other applications.

We own four patent families related to assays and analytical methods designed to identify, classify and characterize DANPCs and other cells differentiated from stem cells. The patent families are directed to assays and analytical approaches for assessing neuronal differentiation at various stages of our manufacturing process, and for assessing functional characteristics of the final cell product, such as engraftment capability, dopamine-related functional properties, and other activities or functions related to biological activity and potency. The assays and analytical methods include assays that use gene expression-based and related approaches and may be used in quality control, comparability analyses and other analytical characterization.

These patent families include two granted patents in the United States. These patent families also include pending PCT applications, pending United States patent applications, and pending patent applications in foreign jurisdictions. The remaining patents, and, if issued, the currently pending patent applications, will expire in 2044-2045, without taking into account any possible patent term adjustment or extension and assuming payment of all applicable maintenance, renewal, annuity or other governmental fees.

Additional Programs and Supporting Technologies

We own one patent family that includes one pending U.S. nonprovisional patent application and a pending PCT application directed to methods of treating PD associated with mutations in the GBA1 gene using non-genetically modified DANPCs, including autologous cell therapy approaches. If patents that issue from applications claiming priority to these applications are obtained, they are expected to expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all applicable maintenance, renewal, annuity or other governmental fees.

We own one patent family that includes one pending U.S. nonprovisional patent application and a pending PCT application directed, among other things, to methods and technologies related to microglia-based cell therapy products, including approaches that may be applicable to the treatment of X-linked adrenoleukodystrophy (X-ALD). If patents that issue from applications claiming priority to these patent applications are obtained, they are expected to expire in 2046, without taking into account any possible patent term adjustment or extension and assuming payment of all applicable maintenance, renewal, annuity or other governmental fees.

Scope and Duration of Intellectual Property Protection

Regulatory Exclusivity

In addition to patent protection, we may be eligible for regulatory exclusivity for sasineprocel under the BPCIA, which provides 12 years of exclusivity for approved biological products in the United States, and similar regulatory frameworks in other jurisdictions.

Uncertainties and Limitations of Patent Protection

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. There is significant uncertainty regarding the scope of patent claims that may be allowed or enforced in the field of cell replacement therapy in the United States and other jurisdictions. The actual protection afforded by our patents will depend on several factors, including:

- The scope of claims allowed by patent offices during prosecution
- Our ability to enforce our patents against potential infringement
- The validity and enforceability of our patents if challenged
- The development of alternative technologies by competitors that do not infringe our patents
- Our ability to maintain our patents by paying maintenance fees and complying with other requirements

We cannot be sure that patents will be granted with respect to any of our pending patent applications, nor can we be sure that any patents granted to us will be commercially useful in protecting our product candidates and manufacturing methods. Changes in patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the U.S. and other countries, may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property.

Third parties may have blocking patents that could prevent us from commercializing our product candidates and practicing our proprietary technology. Our patents may be challenged, narrowed, circumvented, or invalidated, which could limit our ability to stop competitors from marketing related product candidates. In addition, our competitors may independently develop similar technologies, and the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Moreover, because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that before any product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any protection afforded by the patent.

We continually assess and refine our intellectual property strategy as we develop new product candidates and are prepared to file additional patent applications as appropriate to support our strategy or to adapt to competition or seize business opportunities.

For additional information on the risks associated with our intellectual property strategy and portfolio, please see "Risk Factors—Risks Related to Our Intellectual Property."

Licensing and Collaboration Agreements

Our patent portfolio includes both internally developed intellectual property and technology licensed from third parties. We have obtained licenses to key foundational technologies important to support the manufacturing process for sasineprocel, including:

- iPS Academia Japan, Inc.: Methods for reprogramming differentiated cells into iPSCs using the Yamanaka factors. The licensed patents include six patent families covering iPSC cell reprogramming technologies, with issued patents and pending applications in the United States, Japan, and numerous other jurisdictions worldwide, including Australia, Canada, China, Europe, India, Israel, Korea, Mexico, Singapore, and others. This license is non-exclusive, non-transferable, and requires payment of an upfront

fee, annual maintenance fees, milestone payments upon achievement of specified regulatory and commercial milestones, and royalties in the low single digits on net sales of licensed products.

- Sumitomo Pharma Co. Ltd: Use of Sendai viral vectors encoding the Yamanaka factors for reprogramming differentiated cells into iPSCs. The licensed patents include five issued U.S. patents directed to methods of producing iPSCs using Sendai virus vectors, together with corresponding foreign patents and applications. This license is a non-exclusive sublicense of rights originally granted by ID Pharma Co., Ltd. to Sumitomo, and requires payment of annual license fees, milestone payments upon achievement of specified sales thresholds, and royalties in the low single digits on net sales of licensed products. In connection with the Organizational Split, Sumitomo's rights and obligations under the Sumitomo License Agreement were assigned to and/or succeeded by RACTHERA Co., Ltd., with our prior consent.
- The Scripps Research Institute (TSRI): Methods for differentiating DA neurons from iPSCs and bioinformatics assays for characterizing neuronal cell types. There are no patents currently associated with this license. This license requires payment of royalties in the low single digits on net sales of licensed products.
- Cell X Technologies, Inc. and the Cleveland Clinic Foundation: Systems and methods for automated detection, analysis, isolation, and harvesting of biological objects, including iPSCs, as well as related image analysis technologies. The licensed patents include four issued U.S. patents and a pending European patent application directed to automated cell culture systems and machine vision-based cell selection. The licenses are exclusive within the licensed field and territory. The licenses require milestone payments upon achievement of specified development and regulatory milestones but do not require sales-based royalty payments.

For additional information related to these licenses, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments." These licenses impose various financial obligations on us, including upfront fees, annual maintenance fees, milestone payments, and royalties. Our license agreements are also generally subject to customary termination provisions, including termination for breach in certain circumstances. Our failure to comply with the terms of these licenses could result in termination of the licenses and loss of our rights to use the licensed technologies, which would materially harm our business. For additional information regarding risks related to our licensed intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Trademarks

We seek trademark protection in the United States and in certain other jurisdictions where available and when we deem appropriate. We currently have registrations for our "Aspen Neuroscience" and the leaf logo. For additional information on the risks associated with our trademark strategy and portfolio, please see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Cell therapy products are regulated as biological products and must be approved by the FDA through the BLA process, also referred to as licensure, before they may be legally marketed in the United States.

U.S. Biological Product Development Process

In the United States, the FDA regulates biological products, including cell therapy products, under the Federal Food, Drug, and Cosmetic Act (FDCA), and the Public Health Service Act (PHSA) and their implementing regulations. The process of obtaining regulatory approvals and subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. The process

required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies, where applicable and in accordance with GLPs and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB or EC for each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to evaluate the safety, purity and potency of the product candidate for its intended use;
- submission to the FDA of a BLA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the product's continued safety, potency and purity;
- satisfactory completion of potential FDA inspections of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Once a biological product candidate is identified for development, and before testing in humans, it enters the preclinical testing stage. Preclinical tests may include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Results of these preclinical tests, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a full or partial clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin or begin as proposed. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and in such case, the trials may not begin or continue as planned until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the trial until completed and otherwise comply with IRB regulations. The FDA or sponsor may suspend a clinical trial at any

Table of Contents

time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries, including clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of 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 product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional information about the product in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Concurrently with clinical trials, companies may complete additional animal studies and develop additional information about the product characteristics and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, 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.

U.S. Review and Approval Process

The results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product. To support marketing approval, the data submitted must sufficiently establish the safety, purity and potency of the investigational product to the satisfaction of the FDA. The submission of a BLA is subject to the payment of substantial user fees. A waiver of such fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of a submitted BLA within the first 60 days after submission, before accepting the application for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a BLA for filing. In this event, the BLA must be resubmitted with additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent for its intended use and whether the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the Prescription Drug User Fee Act (PDUFA), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" to complete a standard review of an original BLA and act on the submission. This review typically takes twelve months from the date the BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel biological product to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. For cell therapy products, these inspections are particularly rigorous given the complexity of cell therapy manufacturing and the unique requirements for facilities handling living cellular products. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

After the FDA evaluates a BLA and conducts any required inspections of manufacturing facilities where the investigational product and/or its starting materials will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the biological product with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor may resubmit the BLA addressing all the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a biological product's safety and effectiveness after BLA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approval, including the requirement for a REMS, to ensure safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most biological products, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the biological product is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA may send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation.

Regulation of Combination Products

Certain products are comprised of components, such as biologic components and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a biologic-device combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. This office, among other things, serves as a focal point for combination product issues for FDA reviewers and industry and is responsible for assignment of the

FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the biological component generally would be reviewed and approved pursuant to the approval processes set forth in the FDCA and PHSA. In reviewing the BLA for such a product, however, FDA reviewers would consult with their counterparts in FDA's medical device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality Management System Regulation applicable to medical devices.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product 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, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug or biologic product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same biological product for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity within the relevant indication or use, or inability to manufacture the product in sufficient quantities to meet the needs relating to the indication or use of patients with the applicable disease or condition. The designation of such product also entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. However, competitors may receive approval of different products for the indication or use for which the orphan product has exclusivity or obtain approval for the same product but for a different indication or use for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years within the exclusivity-protected indication or use if a competitor obtains approval of the "same drug," as defined by the FDA, or if a product candidate is determined to be contained within the competitor's product for the same indication or use. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited Development and Review Programs

The FDA has several programs intended to expedite the development or review of a marketing application for an investigational biological product. For example, the fast-track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational biological products are eligible for fast-track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast-track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. With regard to a Fast Track product candidate, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast-track program features, as well as more intensive FDA

interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Under the 21st Century Cures Act, the FDA established the RMAT designation program for regenerative medicine therapies, including cell therapies. RMAT designation is granted to regenerative medicine therapies, which are generally defined to include cell therapies, therapeutic tissue engineering products, human cell and tissue products, or any combination product using such therapies or products, that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and that have preliminary clinical evidence indicating that the therapy has the potential to address unmet medical needs for such disease or condition. Benefits of RMAT designation include all the benefits of Fast Track and breakthrough therapy designation, including early interactions with FDA to discuss surrogate or intermediate endpoints for accelerated approval, potential eligibility for priority review and accelerated approval, and increased FDA engagement and guidance during development.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast-track designation, RMAT designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A BLA is eligible for priority review if the product candidate is designed to treat a serious condition and, if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a BLA designated for priority review to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity BLAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Biological products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate 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 approval, the FDA generally requires that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials and may require that such confirmatory trials be underway prior to granting accelerated approval. Biological products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, breakthrough therapy designation, RMAT designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money, and effort in production and quality control to maintain compliance with cGMPs 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 requirements for 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 the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising, and promotion of biological products. A company can make only those claims relating to safety, purity, potency and efficacy 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 communication about off-label use of their products.

Biosimilars and Reference Product Exclusivity

The BPCIA established an abbreviated pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. Biosimilarity requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, which can be shown through analytical studies, animal studies, and clinical studies. Interchangeability requires that a product be biosimilar to the reference product and 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. Under the BPCIA, a reference product sponsor may be granted twelve years of exclusivity from the time of first licensure of the reference product. During this twelve-year period of exclusivity, the FDA may not approve a biosimilar product that relies on the reference product and FDA's previous determination of safety and effectiveness for the reference product for licensure. However, this exclusivity does not prevent the FDA from approving a full BLA for a biological product that is independently shown to be safe, pure, and potent through that applicant's own preclinical data and data from adequate and well-controlled clinical trials.

Table of Contents

A biological product can also obtain pediatric market exclusivity in the United States for biological products. Pediatric exclusivity for biological products, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare laws and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and physician payment transparency requirements regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals as well as similar foreign laws in the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs, suspension and debarment from federal contract and/ or imprisonment.

Coverage and Reimbursement

Successful sales of our products in the U.S. market, if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions, and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, such as price controls, restrictions on reimbursement, requirements for substitution of generic drugs, and the use of step therapy policies where third-party payors first require the use of lower-cost drugs before covering more expensive drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor not to cover our drug candidates could have a material adverse effect on our sales, results of operations, and financial condition.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the U.S., we may be subject to spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs and/or any significant taxes or fees.

U.S. Healthcare Reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, such as price-controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, and use of step therapy policies.

Table of Contents

For example, the ACA was enacted in the United States and made significant changes to federal programs and tax policies regarding healthcare, including changes affecting insurance coverage, affordability and accessibility of insurance, the financing of medical care, the operation of Medicare program. The ACA contains provisions that may reduce the profitability of drug products. Among other things, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, in the absence of legislative changes, the ACA will remain in force in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government reimbursement methodologies for products. On August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; requires manufacturers to pay rebates to HHS if certain Medicare Part B- and Medicare Part D-covered drugs have price increases above an allowable rate of inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which became effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to price negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

The Trump administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate for which we obtain marketing approval. On the one hand, President Trump threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers entered into confidential pricing agreements with the federal government. Subsequently, in April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. On the other hand, the Trump administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by

Table of Contents

Medicare, with the rebate amount based on international reference pricing for the drugs from economically comparable companies. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. In 2026, the U.S. government also launched TrumpRx, a federal initiative to enable patients to gain access to certain prescription drugs or biologics at reduced costs based on pricing available in other countries (i.e., most-favored-nation pricing). Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Existing healthcare reform measures, as well as the implementation of additional cost containment measures or other reforms and initiatives, may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including laws specifically focused on consumer health information that is outside of the scope of HIPAA, and consumer data protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions (including class actions) that lead to significant civil and/or criminal penalties, settlements, and restrictions on data processing.

Employees

Our people are critical to our success and to our ability to execute our strategy and achieve our corporate objectives. As of June 30, 2026, we had 120 full-time employees, including a total of 28 employees with M.D. or Ph.D. degrees. Of these full-time employees, 88 employees are engaged in research and development and 32 are engaged in finance, legal, business development, and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, developing, retaining, incentivizing, and integrating our existing and new employees. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. It is important that we not only attract and retain the best and brightest talent, but also ensure they remain engaged and can thrive in an environment that is committed to helping them grow, succeed and contribute directly to achieving our mission. The principal purposes of our equity incentive plans are to attract, retain, and motivate employees, directors, and selected consultants through the granting of stock-based compensation awards. We value our employees and regularly benchmark total rewards we provide, such as short and long-term compensation, 401(k) contributions, health, welfare, and quality of life benefits, paid time off, and personal leave, against our industry peers to ensure we remain competitive and attractive to potential new hires. We also strive to foster career growth and internal mobility by providing a broad range of training, mentoring and other development opportunities.

We are committed to an intentional, values-based culture grounded in scientific rigor, collaboration, integrity, and a patient-first mindset. We believe this culture supports our ability to attract, develop, and retain the talent necessary to advance our pipeline and operate our business effectively. We strive to foster an inclusive, and safe workplace where employees are encouraged to contribute ideas, collaborate across functions, and connect their work to our shared mission of positively impacting the lives of patients. We believe these practices help us attract and retain the highly skilled and motivated workforce required to deliver on our objectives.

Facilities

Our corporate headquarters are currently located in San Diego, California, where we lease approximately 31,000 square feet of laboratory and office space. This lease commenced in 2019 for an initial term of three years and was subsequently extended in 2021 for an additional term of six years. In August 2026, we entered into the New Lease for approximately 49,000 square feet of laboratory and office space to replace our corporate headquarters upon expiration of that lease. The New Lease commences in July 2027 for an initial term of ninety-three months. In addition, our clinical manufacturing site is also located in San Diego, where we lease approximately 22,000 square feet of GMP manufacturing, warehouse, QC laboratory, and office space, pursuant to a lease agreement that expires on July 31, 2032. We believe that our existing facilities are adequate for our current needs and that our future facilities will be suitable for our needs at that time.

Legal Proceedings

We are not currently a party to any material proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors.

Table of Contents

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age, and position of each of our executive officers and directors as of September 30, 2026.

Name	Age	Position(s)
Executive Officers		
Damien McDevitt, Ph.D.	59	President, Chief Executive Officer and Director
Faheem Hasnain	68	Executive Chairman
Dalen Meeter	48	Chief Financial Officer
Lisa Johnson-Pratt, M.D.	62	Sasineprocel Development Lead and Chief Commercial Officer
Kim Raineri	53	Chief Technology Officer
Jeffrey Boerneke	40	General Counsel and Secretary
Non-Employee Directors		
Thomas Daniel, M.D.	73	Director
Douglas Fisher, M.D.	50	Director
Cindy Perettie	61	Director
Caryn Peterson	67	Director
Andrew Spaventa	42	Director
Peter A. Thompson, M.D.	67	Director

The following are brief biographies describing the backgrounds of our executive officers and directors.

Executive Officers

Damien McDevitt, Ph.D. Dr. McDevitt has served as our Chief Executive Officer and on our board of directors since January 2021. Prior to joining Aspen, Dr. McDevitt was at Akcea Therapeutics, Inc., a publicly-held rare diseases biotechnology company, where he served as Chief Executive Officer from September 2019 through its acquisition by Ionis Pharmaceuticals, a biotechnology company, in October 2020, and as a member of the board of directors from October 2018 through its acquisition by Ionis Pharmaceuticals. He has also served in senior executive roles at Ionis Pharmaceuticals, Acadia Pharmaceuticals, a biopharmaceutical company and GlaxoSmithKline Pharmaceuticals, a pharmaceutical and biotechnology company. Dr. McDevitt earned his B.A. and Ph.D. at Trinity College Dublin, Ireland, and completed a post-doctoral research fellowship at the Institute of Biosciences and Technology, Texas A&M.

We believe that Dr. McDevitt is qualified to serve on our board of directors because of his experience as our Chief Executive Officer, industry knowledge and previous experience at biotechnology companies.

Faheem Hasnain. Mr. Hasnain has served as a member and chairman of our board of directors since April 2020 and as our Executive Chairman since August 2026. Mr. Hasnain has served as chairman of the board of directors of Gossamer Bio, Inc., a publicly-held biopharmaceutical company, since 2018 and as Chief Executive Officer since November 2020 and previously served as Chief Executive Officer in 2018. In addition, Mr. Hasnain has served as a member of the board of directors of Kura Oncology, Inc., a publicly-held biopharmaceutical company, since April 2015. Previously, Mr. Hasnain was the President, Chief Executive Officer and on the board of directors of Receptos, Inc., a publicly-held biopharmaceutical company, from 2010 until the company's acquisition by Celgene Corporation in 2015. Prior to that, Mr. Hasnain was the President and Chief Executive Officer and a director of Facet Biotech Corporation, a publicly-held biology driven antibody company with a focus in multiple sclerosis and oncology. He held that position from 2008 until the company's acquisition by Abbott Laboratories in 2010. Previously, Mr. Hasnain was President, Chief Executive Officer and a director of PDL BioPharma, Inc. (PDL BioPharma), a publicly-held biopharmaceutical company, from 2008 until Facet Biotech was spun off from PDL BioPharma in 2008. From 2004 to 2008, Mr. Hasnain served at Biogen Inc. (Biogen), a publicly-held biotechnology company specializing in neurological disorders, autoimmune disorders and cancer, most recently as Executive Vice President in charge of the oncology/rheumatology strategic business unit. Prior to Biogen, Mr. Hasnain held roles with Bristol Myers Squibb Co., where he was President of the Oncology Therapeutics Network, and at GlaxoSmithKline plc and its predecessor organizations. He was chairman of the board of directors of Panacea Acquisition Corp., a newly incorporated special

purpose acquisition company, from May 2020 through February 2021, and Mirati Therapeutics, Inc., a publicly-held biotechnology company, from 2019 to January 2024. Mr. Hasnain received a B.H.K. and B.Ed. from the University of Windsor Ontario in Canada.

We believe that Mr. Hasnain is qualified to serve as our Executive Chairman and on our board of directors because of his extensive experience as a member of senior management and boards of directors of multiple biopharmaceutical companies as well as his experience building and operating biopharmaceutical companies, strategic partnering and capital raising and investor relations in the biopharmaceutical industry.

Dalen Meeter. Mr. Meeter has served as our Chief Financial Officer since March 2025. Prior to Aspen, Mr. Meeter was at Singular Genomics, at the time a publicly-held next-generation sequencing and spatial multiomics technologies company, where he served as the Chief Financial Officer from October 2022 through its acquisition in a take-private transaction in February 2025, Senior Vice President of Finance from May 2021 to October 2022 and Vice President of Finance from December 2019 to May 2021. Before joining Singular, Mr. Meeter worked in finance leadership at Illumina, Inc., a life science tools company and as an auditor at KPMG. He has also held leadership positions at Websense, Inc., a software company, and Captiva Software, a software company. Mr. Meeter is a certified public accountant and earned his undergraduate degree from the University of California, Santa Barbara, and his MBA from the University of Southern California's Marshall School of Business.

Lisa Johnson-Pratt, M.D. Dr. Johnson-Pratt has served as our Sasineprocel Development Lead and Chief Commercial Officer since January 2026 and previously served as our Executive Vice President, Therapeutic Program Lead from October 2024 to January 2026, our Senior Vice President, Therapeutic Program Lead from January 2024 to October 2024, and our Senior Strategic Advisor from September 2021 to October 2024. Also, since September 2019, Dr. Johnson-Pratt has served as a founder, and since June 2020, as Biotechnology, Cell and Gene Therapy Strategic Commercial Advisor, of Ananias Ventures, where she provides strategic advisory services to the biotechnology healthcare sector. Prior to joining Aspen, Dr. Johnson-Pratt served in various roles including as Senior Vice President at Ionis Pharmaceuticals, Inc., a biotechnology company, from November 2020 to May 2022. Prior to Ionis Pharmaceuticals, Inc., Dr. Johnson-Pratt served as Senior Vice President of Akcea Therapeutics, Inc., a biotechnology company. In addition, Dr. Johnson-Pratt has also held various positions of increasing scope, including Vice President of Global Franchise Operations, at GSK, a biopharmaceutical company and prior to GSK, Dr. Johnson-Pratt held various positions of increasing scope at Merck, a biopharmaceutical company, including serving as the Global Dermatology Portfolio Leader. Dr. Johnson-Pratt served on the board of TRACON Pharmaceuticals, then a publicly-held company, from March 2021 to September 2024. Dr. Johnson-Pratt currently serves on the board of Assembly Biosciences, Inc., a biopharmaceutical company where she was first elected to the board in May 2021. Dr. Johnson-Pratt received her B.S. and M.D. from Howard University, with further post-doctoral training in Internal Medicine, Clinical Pharmacology and Pharmaceutical Medicine.

Kim Raineri. Mr. Raineri has served as our Chief Technology Officer since July 2022. Prior to joining Aspen, Mr. Raineri served as Chief Manufacturing and Technology Officer and a member of the executive team at Tectonic Therapeutic, Inc. (formerly, AVROBIO, Inc.), a biotechnology company, from June 2020 to July 2022. Prior to that, Mr. Raineri was Vice President of Operations for Nikon CeLL innovation Co., Ltd, a Japanese contract development and manufacturing organization and he held management positions at Lonza, a healthcare manufacturing organization as well as CryoLife Inc, a medical device company. Mr. Raineri earned his B.S. from the University of Miami and his MBA from Kennesaw State University.

Jeffrey Boerneke. Mr. Boerneke has served as our General Counsel and Secretary since May 2026. Prior to joining Aspen, Mr. Boerneke served as Senior Vice President, General Counsel and Secretary from February 2022 to April 2026, at Gossamer Bio, Inc., a publicly-held biopharmaceutical company, where he played a key role in the company's initial public offering and strategic global partnership activities. Mr. Boerneke previously served as Corporate Counsel at Amgen Inc., a publicly-held biopharmaceutical company. He began his career as an associate in the corporate group at Latham & Watkins LLP. Mr. Boerneke holds a J.D. from UCLA School of Law and a B.S. in Chemistry from Point Loma Nazarene University.

Table of Contents

Non-Employee Directors

Thomas Daniel, M.D. Dr. Daniel has served on our board of directors since March 2020. Recently, he served as a Venture Partner at ARCH Venture Partners, a venture capital firm, from October 2016 through June 2021. Dr. Daniel currently serves as Chairman of Gate Bioscience, which he joined in June 2022. Dr. Daniel was previously at Celgene Corporation, a pharmaceutical company, where he served as Chairman of Research from January 2016 until June 2016, President of Research and Early Development from December 2006 to January 2016, and Executive Vice President and President of Research and Early Development from February 2012 until January 2016. Prior to joining Celgene Corporation, Dr. Daniel served as the Chief Scientific Officer and director at Ambrx, Inc., a biopharmaceutical company. Prior to Ambrx, Inc., Dr. Daniel served as Vice President of Research at Amgen Inc., a biopharmaceutical company, where he was research site head of Amgen Washington and therapeutic area head of inflammation. Dr. Daniel also served as the Senior Vice President of Discovery Research at Immunex Corporation, a biopharmaceutical company, until its acquisition by Amgen. Since 2017, Dr. Daniel has served as a director at Vividion Therapeutics, a biopharmaceutical company that was previously publicly-held. Dr. Daniel has also served on the board of Gossamer Bio, a biopharmaceutical company, since January 2018. Dr. Daniel serves as a member of the Biomedical Science Advisory Board of Vanderbilt University Medical Center and chairs the Board of Overseers for The Scripps Research Institute. He also serves as senior advisor to several private biotechnology companies. Previously, Dr. Daniel served as a member of the board of directors of VIR Biotechnology, a biotechnology company, from January 2017 to August 2019 and Larimar Therapeutics, a biotechnology company, from March 2016 to May 2022. A nephrologist and former academic investigator, he was previously C.M. Hakim Professor of Medicine and Cell Biology at Vanderbilt University. Dr. Daniel received his M.D. from the University of Texas, Southwestern, trained in molecular genetics at UTSW, and completed his residency in Internal Medicine at Massachusetts General Hospital.

We believe that Dr. Daniel is qualified to serve on our board of directors because of his extensive experience as a member of senior management and boards of directors of multiple biopharmaceutical companies as well as his significant academic and research experience.

Douglas Fisher, M.D. Dr. Fisher has served on our board of directors since March 2022. Dr. Fisher is currently a Partner at Revelation Partners, LLC, a venture capital firm, where he has worked since March 2020. Prior to joining Revelation, Dr. Fisher was a Partner and Executive-In-Residence at InterWest Partners LLC (InterWest), a private equity firm, where he focused on biopharma, diagnostics, and medical device investing. While at InterWest, Dr. Fisher also served as the Chief Business Officer of Sera Prognostics, Inc., a diagnostics company. Dr. Fisher previously served on the board of Precipio, Inc., a biotechnology company, from September 2017 through January 2024 and Obalon Therapeutics, Inc., a medical technology company, from May 2012 through June 2021. Dr. Fisher received an A.B. in economics with honors and distinction, and a B.S. in biology with distinction, from Stanford, where he graduated Phi Beta Kappa. He holds an M.D. from the University of Pennsylvania School of Medicine and an M.B.A. from The Wharton School of the University of Pennsylvania, where he graduated with honors as a Siebel Scholar and Palmer Scholar.

We believe that Dr. Fisher is qualified to serve on our board of directors because of his substantial experience as a venture capitalist and as a director of publicly traded and privately held companies.

Cindy Perettie. Ms. Perettie has served on our board of directors since October 2025. Ms. Perettie has also served as the Executive Vice President and Global Head of Kite Pharma, a biotechnology company and subsidiary of Gilead Sciences, where she is responsible for overseeing the cell therapy business since 2023. From 2021 to 2023, she served as Head of Roche Molecular Lab Diagnostic Solutions at Roche, a pharmaceuticals and diagnostics company, where she oversaw the PCR (polymerase chain reaction) and Sequencing Business. Prior to that, she served as the Chief Executive Officer at Foundation Medicine, a precision medicine company, from 2019 to 2021. Before joining Foundation Medicine, Ms. Perettie was Head of Global Oncology Strategy at Roche's Oncology Unit. In 2012, Ms. Perettie joined Sarah Cannon Research Institute as President of Global Development Innovations. Ms. Perettie started her career at Johns Hopkins University as a senior research associate. Ms. Perettie holds an M.B.A. from Saint Mary's College of California and a bachelor's degree in biology with a minor in chemistry from The State University of New York at Potsdam.

We believe that Ms. Perettie is qualified to serve on our board of directors because of her extensive operational experience as a member of senior management at biotechnology companies and industry knowledge.

Table of Contents

Caryn Peterson. Ms. Peterson has served on our board of directors since May 2021. In addition, Ms. Peterson currently serves as Chief Development Officer at Gossamer Bio, a biopharmaceutical company since May 2026, and previously served as Executive Vice President, Regulatory Affairs from April 2021 to May 2026 and Senior Vice President, Regulatory & Quality from April 2018 to April 2021. Previously, Ms. Peterson served as Managing Partner of Development & Strategic Consulting (DSC) Associates, LLC, a consulting services company, focusing on the development, integration, and implementation of global clinical and regulatory strategy across a broad range of therapeutic areas. From 2008 to 2018, Ms. Peterson also served as Vice President, Regulatory Affairs at Syndax Pharmaceuticals, Inc., a biopharmaceutical company. From 1997 to 2004, Ms. Peterson served as Vice President of Regulatory Affairs at FeRx Incorporated, a drug delivery company, and from 1989 to 1997, Ms. Peterson held managerial positions in both Pharmaceutical Development and Regulatory Affairs at Amylin Pharmaceuticals, a biopharmaceutical company. Prior to joining Amylin, Ms. Peterson was a staff scientist at Hybritech Incorporated, a biotechnology company, from 1981 to 1989. Ms. Peterson has coauthored several research publications and is a co-inventor on multiple patent applications.

We believe that Ms. Peterson is qualified to serve on our board of directors because of her extensive senior leadership experience and particularly her regulatory experience.

Andrew Spaventa. Mr. Spaventa has served on our board of directors since June 2020. Mr. Spaventa was founder, Chief Executive Officer, and Chairman of the board of directors of Singular from October 2017 through February 2025. Mr. Spaventa has served as Managing Partner at Axon Ventures, a venture capital firm focused on healthcare, since March 2014. Mr. Spaventa is a founder of Truvian Sciences. He received his Master's degree in Business Administration and Finance from the University of California, San Diego – Rady School of Management. He also attended University of California San Diego where he obtained his Bachelor's degree in Political Science and International Relations.

We believe that Mr. Spaventa is qualified to serve on our board of directors because of his experience as a venture capital investor, his professional experience in the life science and genomics space and his extensive understanding of our business, operations and strategy.

Peter A. Thompson, M.D. Dr. Thompson has served as a member of our board of directors since March 2020. Dr. Thompson is a Partner at OrbiMed Advisors LLC, an investment firm, where he has served in various roles of increasing responsibility since 2010. Dr. Thompson currently serves on the boards of directors of ARS Pharmaceuticals, Inc. (formerly Silverback Therapeutics, Inc.), a biopharmaceutical company, Corvus Pharmaceuticals, Inc., a biopharmaceutical company, Edgewise Therapeutics, Inc., a biopharmaceutical company and Sionna Therapeutics, Inc., a biopharmaceutical company, as well as several private companies. Previously, Dr. Thompson served on the boards of Alpine Immune Sciences, Inc., a biotechnology company, Decibel Therapeutics, Inc., a biotechnology company, Janux Therapeutics, Inc., a biopharmaceutical company, and PMV Pharmaceuticals, Inc., a precision oncology company. Dr. Thompson also previously served in executive leadership roles at Trubion Pharmaceuticals, Inc., Chiron Corporation, and Becton, Dickinson and Company. Dr. Thompson is an Affiliate Professor of Neurosurgery at the University of Washington. In addition, Dr. Thompson holds numerous patents and is a board-certified internist and oncologist. Dr. Thompson holds a Sc. B. in Molecular Biology and Mathematics from Brown University and an M.D. from Brown University Medical School.

We believe that Dr. Thompson is qualified to serve on our board of directors because of his extensive experience as a member of senior management and boards of directors of multiple biopharmaceutical companies as well as his experience as a venture capital investor.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of eight members and will consist of eight members following the completion of this offering. Our board of directors has determined that all of our directors other than Dr. McDevitt and Mr. Hasnain are independent directors in accordance with the listing requirements of the Nasdaq Stock Market

and in Rule 10A-3 under the Exchange Act. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers. Dr. McDevitt is not considered an independent director because of his position as our Chief Executive Officer. Mr. Hasnain is not considered an independent director because of the services he provides to the Company as Executive Chairman.

Classified Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. McDevitt, Dr. Daniel, and Dr. Thompson, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Mr. Hasnain, Ms. Perettie, and Dr. Fisher, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Ms. Peterson and Mr. Spaventa, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

Board Leadership Structure

Our board of directors is currently chaired by Faheem Hasnain. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the Company continues to grow. We separate the roles of chief executive officer and executive chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the executive chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company. Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Table of Contents

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business, and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic, and reputational risk.

The audit committee reviews information regarding liquidity and operations and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention, and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor, or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees and Independence

Our board of directors has established three standing committees – audit, compensation, and nominating and corporate governance – each of which operates under a charter that has been approved by our board of directors. Our board of directors has also established a research and development committee to advise on scientific matters.

Audit Committee

Our audit committee consists of Andrew Spaventa, Douglas Fisher, and Caryn Peterson. Our board of directors has determined that it satisfies the independence requirements under listing standards and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Andrew Spaventa, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The principal duties and responsibilities of our audit committee include, among other things:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- helping to maintain and foster an open avenue of communication between management and the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent registered public accounting firm, our interim and full fiscal year operating results;
- developing "whistle-blower" procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;

- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes its internal controls environment and procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing standards of the Nasdaq Global Select Market.

Compensation Committee

Our compensation committee consists of Thomas Daniel, M.D., Cindy Perettie, and Peter Thompson, M.D. The chair of our compensation committee is Thomas Daniel, M.D. Our board of directors has determined that each of Thomas Daniel, M.D., Peter Thompson, M.D. and Cindy Perettie is independent under listing standards and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The principal duties and responsibilities of our compensation committee include, among other things:

- approving the retention of compensation consultants and outside service providers and advisors;
- reviewing and approving, or recommending that our board of directors approve, the compensation, individual and corporate performance goals and objectives and other terms of employment of our executive officers, including evaluating the performance of our chief executive officer and, with his assistance, that of our other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our equity and non-equity incentive plans;
- reviewing our practices and policies of employee compensation as they relate to risk management and risk-taking incentives;
- reviewing and approving, or recommending that our board of directors approve, and overseeing the administration of, incentive compensation and equity plans; and
- reviewing and establishing general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing standards of the Nasdaq Global Select Market.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Caryn Peterson and Thomas Daniel, M.D. The chair of our nominating and corporate governance committee is Caryn Peterson. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the listing standards.

The nominating and corporate governance committee's responsibilities include, among other things:

- identifying, evaluating, and selecting, or recommending that our board of directors approve, nominees for election to our board of directors and its committees;
- approving the retention of director search firms;
- evaluating the performance of our board of directors and of individual directors;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;

- evaluating the adequacy of our corporate governance practices and reporting; and
- overseeing the evaluation of the board's performance.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing standards of the Nasdaq Global Select Market.

Research and Development Committee

Our research and development committee consists of Thomas Daniel, M.D., Caryn Peterson, and Peter Thompson, M.D. The chair of our research and development committee is Thomas Daniel, M.D.

The principal duties and responsibilities of our research and development committee include, among other things:

- reviewing and advising our board of directors and management on our research and development priorities and scientific strategy and key development milestones;
- providing scientific and strategic perspectives on the design of our clinical and preclinical programs, our regulatory strategy and our significant interactions with the FDA and comparable foreign regulatory authorities; and
- evaluating the scientific merit of licensing and acquisition opportunities and monitoring emerging scientific and technological developments relevant to our programs.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served during the last completed fiscal year, as a member of the compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee, or as a member of the board of directors of any entity that has one or more executive officers serving as a member of our compensation committee.

Code of Ethics and Business Conduct

We have adopted a written code of ethics and business conduct that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the closing of this offering. Upon the closing of this offering, our code of ethics and business conduct will be available under the Corporate Governance section of our website at *www.aspenneuroscience.com*. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. We have included our website address in this prospectus solely as an inactive textual reference. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Table of Contents

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2025, consisting of our principal executive officer and our two other most highly compensated officers serving at the end of such year, were:

- Damien McDevitt, Ph.D. Chief Executive Officer
- Dalen Meeter, Chief Financial Officer
- Kim Raineri, Chief Technology Officer

Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our named executive officers during the year ended December 31, 2025:

Name and Principal Position(s)	Year	Salary	Option Awards[1]	Non-Equity Incentive Plan Compensation[2]	All Other Compensation[3]	Total
Damien McDevitt, Ph.D.						
Chief Executive Officer	2025	$610,598	$2,803,640	$ 333,003	$ 10,500	$3,757,741
Dalen Meeter[4]						
Chief Financial Officer	2025	$340,417	$1,595,648	$ 152,376	$ 9,707	$2,098,147
Kim Raineri						
Chief Technology Officer	2025	$427,254	$ 586,382	$ 184,698	$ 10,500	$1,208,835

(1) The amounts disclosed represent the aggregate grant date fair value of the stock options granted to our named executive officers during 2025 under the 2018 Plan, computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options are set forth in Note 6 to our audited financial statements included elsewhere in this prospectus. This amount does not reflect the actual economic value that may be realized by the named executive officer.

(2) The amounts disclosed were earned with respect to 2025 performance under our 2025 executive bonus plan and which were paid in March 2026.

(3) The amounts disclosed represent Company-funded 401(k) plan matching contributions.

(4) Mr. Meeter commenced employment with us on March 10, 2025.

2025 Compensation of Named Executive Officers

Base Salaries

Base salaries are intended to provide a level of compensation sufficient to attract and retain our executive team when considered in combination with the other components of our executive compensation program. See the "Salary" column in the Summary Compensation Table above for the base salary amounts earned by the named executive officers for 2025. Historically any annual base salary increases for our executive officers generally become effective commencing on March 10th of the applicable year.

Dr. McDevitt's initial 2025 annual base salary was $593,450 which was increased to $615,111 on March 10, 2025. Mr. Raineri's initial 2025 annual base salary was $415,415 which was increased to $430,370 on March 10, 2025. Mr. Meeter's 2025 annual base salary was set at $430,000 in connection with his commencement of employment with us on March 10, 2025 and he did not receive any subsequent base salary increase during 2025.

Non-Equity Incentive Plan Compensation

For 2025 our named executive officers were eligible to earn cash bonuses under our 2025 executive bonus plan as described below under "2025 Executive Bonus Plan." See the "Non-Equity Incentive Plan Compensation" column in the Summary Compensation Table above for the cash incentive amounts earned by the named executive officers with respect to 2025 performance.

Option Awards

In 2025 we granted our named executive officers stock options for the applicable number of shares and with the vesting terms as further specified in the "Outstanding Equity Awards as of December 31, 2025" table below.

Pursuant to the terms of his employment offer letter, Mr. Meeter was granted an initial stock option for 101,193 shares in March 2025 in connection with his commencement of employment with us and an additional stock option for 34,405 shares in November 2025 in connection with our Series C preferred stock financing, which was a qualifying financing under the terms of his offer letter. In connection with our Series C preferred stock financing, our named executive officers also received refresh stock option grants in November 2025 for the following number of shares: Dr. McDevitt – 387,063 shares; Mr. Meeter – 88,543 shares, and Mr. Raineri – 80,954 shares.

Outstanding Equity Awards as of December 31, 2025

The following table presents the outstanding equity incentive plan awards held by each named executive officer and which are exercisable and unexercisable in each case as of December 31, 2025.

			Option Awards [1]				Stock Awards [1]	
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($) [2]	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) [3]
Damien McDevitt, Ph.D.	11/26/2025 [4]	11/20/2025	8,063	378,999	5.74	11/25/2035		
	12/16/2024 [5]	7/1/2022	168,117	28,703	8.70	12/15/2034		
	3/24/2021 [6]						46,803	$ 407,186
	3/24/2021 [7]						46,804	$ 407,195
Dalen Meeter	11/26/2025 [8]	10/1/2025	—	34,405	5.74	11/25/2035		
	11/26/2025 [9]	11/20/2025	1,844	86,699	5.74	11/25/2035		
	3/13/2025 [8]	3/10/2025	—	101,193	8.70	3/12/2035		
Kim Raineri	11/26/2025 [9]	11/20/2025	1,686	79,267	5.74	11/25/2035		
	9/27/2023 [8]	10/1/2023	16,443	13,914	7.42	9/26/2033		
	9/7/2022 [9]	7/18/2022	60,504	10,330	7.71	9/6/2032		

(1) All of the stock options and stock awards were granted under the 2018 Plan.

(2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors.

(3) The market value of the unvested shares is calculated based on an estimated fair market value of $8.70 per share as of December 31, 2025.

(4) The shares subject to the option were previously eligible to vest in 48 equal monthly installments measured from the vesting commencement date, subject to continuous service as of each such vesting date. As described below, in August 2026, Dr. McDevitt agreed to extend the monthly vesting schedule of the remaining unvested shares subject to this option, such that this option will vest in full six years following its vesting commencement date

of November 20, 2025, rather than pursuant to its original four year vesting schedule. 100% of the unvested shares will vest immediately upon the consummation of a Change in Control (as defined in the 2026 Plan), subject to continued service through the date of the Change in Control.

(5) 1/4th of the shares subject to the option will vest on the one year anniversary of the vesting commencement date, and the balance of the shares will vest in 36 equal monthly installments measured from the one year anniversary of the vesting commencement date, subject to continuous service as of each such vesting date. 100% of the unvested shares will vest immediately upon the consummation of a Change in Control (as defined in the 2026 Plan), subject to continued service through the date of the Change in Control.

(6) The shares were purchased by Dr. McDevitt at $3.46 per share in April 2021 and are subject to our right of repurchase upon Dr. McDevitt's termination of service, which repurchase right lapses upon his continued services through the earlier of the date of enrollment of the first patient in a Phase 2 or Phase 3 trial-ready cohort for a product candidate or a Change in Control (as defined in the 2026 Plan).

(7) The shares were purchased by Dr. McDevitt at $3.46 per share in April 2021 and are subject to our right of repurchase upon Dr. McDevitt's termination of service, which repurchase right lapses upon his continued services through the earlier of the date of receipt of a bona fide written third party offer to acquire the Company or substantially all its assets, subject to the Company's entering into exclusivity with such third party on such or more favorable terms, or a Change in Control (as defined in the 2026 Plan).

(8) 1/4th of the shares subject to the option will vest on the one year anniversary of the vesting commencement date, and the balance of the shares will vest in 36 equal monthly installments measured from the one year anniversary of the vesting commencement date, subject to continuous service as of each such vesting date. 100% of the unvested shares will vest immediately upon a qualifying termination of service in connection with the consummation of a Change in Control (as defined in the 2026 Plan), subject to execution of a release.

(9) The shares subject to the option will vest in 48 equal monthly installments measured from the vesting commencement date, subject to continuous service as of each such vesting date. 100% of the unvested shares will vest immediately upon a qualifying termination of service in connection with the consummation of a Change in Control (as defined in the 2026 Plan), subject to execution of a release.

Nonqualified Deferred Compensation and Pension Benefits

Our named executive officers did not participate in, or earn any benefits under, any nonqualified deferred compensation plan or any pension or defined benefit retirement plan sponsored by us during the year ended December 31, 2025. Our board of directors may elect to provide our officers and other employees with such benefits in the future if it determines that doing so is in our best interests.

Employment Agreements

Below are descriptions of our employment agreements or offer letters with each of our named executive officers, setting forth the terms and conditions of such executive's employment with us. The employment agreements or offer letters generally provide for at-will employment. Each of our named executive officers has executed our standard proprietary information and inventions agreement.

For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers please see "—Potential Payments Upon Termination or Change in Control" below.

Damien McDevitt

In January 2021, we entered into an executive employment agreement with Damien McDevitt, Ph.D. our Chief Executive Officer. The executive employment agreement provided for his initial annual salary, which was subsequently increased, and which is currently set at $636,640 per year pursuant to the most recent increase to his base salary that became effective March 10, 2026. Pursuant to the executive employment agreement, Dr. McDevitt is eligible to receive an annual discretionary cash bonus with a target bonus opportunity equal to 50% of his base salary,

based on performance objectives. Dr. McDevitt is also entitled to certain severance benefits, the terms of which are described below under "—Potential Payments Upon Termination or Change in Control."

In August 2026, we entered into a loan forgiveness and option amendment agreement with Dr. McDevitt. Pursuant to this agreement, we forgave the outstanding principal and accrued interest, in the aggregate amount of approximately $2,114,989.07, owed by Dr. McDevitt under promissory notes that Dr. McDevitt entered into in order to pay the purchase price for shares of our common stock received upon the exercise of stock options. In exchange for such loan forgiveness, Dr. McDevitt agreed to extend the monthly vesting schedule of the remaining unvested shares subject to the option to purchase 387,063 shares that had been granted to Dr. McDevitt in November 2025, such that this option will vest in full six years following its vesting commencement date of November 20, 2025, rather than pursuant to its original four year vesting schedule. In addition, Dr. McDevitt further agreed that any refresh or top-up option or other equity award that may be granted to him in connection with this offering will be subject to a six-year monthly or quarterly vesting schedule. In addition, pursuant to this agreement, Dr. McDevitt's option was further amended to provide for vesting acceleration in the event of Dr. McDevitt's qualifying termination of employment, the terms of which are described below under "—Potential Payments Upon Termination or Change in Control."

Dalen Meeter

In March 2025, we entered into an offer letter agreement with Dalen Meeter, our Chief Financial Officer. The offer letter agreement provided for his initial annual base salary which was subsequently increased, and which is currently set at $445,050 per year pursuant to the increase to his base salary that became effective March 10, 2026. Pursuant to the offer letter agreement, Mr. Meeter is eligible to receive an annual discretionary cash bonus with a target bonus opportunity equal to 40% of his base salary, based on performance objectives. Mr. Meeter is also entitled to certain severance benefits, the terms of which are described below under "—Potential Payments Upon Termination or Change in Control."

Kim Raineri

In May 2022, we entered into an offer letter agreement with Kim Raineri, our Chief Technology Officer. The offer letter agreement provides for an initial annual base salary, which was subsequently increased, and which is currently set at $445,443 per year pursuant to the most recent increase to his base salary that became effective March 10, 2026. Pursuant to the offer letter agreement, Mr. Raineri is eligible to receive an annual discretionary cash bonus with a target bonus opportunity equal to 40% of his base salary, based on performance objectives. Mr. Raineri is also entitled to certain severance benefits, the terms of which are described below under "—Potential Payments Upon Termination or Change in Control."

Potential Payments Upon Termination or Change in Control

In connection with this offering, we intend to adopt an Officer Severance and Change in Control Plan (the Severance and CIC Plan) and related participation agreements with each of our named executive officers and other eligible officers with the following terms that will supersede and replace any severance and change in control benefit agreements that we previously entered into with eligible officers, including any such benefits that would otherwise be provided to them under their existing employment agreements and employment offer letters.

Eligibility

Individuals eligible to participate in the Severance and CIC Plan will generally include all Company officers reporting to the Chief Executive Officer and specifically excluding any individual serving as Executive Chair. To receive benefits, the eligible officer must experience an involuntary termination by the Company without Cause (other than as a result of the officer's death or disability) or a resignation by the officer for Good Reason, as such terms are defined in the Severance and CIC Plan, and timely execute a separation agreement and general release of claims in the form provided by the Company and return all Company property.

Table of Contents

Regular Termination Benefits

A regular termination is an involuntary termination that occurs during the period that is either more than three months before or more than 12 months after a Change in Control. In connection with a regular termination, the officer will be eligible to receive the following benefits:

- continued payment of base salary in accordance with the Company's regular payroll practices for
  - 12 months if the officer is the Chief Executive Officer,
  - nine months if the officer is a Tier II Officer (a C-Suite officer who reports directly to the Chief Executive Officer) and
  - six months if the officer is a Tier III Officer (a Senior Vice President or Vice President who reports directly to the Chief Executive Officer).
- the Chief Executive Officer also will receive 100% of the target bonus for the calendar year in which the termination occurs, payable in a lump sum on the first payroll period following the effective date of the release.
- subject to timely election of COBRA coverage, the Company also will pay directly to the carrier the full COBRA premiums for the officer and the officer's eligible dependents until the earlier of the following periods or expiration of COBRA or analogous state-law coverage or the date the officer becomes eligible for substantially equivalent coverage in connection with new employment:
  - 12 months for the Chief Executive Officer,
  - nine months for a Tier II Officer, and
  - six months for a Tier III Officer.

Pursuant to Mr. Meeter's participation agreement, upon a regular termination, Mr. Meeter also will be entitled to receive (i) a pro rata portion of his target bonus for the calendar year of termination, payable in a lump sum following the effective date of his release, and (ii) accelerated vesting of the stock options granted to him on March 13, 2025 for 101,193 shares and November 26, 2025 for 34,405 shares, as if he had continued in employment for an additional nine months following the termination date.

Change in Control Termination Benefits

A change in control termination is an involuntary termination that occurs during the period that begins three months before and ends 12 months after the effective date of a Change in Control. In connection with a change in control termination, an officer will be eligible to receive the following benefits:

- cash severance paid in a single lump sum on the first payroll period following the later of the effective date of the Change in Control and the effective date of the officer's release, consisting of the following applicable number of months of base salary and percentage of target bonus:
  - 18 months of base salary plus 150% of target bonus for the Chief Executive Officer,
  - 12 months of base salary plus 100% of target bonus for a Tier II Officer, and
  - nine months of base salary plus 75% of target bonus for a Tier III Officer,
- any annual bonus for a calendar year preceding the Change in Control Termination that remains unpaid and was otherwise earned subject solely to continued service, payable at the same time as the corresponding annual cash bonuses are paid to officers who remain employed,
- subject to timely election of COBRA coverage, the Company also will pay directly to the carrier the full COBRA premiums for the officer and the officer's eligible dependents until the earlier of the following periods or expiration of COBRA or analogous state-law coverage or the date the officer becomes eligible for substantially equivalent coverage in connection with new employment:
  - 18 months for the Chief Executive Officer,

Table of Contents

- 12 months for a Tier II Officer, and
- nine months for a Tier III Officer,

- to the extent not previously vested, all outstanding equity awards held by the officer will fully vest and, where applicable, become exercisable, any Company reacquisition or repurchase rights will lapse and any shares issuable upon vesting will be issued, and for such purposes performance-based awards will vest based on the greater of 100% of target performance or actual performance for the applicable performance period.

Change in Control Acceleration

Separately, subject to the officer's continued employment through the date of a Change in Control, if the officer's equity awards are not assumed, continued or substituted by the acquiring or surviving entity, all of the officer's outstanding equity awards will fully vest upon the Change in Control. Any performance-based vesting conditions with multiple potential levels will be deemed satisfied at the greater of the performance level actually attained through the date of the Change in Control or the applicable target performance level. For this purpose, equity awards generally will be treated as assumed, continued or substituted if, following the Change in Control, the officer has the right to purchase or receive, for each share subject to an award, the same consideration received by the Company's stockholders for each share of common stock, after giving effect to any applicable exercise or purchase price and subject to the applicable vesting conditions.

Pursuant to Dr. McDevitt's participation agreement and subject to his continued services through a Change in Control, all of his then-outstanding and unvested equity awards granted to him before this offering will accelerate vesting immediately before and contingent upon that Change in Control. Equity awards granted to Dr. McDevitt upon or after the date of this offering will not be eligible for this additional Change in Control acceleration.

Definitions. For purposes of the Severance and CIC Plan, the following terms have the following meanings:

- "Cause" means (i) acts or omissions constituting gross negligence, recklessness or willful misconduct with respect to the officer's obligations or otherwise relating to the Company's business; (ii) willful, reckless or negligent acts or conduct adverse to the Company's interests; (iii) a material breach of the officer's offer letter, proprietary information and inventions agreement (PIIA) or other agreement with the Company; (iv) a knowing breach of any other agreement with the Company or Company policy; (v) conviction or plea of nolo contendere for fraud, misappropriation or embezzlement, or commission of any felony or crime of moral turpitude; or (vi) failure to perform the officer's duties, as determined in the sole and exclusive discretion of the Board. If a termination is based on any of clauses (i), (ii), (iii), (iv) or (vi), the officer will have 15 days after receiving notice to cure the issue, if curable.
- "Good Reason" means (i) a material diminution in the officer's authority, duties or responsibilities; (ii) a reduction of more than 10% in the officer's base salary, unless the reduction is part of, and generally consistent with, a general reduction applicable to similarly situated officers; (iii) the Company's material breach of the officer's employment agreement; or (iv) relocation of the officer's principal place of work that increases the officer's daily commute by more than 35 miles without the officer's prior written approval. The Company or its successor will have 30 days after receiving written notice to cure the circumstance, and the officer must terminate employment within 60 days after expiration of the cure period. A Change in Control and a subsequent conversion of the Company to a division or unit of the surviving or acquiring entity will not, by itself, constitute a material diminution absent a material diminution of the officer's authority, duties or responsibilities with respect to that division or unit.
- "Change in Control" has the meaning set forth in the 2026 Plan, as in effect on the date of this offering.

General Provisions

The Severance and CIC Plan includes a "best-after-tax" cutback provision. If any payment or benefit that the officer would receive would constitute a "parachute payment" within the meaning of Section 280G of the Code and would, absent a reduction, be subject to the excise tax imposed by Section 4999 of the Code, the payment or benefit will be reduced to the largest amount that either would result in no portion being subject to the excise tax or, after taking into account applicable federal, state and local employment and income taxes and the excise tax, would provide the officer with the greater after-tax economic benefit than the full amount subject to the excise tax.

All payments and benefits under the Severance and CIC Plan will be subject to the Company's compensation recovery policy and any other clawback policy required by applicable law or listing standards.

Employee Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our paid time off, medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees.

401(k) Retirement Savings Plan

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. The 401(k) plan is intended to qualify as a tax-qualified retirement plan under the Internal Revenue Code of 1986, as amended, or the Code. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees and defer a portion of their compensation, within prescribed limits, through payroll contributions to the 401(k) plan.

Clawback Policy

In connection with this offering, we intend to adopt a compensation recovery policy that is compliant with the Nasdaq Listing Rules, as required by the Dodd-Frank Act, to be effective upon the consummation of this offering.

Employee Incentive Plans

2025 Executive Bonus Plan

Our named executive officers were eligible to earn cash bonuses based on the level of achievement of our 2025 corporate performance goals and their 2025 target bonus amounts. For Messrs. Meeter and Raineri, 2025 bonus eligibility was based on a combination of corporate performance and individual performance, while Dr. McDevitt's 2025 bonus was determined based solely on our corporate performance. Target bonus amounts were set as a percentage of their respective base salaries at 50% for Dr. McDevitt and at 40% for each of Messrs. Meeter and Raineri. For 2025, our corporate performance goals were based on further development of sasineprocel, automated manufacturing initiatives, pipeline strategy, financing, risk mitigation planning and employee engagement goals. Our board of directors determined that we achieved our 2025 corporate performance goals at 109% of the target level. Messrs. Meeter and Raineri's individual 2025 performance was also assessed to be above the target performance level. Accordingly, each of our named executive officers' 2025 bonuses was awarded above the target level, resulting in the 2025 bonus payout levels as reported above in the summary compensation table.

Employee Cash Incentive Plan

Our board of directors adopted the Cash Incentive Plan in October 2026 which is applicable commencing with our 2026 bonus program. Our Cash Incentive Plan provides for the grant of cash-based incentive awards to our employees, including our named executive officers. The following summary describes the material terms of our Cash Incentive Plan. This summary is not a complete description of all provisions of our Cash Incentive Plan and is qualified in its entirety by reference to our Cash Incentive Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Administration. Our Cash Incentive Plan will be administered by an officer committee consisting of our Chief Executive Officer and our Chief Financial Officer for employees who are not executive officers and by our compensation committee for our executive officers. As used in this summary, the term "Administrator" refers to our compensation committee or the officer committee, as applicable. The Administrator has the discretionary authority to, among other things, determine award recipients, grant awards, establish all terms and conditions of awards, interpret the Cash Incentive Plan and awards, approve target and actual awards, adopt sub-plans, prescribe rules for administration, interpretation and application of the Cash Incentive Plan, and otherwise do all things necessary or desirable to carry out the purposes of our Cash Incentive Plan.

Eligibility and Participation. Our employees and those of our affiliates will be eligible to participate in our Cash Incentive Plan and will be selected from time to time by the Administrator to participate in our Cash Incentive Plan.

Awards; Performance Criteria. Awards under our Cash Incentive Plan will be made based on, and subject to achieving, specified performance goals established by the Administrator in its discretion for the applicable performance period. The target award will be set in a participant's written employment offer letter or other written agreement with the company or otherwise communicated in writing by the Administrator. For each award granted under our Cash Incentive Plan, the Administrator will establish the performance goals applicable to the award for the specified performance period, the amount or amounts payable if the performance goals are achieved and such other terms and conditions as the Administrator deems appropriate. The performance goals may be on the basis of any factors the Administrator determines relevant, and may be on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Payments Under an Award. A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with our Cash Incentive Plan and the terms of the award. Following the end of a performance period, the Administrator will determine whether and to what extent the applicable performance goals have been satisfied and will determine the amount payable under each award. The Administrator has the discretionary authority to increase or decrease the amount actually paid under any award. The actual cash award amounts will be fully paid in cash (or its equivalent) no later than March 15th of the calendar year following the year in which the performance goals were attained. Unless otherwise determined by the Administrator, participants generally must be employed by the company in good standing on the bonus payment date in order to be eligible to receive payment. However, if a participant was employed in good standing through the last day of a calendar year and is terminated without cause, as such term is defined in the Cash Incentive Plan, prior to the date that actual awards in respect of performance for such calendar year are determined and paid, such participant is also eligible to receive an actual award at the same time as actual awards are regularly paid to other eligible participants, subject to the participant's timely provision of a release of claims. However, to the extent such participant may otherwise be entitled to such actual award as a severance benefit under any separate severance benefit agreement or severance pay plan, such participant will not be entitled to such actual award payment under the Cash Incentive Plan, and such participant's severance benefit eligibility will be determined solely by the terms of such other severance arrangement or plan.

Amendment and Termination. The Administrator may (i) amend our Cash Incentive Plan and the terms of any outstanding award granted under the Cash Incentive Plan or (ii) terminate the Cash Incentive Plan, provided that any amendment will not alter or impair any participant's rights or obligations under any actual cash award amount previously earned without their consent.

Employee Stock Plans

2026 Equity Incentive Plan

Our board of directors adopted the 2026 Plan in October 2026, and our stockholders approved the 2026 Plan in October 2026. The 2026 Plan became effective upon the execution of the underwriting agreement for this offering. The 2026 Plan is the successor to our 2018 Stock Plan, or the 2018 Plan, which is described below. No further grants will be made under the 2018 Plan following the effectiveness of the 2026 Plan.

Types of Awards. Our 2026 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards, or collectively, awards. ISOs may be granted only to our employees, including our officers, and the employees of our affiliates. All other awards may be granted to our employees, including our officers, our non-employee directors and consultants and the employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of common stock that may be issued under our 2026 Plan will initially be 6,799,243 shares, which number is the sum of: 3,634,825 new shares, plus the applicable number of returning shares from our 2018 Plan not exceeding a maximum of 3,164,418 such returning shares. For such purposes, returning shares from our 2018 Plan means the applicable number shares subject to equity awards granted under the 2018 Plan that are outstanding on the date of this offering, and that are not issued because such share award or any portion thereof expires or otherwise terminates without all of the shares covered by such share award having been issued, are not issued because such award or any portion thereof is settled in cash, are forfeited back to or repurchased by us because of the failure to meet a contingency or condition required for the vesting of such shares, are used to pay the exercise price of an award, or are used to satisfy tax withholding obligations with respect to an award.

The number of shares of common stock reserved for issuance under our 2026 Plan will automatically increase on January 1 of each year, beginning on January 1, 2027, and continuing through and including January 1, 2036, by 5% of the sum of the total number of shares of common stock outstanding plus the number of shares issuable upon the exercise of any unexercised pre-funded warrants, in each case which are outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2026 Plan is 6,799,243 shares.

Shares issued under our 2026 Plan will be authorized but unissued or reacquired shares of common stock. Shares subject to awards granted under our 2026 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2026 Plan. Additionally, any shares subject to awards that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations to an award, and any shares subject to awards which are not issued because the award is settled in cash, or because the award expires or otherwise terminates without all the shares having been issued, will become available for future grant under our 2026 Plan.

In any one year period measured commencing on the date of our annual meeting of stockholders for a particular year that is held following the closing of our initial public offering and ending on the day immediately prior to the date of our annual meeting of stockholders for the next subsequent year, the maximum number of shares of common stock subject to stock awards granted under the 2026 Plan or otherwise during any period to any non-employee director, taken together with any cash fees paid by us to such non-employee director during such period for service on the board of directors (but excluding any expense reimbursements or distributions from any deferred compensation program applicable to the non-employee director), will not exceed $750,000 in total value, or $1,000,000 in total value for the year in which the non-employee director is first appointed or elected to the board (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).

Executive Chair Reserve. In addition to the general share reserve, the 2026 Plan establishes a separate reserve of 872,358 shares of common stock, referred to as the Executive Chair Reserve, which is available solely for the issuance of shares pursuant to awards granted to our Executive Chair, Faheem Hasnain, in satisfaction of the Company's obligations under the Executive Chair Agreement (as defined below). The Executive Chair Reserve is separate from, and in addition to, the general share reserve (including any annual increases thereto). Shares from the Executive Chair Reserve may not be granted to any other participant under the 2026 Plan. To the extent shares from the Executive Chair Reserve are not granted, or are subject to an award that expires, is forfeited, cancelled, settled in cash, or otherwise terminates without issuance, or become no longer issuable because the applicable conditions are not satisfied, such shares will be permanently cancelled and will not become available for issuance under the 2026 Plan to any other participant. For the avoidance of doubt, the Company's obligation to grant awards from the Executive Chair Reserve may, in the Company's discretion, be satisfied in cash in lieu of shares to the extent provided in the Executive Chair Agreement, and any shares not issued as a result will be permanently cancelled. No shares from the Executive Chair Reserve may be transferred to or combined with the general share reserve. The 2026 Plan requires stockholder approval for any amendment to the 2026 Plan that would modify the exclusive use restrictions applicable

to the Executive Chair Reserve or make shares from the Executive Chair Reserve available for awards to any person other than the Executive Chair.

Plan Administration. Our compensation committee may administer our 2026 Plan. We sometimes refer to the compensation committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards, and (2) determine the number of shares subject to such awards.

The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2026 Plan.

In addition, subject to the terms of the 2026 Plan, the administrator also has the power to modify outstanding awards under our 2026 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions of the 2026 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 2026 Plan vest at the rate specified in the stock option agreement as specified in the stock option agreement by the administrator.

The administrator determines the term of stock options granted under the 2026 Plan, up to a maximum of ten 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. The option term may be extended in the event that either an exercise of the option or an immediate sale of shares acquired upon exercise of the option following such a termination of service 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 disability or 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 12 months in the event of disability, and 18 months in the event of the optionholder's death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. 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 administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO and (5) other legal consideration approved by the administrator.

Options may not be transferred to third-party financial institutions for value. Unless the administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, 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 common stock with respect to ISOs that are exercisable for the first time by an option 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 be treated as NSOs. No ISOs 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 parent or subsidiary corporations, 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 Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the administrator. Restricted stock awards may be granted in consideration for cash, check, bank draft or money order, services rendered to us or our affiliates or any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the administrator. A restricted stock award may be transferred only upon such terms and conditions as set by the administrator. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the 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 units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2026 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator.

The administrator determines the term of stock appreciation rights granted under the 2026 Plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provide otherwise, 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. The stock appreciation right term 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. 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. Our 2026 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the common stock.

The performance goals may be based on any measure of performance selected by the board of directors. The compensation committee may establish performance goals on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices.

Other Awards. The administrator may grant other awards based in whole or in part by reference to common stock. The administrator will set the number of shares under the 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 number of shares reserved for issuance under the 2026 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 upon the exercise of ISOs and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Change in Control. A "Change in Control" of the Company occurs upon (a) a person (with certain exceptions described in the 2026 Plan) acquiring direct or indirect beneficial ownership of 50% or more of the total fair market value or total combined voting power of Company's then-outstanding securities entitled to vote generally in the election of the Company's Board; (b) stockholder approval of a liquidation or dissolution of the Company; or (c) the occurrence of any of the following events upon which the stockholders of the Company immediately before the event do not retain immediately after the event direct or indirect beneficial ownership of more than 50% of the voting securities of the Company, its successor or the entity to which the assets of the company were transferred: (i) a sale or exchange by the stockholders in a single transaction or series of related transactions of more than 50% of the Company's voting stock; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange or transfer of all or substantially all of the assets of the Company (other than a sale, exchange or transfer to one or more subsidiaries of the Company).

If a Change in Control occurs, the surviving, continuing, successor or purchasing entity or its parent may, without the consent of any participant, either assume or continue outstanding awards or substitute substantially equivalent awards for its stock. If so determined by the compensation committee, stock-based awards will be deemed assumed if, for each share subject to the award prior to the Change in Control, its holder is given the right to receive the same amount of consideration that a stockholder would receive as a result of the Change in Control. Any awards which are not assumed or continued in connection with a Change in Control or exercised or settled prior to the Change in Control will terminate effective as of the time of the Change in Control. In connection with a Change in Control, the compensation committee may also provide for the assignment or lapse of any reacquisition or repurchase right applicable to any awards. Awards may also be cancelled to the extent not vested or not exercised prior to the Change in Control, in exchange for no consideration or in exchange for such consideration as the compensation committee may determine in its discretion. The 2026 Plan also permits the compensation committee, in its discretion, to cancel each or any outstanding award denominated in shares upon a Change in Control in exchange for a payment to the participant with respect to each share subject to the cancelled award of an amount with a fair market value equal to the excess of the consideration to be paid per share of common stock in the Change in Control transaction over the exercise price or purchase price per share, if any, under the award, and which payments may be made on the same vesting schedule as the cancelled award, or alternatively accelerated to the Change in Control, if so determined by the compensation committee. Subject to the restrictions of Section 409A of the Code, the compensation committee may provide for the acceleration of vesting or settlement of any or all outstanding awards upon such terms and to such extent as it determines.

The vesting of all awards held by non-employee directors will be accelerated in full upon a Change in Control, and, except to the extent assumed, continued or substituted as described above or otherwise restricted by Section 409A, shall be settled effective immediately prior to the time of consummation of the Change in Control if not exercised prior to the Change in Control.

The 2026 Plan also authorizes the compensation committee, in its discretion and without the consent of any participant, to cancel each or any award denominated in shares of stock upon a Change in Control in exchange for a payment to the participant with respect to each vested share (and each unvested share if so determined by the compensation committee) subject to the cancelled award of an amount equal to the excess of the consideration to be paid per share of common stock in the Change in Control transaction over the exercise or purchase price per share, if any, under the award. Subject to the restrictions of Section 409A or Section 424 of the Code, the compensation committee may determine that an award may be subject to the same post-closing purchase price adjustments, escrow terms, offset rights, holdback terms, earnouts and similar conditions as the other holders of the Company's common stock. The Committee may also terminate unvested or unexercised awards for no consideration in connection with the Change in Control.

Transferability. A participant may not transfer awards under our 2026 Plan other than by will, the laws of descent and distribution or as otherwise provided under our 2026 Plan.

Plan Amendment or Termination. The compensation committee has the authority to amend, suspend or terminate the 2026 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 adopted our 2026 Plan. No awards may be granted under our 2026 Plan while it is suspended or after it is terminated.

2018 Stock Plan

The Company maintains the 2018 Plan. The maximum aggregate number of shares of common stock that may be issued under the 2018 Plan is 4,264,902. The purpose of the 2018 Plan is to provide awards in the form of stock options and restricted stock awards in order to provide an incentive to attract, retain and reward persons performing services for the Company and to motivate such persons to contribute to the growth and profitability of the Company. Employees, directors and consultants are eligible to receive awards under the 2018 Plan.

After the effective date of the 2026 Plan, no additional awards will be granted under the 2018 Plan. However, the 2018 Plan will continue to govern the terms and conditions of the outstanding awards granted under it.

Administration. The board administers the 2018 Plan. Subject to the terms of the 2018 Plan, the administrator has the power to, among other things, determine the persons to whom the awards shall be granted and the number of shares of stock subject to each award, determine the type of award granted, determine the fair market value of shares of stock, determine the terms, conditions and restrictions applicable to each award, modify from time to time any award or waive any restrictions or conditions applicable to any award, reprice or adjust the exercise price of any option, or grant in substitution for any option, a new award covering the same or a different number of shares of stock, accelerate the exercisability or vesting of any award including the period following a participant's termination of service, prescribe, amend or rescind any policies relating to the plan, and correct any defect or reconcile any inconsistency in the plan or any award agreement.

Treatment Upon a Change in Control of the Company. If a "Change in Control" of the Company occurs, as defined in the 2018 Plan, and which generally has the same meaning as defined in the 2026 Plan, then the board may provide for any one or more of the following except to the extent otherwise provided in the applicable form of award agreement: (a) acceleration of the exercisability and/or vesting in connection with a Change in Control of each or any outstanding award or portion thereof and shares acquired pursuant thereto, including termination of the participant's service prior to, upon or following the Change in Control; (b) provide for the surviving, continuing, successor, or purchasing corporation or other business entity or parent thereof following the Change in Control, as the case may be (the Acquiror), without the consent of any participant, to assume or continue the Company's rights and obligations under each award or portion thereof outstanding immediately prior to the Change in Control or substitute for each or any such outstanding award or portion thereof a substantially equivalent award with respect to the Acquiror's stock; and/or (c) cancel any award or portion thereof in exchange for a payment with respect to each vested share (and each unvested share, if so determined by the board) of stock subject to such canceled award in (i) cash, (ii) stock of the Company or of a corporation or other business entity a party to the Change in Control, or (iii) other property which, in any such case, shall be in an amount having a fair market value equal to the fair market value of the consideration to be paid per share of stock in the Change in Control, reduced (but not below zero) by the exercise or purchase price per share, if any, under such award.

Adjustments in Capital Structure. The 2018 Plan also provides that the board may make appropriate and proportionate adjustments to the number of shares subject to outstanding awards to prevent dilution or enlargement of participants' rights in the event of changes in our capitalization through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split, split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure, or in the event of payment of a dividend or distribution to the stockholders in a form other than stock (excepting regular, periodic cash dividends).

Subsequent to this offering, the Company will not grant any additional awards under the 2018 Plan. Instead, the Company will grant equity awards under the 2026 Plan. The 2018 Plan, however, will continue to govern the terms and conditions of all outstanding equity awards granted under the 2018 Plan prior to this offering.

Table of Contents

2026 Employee Stock Purchase Plan

Our board of directors adopted the ESPP in October 2026, and our stockholders approved the ESPP in October 2026. The ESPP became effective upon the execution of the underwriting agreement for 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 includes two components. One component is designed to allow our eligible U.S. employees to purchase common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. In addition, purchase rights may be granted under a component that does not qualify for such favorable tax treatment when necessary or appropriate to permit participation by our eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Authorized Shares. The maximum aggregate number of shares of common stock that may be issued under our ESPP is 290,786 shares. The number of shares of common stock reserved for issuance under our ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 and continuing through and including January 1, 2036, by the lesser of 1% of the sum of the total number of shares of our common stock outstanding plus the number of shares of stock issuable upon the exercise of any unexercised pre-funded warrants, in each case which are outstanding on December 31 of the preceding calendar year, (2) 436,179 shares and (3) a number of shares determined by our board. Shares subject to purchase rights granted under our ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our ESPP.

Plan Administration. Our board, or a duly authorized committee thereof, will administer our ESPP. Our board has delegated concurrent authority to administer our ESPP to the compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings with specific terms approved by the administrator and under which eligible employees are granted purchase rights to purchase shares of 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 common stock will be purchased for our eligible 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, a percentage of their Compensation (as defined in the ESPP) not to exceed a maximum amount specified by the administrator for the purchase of common stock under the ESPP. Unless otherwise determined by the administrator, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of common stock on the first date of an offering or (b) 85% of the fair market value of a share of common stock on the date of purchase. For the initial offering, which we expect will commence upon the execution and delivery of the underwriting agreement relating to this offering, the fair market value on the first day of the initial offering will be the price at which shares are first sold to the public.

Limitations. Our employees, including executive officers, or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by the administrator: (1) customary employment with us or one of our affiliates for more than 20 hours per week, or (2) customary employment more than five months per calendar year. An employee may not be granted rights to purchase stock under our ESPP if such employee (1) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of common stock, or (2) holds rights to purchase stock under our ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

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 compensation committee will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Change in Control. In the event of a "Change in Control", which has the same meaning in the ESPP as defined under the 2026 Plan, an acquiring or successor corporation may assume the Company rights and obligations under outstanding purchase rights or substitute substantially equivalent purchase rights. If the acquiring or successor corporation does not assume or substitute for outstanding purchase rights, then the purchase date of the offering periods then in progress under the ESPP will be accelerated to a date that is within fifteen (15) business days prior to the Change in Control.

ESPP Amendment or Termination. The administrator has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not adversely affect 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.

Non-Employee Director Compensation

We have previously provided a cash retainer and equity-based compensation to certain of our non-employee directors. In addition, all of our non-employee directors are entitled to reimbursement of direct expenses incurred in connection with attending meetings of our board of directors or committees thereof. In January 2026, the board of directors amended all outstanding non-employee director options so that all such options will immediately accelerate vesting upon a change in control, subject to continued services through the change in control.

During 2025, each of Dr. Daniel, Messrs. Spaventa and Hasnain, and Ms. Peterson were eligible to earn an annual cash retainer of $35,000. Commencing January 1, 2026, the annual cash retainer provided to each of Dr. Daniel, Mr. Spaventa and Ms. Peterson was increased from $35,000 to $40,000 and the annual cash retainer provided to Mr. Hasnain was increased from $35,000 to $60,000. Such annual cash retainers are earned and payable in arrears in four equal quarterly installments subject to continuing service for the full calendar quarter.

In connection with this offering, our board of directors expects to approve a new policy for setting non-employee director compensation, which will take effect following the completion of this offering. Under this director compensation policy that we intend to approve, we will pay our non-employee directors, other than the chairperson of the board, an annual cash retainer of $40,000 and any non-employee chairperson of our board of directors will be paid an annual cash retainer of $70,000. Members of the following committees of our board of directors will be paid the following additional cash retainers:

Board Committee	Chairperson Fee	Member Fee
Audit Committee	$ 16,000	$ 8,000
Compensation Committee	$ 12,000	$ 6,000
Nominating and Corporate Governance Committee	$ 10,000	$ 5,000
Research and Development Committee	$ 20,000	$ 6,000

All annual cash retainer fees will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors, on such committee or in such position and no fee shall be payable in respect of any period prior to the completion of this offering.

We also will continue to reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

Each new non-employee director who joins our board of directors following the closing of this offering will receive a stock option grant under the 2026 Plan for 23,500 shares and which will vest in 36 equal monthly installments following the date of grant subject to the non-employee director's continuous service through applicable vesting dates.

On the date of each annual meeting of our stockholders following the closing of this offering, each continuing non-employee director will receive a stock option grant under the 2026 Plan for 11,750 shares which will vest in full upon the earlier of the one year anniversary of the grant date or the date of the next annual meeting, subject to the non-employee director's continuous service.

The policy will provide that all our non-employee director equity awards will immediately accelerate vesting upon a change in control, subject to continued services through the change in control.

Ms. Perettie will not be eligible to receive any cash retainer fee or equity award benefits under our non-employee director compensation policy due to the restrictions in her separate agreement with Kite Pharma, a subsidiary of Gilead Sciences. Mr. Hasnain will also not be eligible for benefits under our non-employee director compensation policy while he remains employed as our Executive Chair.

Executive Chair Employment Agreement with Mr. Hasnain

In July 2026, we entered into an employment agreement with Mr. Hasnain to serve as our Executive Chair, effective August 3, 2026 (the Executive Chair Agreement). The Executive Chair Agreement provides that Mr. Hasnain's initial annual salary is $300,000 per year and he is eligible to receive an annual discretionary cash bonus with a target bonus opportunity equal to 55% of his base salary, based on performance objectives.

Pursuant to the Executive Chair Agreement, Mr. Hasnain is also eligible to receive, subject to his continued employment through the applicable dates listed below the following equity incentive awards provided that this offering is completed by December 31, 2026:

- in connection with the completion of this offering, an award of restricted stock units with the amount of shares subject to such award equal to 1% of our shares outstanding on a fully diluted basis as of immediately following completion of this offering, which will be fully vested upon grant and with a deferred settlement feature so that the shares will in all cases be issued during the 2027 calendar year;

- upon the second anniversary of the completion of this offering and subject to Mr. Hasnain's continued employment as our Executive Chair through such date, an award of restricted stock units with the amount of shares subject to such award equal to 1% of our shares outstanding on a fully diluted basis immediately following completion of this offering, minus a number of shares with a then current fair market value not exceeding the value of such number of shares as measured of the date of this offering, which will be fully vested upon grant, referred to as the second anniversary grant;

- if our 90-day average closing price per share is at least 200% of the price per share in this offering at any time prior to the second anniversary of the completion of this offering, an award of restricted stock units with the amount of shares subject to such award equal to 1% of our shares outstanding on a fully diluted basis immediately following completion of this offering, minus a number of shares with a then current fair market value not exceeding the value of such number of shares as measured of the date of this offering , which will be fully vested upon grant;

- if our 90-day average closing price per share is at least 600% of the price per share in this offering at any time prior to the third anniversary of the completion of this offering, an award of restricted stock units with the amount of shares subject to such award equal to 1% of our shares outstanding on a fully diluted basis immediately following completion of this offering, minus a number of shares with a then current fair market value not exceeding the value of such number of shares as measured of the date of this offering, which will be fully vested upon grant; and

- if our 90-day average closing price per share is at least 800% of the price per share in this offering at any time prior to the fourth anniversary of the completion of this offering, an award of restricted stock units with the amount of shares subject to such award equal to 1% of our shares outstanding on a fully diluted basis immediately following completion of this offering, minus a number of shares with a then current fair market value not exceeding the value of such number of shares as measured of the date of this offering, which will be fully vested upon grant.

In addition, subject to Mr. Hasnain's employment through a change in control (as defined in the 2026 Plan) that occurs before the fourth anniversary of the completion of this offering, Mr. Hasnain is eligible to receive either such of the foregoing equity awards that were not previously granted, or alternatively the right to receive a portion of the proceeds from the change in control that he would have been entitled to receive if the equity award had been granted immediately prior to the change in control, provided that with respect to the 200%, 600% or 800% 90-day average closing price RSU awards the fair market value of the proceeds payable to the holder of a share of common stock in connection with the change in control must not be less than the applicable 200%, 600% or 800% price goal threshold, which are referred to collectively as the Change in Control Awards.

The Executive Chair Agreement provides that in the event of a termination by the Company without "cause," Mr. Hasnain will receive the following severance benefits, subject to the execution and non-revocation of a release agreement and his compliance with other obligations set forth in the Executive Chair Agreement: (a) eighteen (18) months' base salary, paid in equal installments in accordance with the Company's regular payroll and (b) (i) if the second anniversary grant described above has not been granted, either the grant of such award or a cash payment equal to the fair market value of such award as of the date of termination as if it had been granted on such date; and (ii) if any of the 200%, 600% or 800% 90-day average closing price per share RSU awards described above have not been granted and the applicable price goal (200%, 600% or 800%, respectively) is attained within ninety (90) days following such termination, either the grant of such award or a cash payment equal to the fair market value of such award as of the date of termination as if it had been granted on such date.

If a change in control occurs within 90 days following such termination by the Company without "cause" but before the fourth anniversary of the completion of this offering, Mr. Hasnain is eligible to receive any applicable Change in Control Awards that have not been granted as determined based on the applicable RSU awards previously granted to Mr. Hasnain and the fair market value of the transaction proceeds payable in connection with the change in control. The Executive Chair Agreement includes a non-duplication of benefits clause such that Mr. Hasnain is not eligible to receive both the severance benefit RSUs awards (or cash equivalents) and the Change in Control Awards with respect to the same intended RSU awards. The Executive Chair Agreement includes a Section 280G "modified cutback" provision.

For purposes of Mr. Hasnain's severance benefits described above, "cause" is defined as (a) acts or omissions constituting gross negligence, recklessness or willful misconduct on Mr. Hasnain's part with respect to his obligations or otherwise relating to the business of the Company; (b) any acts or conduct by him that are materially adverse to the Company's interests; (c) his material breach of the Executive Chair Agreement, the PIIA or the Arbitration Agreement (both as defined in the Executive Chair Agreement); (d) his breach of any other agreement with the Company or any of the Company policies; (e) his conviction or entry of a plea of *nolo contendere* for fraud, misappropriation or embezzlement or any felony or crime of moral turpitude; (f) his failure to perform his duties as determined in the sole and exclusive discretion of the board; (g) his inability to perform the essential functions of his position, with or without reasonable accommodation, due to Permanent Disability (as defined in the Executive Chair Agreement); (h) his death; or (i) the winding down or dissolution of the Company. In the event of a termination based on (b), (c), (d) or (f), Mr. Hasnain will have fifteen (15) days from receipt of notice from the Company to cure the issue, if curable.

In September 2026, we entered into loan forgiveness and option amendment agreements with each of Messrs. Hasnain and Spaventa. Pursuant to these agreements, we forgave the outstanding principal and accrued interest, in the amount of approximately $212,928 for Mr. Hasnain and $30,550 for Mr. Spaventa, under promissory notes that were entered into to pay the purchase price for shares of our common stock received upon the exercise of stock options by each of Messrs. Hasnain and Spaventa. In exchange for the Company forgiving such amounts, Mr. Hasnain agreed to extend the monthly vesting schedule of the remaining unvested shares subject to an option to purchase 41,489 shares granted to him in November 2025, and Mr. Spaventa agreed to extend the monthly vesting schedule of the then remaining unvested shares subject to an option to purchase 19,226 shares granted to him in November 2025, in each case such that these options will vest in full after six years following the vesting commencement date of November 20, 2025, rather than the original four years following such date. In addition, Mr. Hasnain agreed that any refresh or top-up option or other equity award that may be granted to him in connection with this offering will be subject to a six year monthly or quarterly vesting schedule.

For additional information regarding the loan forgiveness agreements and related option amendments, see the section titled "Certain Relationships and Related Person Transactions—Executive Officer Promissory Notes and Related Transactions."

The following table sets forth information regarding the compensation earned or awarded for service on our board of directors during the fiscal year ended December 31, 2025. Dr. McDevitt, our Chief Executive Officer is also a member of our board of directors, but did not receive any additional compensation for his service as a director. Dr. McDevitt's compensation as an executive officer is set forth in the section titled "Executive Compensation—Summary Compensation Table."

Name	Fees earned or paid in cash	Option awards ($)[1]	Total ($)
Thomas Daniel, M.D.	$ 35,000	$ 339,423 [2]	$ 374,423
Faheem Hasnain	$ 35,000	$ 300,521 [3]	$ 335,521
Caryn Peterson	$ 35,000	$ 139,266 [4]	$ 174,266
Andrew Spaventa	$ 35,000	$ 139,266 [5]	$ 174,266
Peter Thompson, M.D. [6]	—	—	—
Cindy Perettie [6]	—	—	—
Douglas Fisher, M.D. [6]	—	—	—

(1) The amounts reported in this column do not reflect dollar amounts actually received by the non-employee director. Instead, the amounts reflect the aggregate grant date fair value of the stock options granted to the non-employee director during 2025 under the 2018 Plan, computed in accordance with FASB ASC Topic 718. As required by SEC rules, the amount shown excludes the impact of estimated forfeitures related to service-based vesting conditions. The amount reported in this column reflects the accounting cost for these stock options and does not correspond to the actual economic value that may be received by the non-employee director upon the exercise of the stock options or any sale of the underlying shares of common stock.

(2) In November 2025, we granted Dr. Daniel an option to purchase 36,429 shares of common stock and in December 2025, we granted Dr. Daniel an option to purchase 10,119 shares of common stock, each with an exercise price of $5.74 per share. The shares subject to each of the options will vest in 48 equal monthly installments over a four-year period measured from the vesting commencement date of November 20, 2025, subject to continued services. As of December 31, 2025, Dr. Daniel held an aggregate of 113,820 outstanding and unexercised stock options and did not hold any other stock awards.

(3) In November 2025, we granted Mr. Hasnain an option to purchase 41,489 shares of common stock with an exercise price of $5.74 per share. The shares subject to the option will vest in 48 equal monthly installments over a four-year period measured from the vesting commencement date of November 20, 2025, subject to continued services. As of December 31, 2025, Mr. Hasnain held an aggregate of 68,811 outstanding and unexercised stock options and did not hold any other stock awards. As described above, in September 2026, Mr. Hasnain agreed to extend the monthly vesting schedule of the remaining unvested shares subject to his option, such that this option will vest in full six years following its vesting commencement date of November 20, 2025, rather than pursuant to its original four year vesting schedule.

(4) In November 2025, we granted Ms. Peterson an option to purchase 19,226 shares of common stock with an exercise price of $5.74 per share. The shares subject to the option will vest in 48 equal monthly installments over a four-year period measured from the vesting commencement date of November 20, 2025, subject to continued services. As of December 31, 2025, Ms. Peterson held an aggregate of 56,357 outstanding and unexercised stock options and did not hold any other stock awards.

(5) In November 2025, we granted Mr. Spaventa an option to purchase 19,226 shares of common stock with an exercise price of $5.74 per share. The shares subject to the option will vest in 48 equal monthly installments over a four-year period measured from the vesting commencement date November 20, 2025. As of December 31, 2025, Mr. Spaventa held an aggregate of 48,572 outstanding and unexercised stock options and did not hold any other stock awards. As described above, in September 2026, Mr. Spaventa agreed to extend the monthly vesting schedule of the remaining unvested shares subject to his option, such that this option will vest in full six years following its vesting commencement date of November 20, 2025, rather than pursuant to its original four year vesting schedule.

(6) These non-employee directors did not receive any cash compensation, equity grants or other compensation during the year ended December 31, 2025. These non-employee directors did not hold any unexercised stock options or other stock awards as of December 31, 2025.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2023 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets at year-end for our last two completed fiscal years, 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 in the section titled "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers, and stockholders.

Convertible Preferred Stock Financings

Series C Convertible Preferred Stock Financings. In various closings from October 2025 to November 2025, we sold to investors in private placements an aggregate of 76,173,492 shares of Series C convertible preferred stock, pursuant to a Series C preferred stock purchase agreement originally entered into in October 2025, as amended in October 2025 to provide for additional closings. The per share purchase price was $1.5179, and we received gross proceeds of approximately $115.6 million.

The following table summarizes the Series C convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the applicable closing of the Series C convertible preferred stock, and entities affiliated with certain of our executive officers and directors. Each outstanding share of convertible preferred stock, including the shares identified in the table below, will convert into shares of common stock and the conversion ratios will be proportionally adjusted immediately prior to the closing of this offering.

Participants	Series C Convertible Preferred Stock (Shares)
5% or Greater Stockholders[1]	
OrbiMed Private Investments VII, LP[2]	5,011,393
Gilead Sciences, Inc.	16,470,124
Frazier Life Sciences X, L.P.	2,595,550
Q Healthcare Holding LLC	13,176,099
ARCH Venture Fund X, L.P.[3]	2,568,823
ARCH Venture Fund X Overage, L.P.[3]	2,118,277
Platinum Falcon B 2018 RSC Limited	2,510,268
Officers and Directors	
Andrew Spaventa[4]	1,780,946
Thomas Daniel, M.D.[5]	173,972
Faheem Hasnain[6]	70,352
Douglas Fisher, M.D.[7]	731,274

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled "Principal Stockholders."

(2) Peter A. Thompson, M.D., a member of our board of directors, is a Member of OrbiMed Advisors LLC, the managing member of the general partner of OrbiMed Private Investments VII, LP. Dr. Thompson was designated to serve on our board of directors as a representative of the holders of our Series A convertible preferred stock by OrbiMed.

(3) Thomas Daniel, M.D., a member of our board of directors, is a Venture Partner of ARCH Venture Partners, LLC, the general partner of ARCH Venture Fund X, L.P. and ARCH Venture Fund X Overage, L.P. Dr. Daniel was designated to serve on our board of directors as a representative of the holders of our Series A convertible preferred stock by the ARCH entities.

(4) Represents shares purchased by Axon Holdings, LLC Series XXI, an entity affiliated with Mr. Spaventa.

(5) Represents shares purchased by the Thomas Oran Daniel Living Trust (Series A) and the 2024 Corinne Marie Daniel Irrevocable Trust Dated 12/19/2024 and 2024 Lyle Robert Daniel Irrevocable Trust Dated 12/19/2024 (Series C), trusts affiliated with Dr. Daniel.

(6) Represents shares purchased by the Hasnain Revocable Trust, a trust affiliated with Mr. Hasnain.

(7) Represents shares purchased by Revelation Healthcare Fund III, L.P., an entity affiliated with Dr. Fisher.

Investors' Rights Agreement

We entered into an investors' rights agreement in October 2018, as last amended and restated in October 2025 (Investors' Rights Agreement), with the holders of our convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the Investors' Rights Agreement), all rights under this agreement will terminate upon closing of this offering. The registration rights will continue following this offering and will terminate five years after the closing of this offering. See the section titled "Description of Capital Stock—Registration Rights" for more information regarding these registration rights.

Voting Agreement

We entered into a voting agreement in October 2018, as last amended and restated in October 2025 (Voting Agreement), with the holders of our convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated, pursuant to which the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Caryn Peterson, Peter A. Thompson, M.D., Thomas Daniel, M.D., Douglas Fisher, M.D., Andrew Spaventa, Damien McDevitt, Ph.D., and Faheem Hasnain. Pursuant to the Voting Agreement, Dr. McDevitt, as our Chief Executive Officer, serves on our board of directors as the CEO director. Mr. Spaventa was initially selected to serve on our board of directors as representative of the holders of our common stock, Ms. Peterson was initially selected to serve on our board of directors as representative of the holders of our Series Seed convertible preferred stock, Dr. Thompson and Dr. Daniel were initially selected to serve on our board of directors as representatives of the holders of our Series A convertible preferred stock, and Dr. Fisher was initially selected to serve on our board of directors as a representative of the holders of our Series B convertible preferred stock. Mr. Hasnain was initially selected to serve on our board of directors as the independent director and Chairman of the board of directors.

The Voting Agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed, or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail in the section titled "Management—Board Composition and Election of Directors."

Right of First Refusal and Co-Sale Agreement

We entered into a right of first refusal and co-sale agreement in October 2018, as last amended and restated in October 2025 (ROFR Agreement), with holders of our common stock affiliated with our executive officers, which entities are referred to in the ROFR Agreement as key holders, and certain other holders of convertible preferred stock, including the holders of more than 5% of our capital stock listed above. Pursuant to the ROFR Agreement, we have a right of first refusal on certain transfers of our shares by the key holders, holders of our convertible preferred stock have a secondary right of first refusal on such transfers, and such convertible preferred stockholders have a right of co-sale in respect of such transfers. The ROFR Agreement will terminate upon the closing of this offering.

Table of Contents

Executive Officer Promissory Notes and Related Transactions

In August 2024, Kameel Farag, our former Chief Financial Officer, sold 50,293 shares of common stock to a preferred shareholder of the Company which were previously early exercised through a promissory note and paid the outstanding promissory note balance of $0.2 million to the Company.

In December 2024, we entered into an agreement to repurchase 196,821 shares of common stock for $1.6 million issued to Dr. McDevitt, which was used to cancel principal and interest of $1.6 million on an outstanding promissory note for the early exercise of shares by Dr. McDevitt. Concurrently, we granted Dr. McDevitt 196,820 new awards with the same vesting terms.

In August 2026, we entered into an agreement to forgive the outstanding principal and accrued interest of approximately $2.1 million on three promissory notes issued to Dr. McDevitt for the early exercise of stock options, representing 561,646 shares of underlying common stock. In connection with the forgiveness, Dr. McDevitt agreed to amend the vesting schedule applicable to his November 2025 option grant for 387,063 shares of common stock, extending the vesting period from four to six years for the remaining unvested options.

In September 2026, we entered into agreements to forgive the outstanding principal and accrued interest of approximately $212,928 and $30,550 on promissory notes issued to Faheem Hasnain and Andrew Spaventa, respectively, for the early exercise of stock options, representing 53,314 and 7,747 shares of underlying common stock, respectively. In connection with the forgiveness, Mr. Hasnain and Mr. Spaventa each agreed to amend the vesting schedule applicable to their November 2025 option grants for 41,489 and 19,226 shares of common stock, respectively, extending the vesting period from four to six years for the remaining unvested options.

For additional information regarding the loan forgiveness agreements and related option amendments, see the section titled “Executive and Director Compensation—Non-Employee Director Compensation.”

Employment of Immediate Family Members of Executive Officers

We currently employ immediate family members of two of our executive officers.

Conor McDevitt, the son of Dr. McDevitt, our Chief Executive Officer, has been employed by us since December 10, 2025 as a Transformational Business Analyst. For the year ended December 31, 2025, Mr. McDevitt’s total compensation, including base salary, bonus and other compensation, including consulting fees paid prior to Mr. McDevitt’s hire date and the grant date fair value of the stock options granted to Mr. McDevitt, was approximately $91,000. Mr. McDevitt’s total compensation, including base salary, bonus and other compensation for the 2026 fiscal year is expected to be approximately $142,000.

Miranda Pratt, the daughter of Dr. Johnson-Pratt, our Sasineprocel Development Lead and Chief Commercial Officer, has been employed by us since December 1, 2025 as a Scientific Communications Manager. For the year ended December 31, 2025, Ms. Pratt’s total compensation, including base salary, bonus and other compensation, including consulting fees paid prior to Ms. Pratt’s hire date and the grant date fair value of the stock options granted to Ms. Pratt, was approximately $52,000. Ms. Pratt’s total compensation, including base salary, bonus and other compensation for the 2026 fiscal year is expected to be approximately $161,000.

The compensation levels of Mr. McDevitt and Ms. Pratt were based on reference to internal pay equity when compared to the compensation paid to employees in similar positions, that were not related to our executive officers and directors. They were also each eligible for equity awards on the same general terms and conditions applicable to other employees at the Company in similar positions, who were not related to our executive officers and directors.

Table of Contents

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines, and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws that will be in effect upon the closing of this offering will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement, or payment of a judgment under certain circumstances. For further information, see the section titled "Description of Capital Stock — Limitations on Liability and Indemnification of Officers and Directors."

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness, and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Table of Contents

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of September 15, 2026 and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 19,727,905 shares of common stock outstanding on September 15, 2026 which gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of our common stock immediately prior to the closing of this offering. We have based our calculation of the percentage of beneficial ownership after this offering on 29,102,905 shares of our common stock outstanding immediately after the closing of this offering, which reflects the conversion of our convertible preferred stock into common stock as described in the prior sentence and further reflects the issuance of shares of common stock in this offering, assuming that the underwriters will not exercise their option to purchase up to an additional 1,406,250 shares of our common stock.

In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable or otherwise vest within 60 days of September 15, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

The table below excludes any potential purchases in this offering by the beneficial owners identified in the table below.

Table of Contents

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Aspen Neuroscience, Inc., 10835 Road to the Cure, Suite 100, San Diego, California 92121. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Stockholders			
Entities affiliated with OrbiMed Private Investments VII, LP[1]	2,589,132	13.1%	8.9%
Entities affiliated with Gilead Sciences, Inc. [2]	1,666,663	8.4%	5.7%
Entities affiliated with Frazier Life Sciences X, L.P. [3]	1,340,988	6.8%	4.6%
Entities affiliated with Q Healthcare Holding LLC [4]	1,333,330	6.8%	4.6%
Entities affiliated with ARCH Venture Fund X, L.P.[5]	2,421,589	12.3%	8.3%
Entities affiliated with Abu Dhabi Investment Authority [6]	1,296,927	6.6%	4.5%
Entities affiliated with Medical Excellence Capital Partners, LP [7]	1,078,524	5.5%	3.7%
Named Executive Officers and Directors			
Damien McDevitt [8]	835,259	4.2%	2.8%
Dalen Meeter [9]	71,771	*	*
Kim Raineri [10]	112,786	*	*
Faheem Hasnain [11]	126,495	*	*
Thomas Daniel, M.D.[12]	113,082	*	*
Douglas Fisher, M.D.	-	-	-
Cindy Perettie	-	-	-
Caryn Peterson [13]	41,536	*	*
Andrew Spaventa [14]	382,305	1.9%	1.3%
Peter A. Thompson, M.D. [15]	2,589,132	13.1%	8.9%
All executive officers and directors as a group (12 persons) [16]	4,336,349	21.2%	14.5%

* Less than 1%.

(1) Consists of 2,589,132 shares of our common stock held by OrbiMed Private Investments VII, LP (OPI VII). OrbiMed Capital GP VII LLC (OrbiMed GP), is the general partner of OPI VII. OrbiMed Advisors LLC (OrbiMed Advisors) is the managing member of OrbiMed GP. By virtue of such relationships, OrbiMed GP and OrbiMed Advisors may be deemed to have voting and investment power with respect to the shares held by OPI VII. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, W. Carter Neild, and Geoffrey C. Hsu. Each of OrbiMed GP, OrbiMed Advisors, Dr. Gordon, Mr. Hsu, and Mr. Neild disclaim beneficial ownership of the shares held by OPI VII, except to the extent of its or his pecuniary interest therein if any. The address for each of the entities and individuals identified in this footnote is c/o OrbiMed Advisors LLC, 601 Lexington Avenue 54th Floor, New York, NY 10022.

(2) Consists of 1,666,663 shares of our common stock held by Gilead Sciences, Inc. (Gilead). The address for Gilead is 333 Lakeside Drive, Foster City, California 94404.

(3) Consists of 1,340,988 shares of our common stock held by Frazier Life Sciences X, L.P. (FLS X). FHMLS X, L.P. is the general partner of FLS X, and FHMLS X, L.L.C. is the general partner of FHMLS X, L.P. James Topper, M.D., Ph.D., and Patrick Heron are the sole managing members of FHMLS X, L.L.C. and share voting and investment power of the securities held by FLS X. Dr. Topper and Mr. Heron disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein. The address for above referenced entities and persons is 1001 Page Mill Rd., Building 4, Ste. B, Palo Alto, CA 94304.

Table of Contents

(4) Q Healthcare Holding LLC (Q Healthcare) is a limited liability company formed pursuant to the regulations of the Qatar Financial Centre and is a wholly-owned subsidiary of Qatar Investment Authority ("QIA"). QIA is the sole member of Q Healthcare. Q Healthcare directly holds 1,333,330 shares of our common stock. Each of QIA and Q Healthcare may be deemed to beneficially own the shares of our common stock held by Q Healthcare. The business address of Q Healthcare and QIA is Ooredoo Tower (Building 14), Al Dafna Street (Street 801), Al Dafna (Zone 61), Doha, Qatar.

(5) Consists of (i) 1,327,182 shares of our common stock held by ARCH Venture Fund X, L.P. (ARCH X) and (ii) 1,094,407 shares of our common stock held by ARCH Venture Fund X Overage, L.P. (ARCH X Overage). ARCH Venture Partners X, L.P. (AVP X LP), is the sole general partner of ARCH X. ARCH Venture Partners X Overage, L.P. (AVP X Overage LP), is the sole general partner of ARCH X Overage. ARCH Venture Partners X, LLC (AVP X LLC), is the sole general partner of each of AVP X LP and AVP X Overage LP. Keith Crandell, Kristina Burow, Steven Gillis, and Robert Nelsen, collectively the AVP X Committee Members, comprise the investment committee of AVP X LLC. AVP X LP and AVP X Overage LP may be deemed to beneficially own the shares held by ARCH X and ARCH X Overage, respectively, AVP X LLC may be deemed to beneficially own the shares held by ARCH X and ARCH X Overage, and each of the AVP X Committee Members may be deemed to share the power to direct the disposition and vote of the shares held by ARCH X and ARCH X Overage. Each of AVP X LP, AVP X Overage LP, AVP X LLC, and the AVP X Committee Members disclaims beneficial ownership except to any pecuniary interest therein. The address for these entities and individuals is in c/o Arch Venture Partners, 8755 W. Higgins Road, Suite 1025, Chicago, IL 60631.

(6) Consists of 1,296,927 shares of our common stock held by Abu Dhabi Investment Authority (ADIA), directly or through one or more of its direct or indirect subsidiaries, including primarily Platinum Falcon B 2018 RSC Limited (Platinum Falcon), a restricted scope company incorporated in the Abu Dhabi Global Market. ADIA is a public institution established by the Government of the Emirate of Abu Dhabi. By reason of its ownership of Platinum Falcon and pursuant to the rules and regulations of the SEC, ADIA may also be deemed to share investment and voting power over and, therefore, beneficial ownership of, the shares held directly by Platinum Falcon. The address for ADIA is 211 Corniche Street, P.O. Box 3600, Abu Dhabi, United Arab Emirates and the address for Platinum Falcon B 2018 RSC Limited is Level 26, Al Khatem Tower, Abu Dhabi Global Market Square, Al Maryah Island, Abu Dhabi, United Arab Emirates.

(7) Consists of (i) 515,192 shares of our common stock held by Medical Excellence Capital Partners, LP and (ii) 563,332 shares of our common stock held by Medical Excellence Capital Partners II, LP.The address for each of the entities identified in this footnote is 355 Old Mill Road, Nissequogue, NY 11780.

(8) Consists of (i) 485,751 shares of our common stock held by Damien McDevitt and Pamela Marnell-McDevitt, Co-trustees of the Marnell-McDevitt Family Trust dated May 2, 2019, of which 93,607 shares remain subject to performance-based vesting conditions and forfeiture if such conditions are not satisfied, (ii) 25,299 shares of our common stock held by Finn McDevitt, Trustee of the Finn McDevitt 2025 Irrevocable Trust, (iii) 25,299 shares of our common stock held by Aran McDevitt, Trustee of the Aran McDevitt 2025 Irrevocable Trust, (iv) 25,299 shares of our common stock held by Conor McDevitt, Trustee of the Conor McDevitt 2025 Irrevocable Trust and (v) 273,611 shares subject to options that are exercisable within 60 days of September 15, 2026.

(9) Represents 71,771 shares subject to options that are exercisable within 60 days of September 15, 2026.

(10) Represents 112,786 shares subject to options that are exercisable within 60 days of September 15, 2026.

(11) Consists of (i) 26,658 shares of our common stock held by Faheem Hasnain, (ii) 36,349 shares of our common stock held by Hasnain Revocable Trust, (iii) 13,329 shares of our common stock held by Premier Trust, Inc., Trustee of the Myles J. Hasnain 2021 Irrevocable Trust, (iv) 13,329 shares of our common stock held by Premier Trust, Inc., Trustee of the Aaron D. Hasnain 2021 Irrevocable Trust and (v) 36,830 shares subject to options that are exercisable within 60 days of September 15, 2026.

Table of Contents

(12) Consists of (i) 17,572 shares of our common stock held by 2024 Corinne Marie Daniel Irrevocable Trust Dated 12/19/2024, (ii) 17,572 shares of our common stock held by 2024 Lyle Robert Daniel Irrevocable Trust Dated 12/19/2024, and (iii) 77,938 shares subject to options that are exercisable within 60 days of September 15, 2026.

(13) Represents 41,536 shares subject to options that are exercisable within 60 days of September 15, 2026.

(14) Consists of (i) 7,747 shares of our common stock held by Andrew Spaventa, (ii) 49,914 shares of our common stock held by The Andrew K. Spaventa Living Trust Dated April 9, 2014, (iii) 20,239 shares of our common stock held by Sharon Spaventa, (iv) 20,239 shares of our common stock held by Jon Spaventa, (v) 70,194 shares of common stock held directly by Axon Holdings, LLC Series XIII - Aspen Seed, of which Mr. Spaventa is a managing partner, (vi) 180,221 shares of our common stock held directly by Axon Holdings, LLC Series XXI - Aspen C, of which Mr. Spaventa is a managing partner, and (vii) 33,751 shares subject to options that are exercisable within 60 days of September 15, 2026.

(15) Consists of 2,589,132 shares of our common stock held by OPI VII. OrbiMed GP is the general partner of OPI VII, and OrbiMed Advisors is the managing member of OrbiMed GP. By virtue of such relationships, OrbiMed GP and OrbiMed Advisors may be deemed to have voting power and investment power over the securities held by OPI VII and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, W. Carter Neild and Geoffrey C. Hsu, each of whom disclaims beneficial ownership of the shares held by OPI VII. Peter A. Thompson, M.D., a member of our board of directors, is a member of OrbiMed Advisors. Dr. Thompson disclaims beneficial ownership of the shares held by OPI VII, except to the extent of his pecuniary interest therein, if any.

(16) Consists of (i) 3,624,143 shares of our common stock beneficially owned by our current executive officers and directors and (ii) 712,206 shares subject to options that are exercisable within 60 days of September 15, 2026.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation (Charter) and amended and restated bylaws (Bylaws) that will be in effect upon the closing of this offering, our investors' rights agreement and of the Delaware General Corporation Law (DGCL). Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our Charter, Bylaws, and our investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Following the closing of this offering, our authorized capital stock will consist of 500,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock

As of June 30, 2026, there were 19,703,600 shares of our common stock outstanding and held of record by 127 stockholders, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 17,971,324 shares of common stock, which will automatically occur immediately prior to the closing of this offering, and (ii) the Note Forgiveness, including the treatment of 622,707 shares of common stock as outstanding. Based on the number of shares of common stock outstanding as of June 30, 2026, and further assuming the issuance by us of 9,375,000 shares of common stock in this offering, there will be 29,078,600 shares of common stock outstanding upon the closing of this offering.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter.

Dividend Rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. See "Dividend Policy" for more information.

Liquidation

In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

No Preemptive or Similar Rights

Holders of common stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking funds provisions applicable to the common stock.

Fully Paid and Non-assessable

All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable.

The rights, preferences, and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Upon the closing of this offering, all of our previously outstanding shares of convertible preferred stock will have been converted into common stock, there will be no authorized shares of our previously outstanding convertible preferred stock, and we will have no shares of preferred stock outstanding.

Under the terms of our Charter, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock. The shares of preferred stock may be issued in series, and shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions providing for the issuance of such stock adopted from time to time by our board of directors. Our board of directors is expressly vested with the authority to determine and fix in the resolution or resolutions providing for the issuances of all or any of the remaining preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations, or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Delaware.

Options

As of June 30, 2026, options to purchase 3,043,497 shares of our common stock were outstanding, of which 1,344,458 were vested as of that date. For additional information regarding the terms of our 2018 Plan, see the section titled “Executive and Director Compensation— Employee Stock Plans—2018 Stock Plan.”

Warrants

As of June 30, 2026, the warrants to purchase 17,778 shares of our common stock are outstanding. On December 20, 2022 in connection with a Loan and Security Agreement (the Loan Agreement) with a lender (the Lender), we issued Lender a warrant to purchase 13,333 shares of our common stock at an exercise price of $7.71 per share. In conjunction with amending our line of credit with Lender on November 15, 2024, we issued Lender a warrant to purchase 4,445 shares of our common stock at an exercise price of $7.71. The warrants contain a net exercise provision under which the Lender may, in lieu of payment of the exercise price in cash, surrender the warrant, and receive, a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. The warrants expire ten years from their date of issuance.

Registration Rights

Investors’ Rights Agreement

Upon the closing of this offering, holders of 18,956,358 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of convertible preferred stock immediately prior to the closing of this offering and 985,034 shares of common stock held by certain key holders, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an investors’ rights agreement by and among us and certain investors. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

Form S-1. If at any time during the six months following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 35% of the registrable securities then outstanding request in writing that we effect a registration with respect to the registrable securities having an aggregate offering price, net of selling expenses, of at least $10.0 million, we may be required to provide notice of such request to all holders of registrable securities and offer them the opportunity to participate in such registration (other than certain key holders who do not

Table of Contents

have demand registration rights), and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, the board determines in its good faith judgment that it would be materially detrimental to us and our stockholders for such registration statement to become effective.

Form S-3. If at any time we become entitled under the Securities Act to register our shares on Form S-3, and the holders of at least 20% of the registrable securities then outstanding request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the anticipated aggregate offering price, net of expenses, is at least $1.0 million, we may be required to provide notice of such request to all holders of registrable securities and offer them the opportunity to participate in such registration (other than certain key holders who do not have demand registration rights), and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, the board determines in its good faith judgment that it would be materially detrimental to us and our stockholders for such registration statement to become effective.

If the holders requesting registration intend to distribute their shares by means of an underwritten offering, the underwriter will be selected by the board of directors and shall be reasonably acceptable to a majority in interest of the initiating holders of registrable securities. The underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares in accordance with the cut-back provisions of the investors' rights agreement.

Piggyback Registration Rights

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwritten offering, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares in accordance with the cut-back provisions of the investors' rights agreement.

Indemnification

Our investors' rights agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of, among other things, material misstatements or omissions in a registration statement attributable to us, and they are obligated to indemnify us for, among other things, material misstatements or omissions attributable to them.

Expenses

Other than underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of registrable securities, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements not to exceed $50,000 of a counsel for the selling securityholders, blue sky fees and expenses, and the expenses of any special audits incident to the registration.

Termination of Registration Rights

The registration rights terminate upon the earlier of (i) the closing of a Deemed Liquidation Event or SPAC Transaction (as each such term is defined in our current certificate of incorporation), (ii) five years after the date of this offering or (iii) with respect to a particular holder, such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all shares by such holder without limitation during a three-month period without registration.

Table of Contents

Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws

Delaware law, our Charter, and our Bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our Bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. These provisions may preclude our stockholders from bringing matters before an annual meeting of stockholders or from making nominations at an annual meeting of stockholders.

Elimination of Stockholder Action by Written Consent

Our Charter and Bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our Charter provides that our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, with one class being elected each year by our stockholders. For more information on the classified board of directors, see the section titled “Management—Board Composition and Election of Directors.” This system of electing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our Charter provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than a two-thirds majority of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Table of Contents

Stockholders Not Entitled to Cumulative Voting

Our Charter does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our Charter provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any stockholder (including a beneficial owner of stock) to bring: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of, or claim based on, breach of a fiduciary duty owed by any of our directors, officers, employees, agents or stockholders to us or to our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, the Charter or the Bylaws; (iv) any action to interpret, apply, enforce or determine the validity of the Charter or Bylaws; or (v) any action asserting a claim against us governed by the internal affairs doctrine. Our Charter also provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act, the Exchange Act, and any claims for which federal courts have exclusive jurisdiction.

For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 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. Our Charter also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

Limitations on Liability and Indemnification of Officers and Directors

Our Charter provides that no director or officer will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director or officer, except as required by applicable law, as in effect from time to time. Currently, Delaware law requires that liability be imposed for the following:

- any breach of the director's duty of loyalty to our company or our stockholders;
- any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; and
- any transaction from which the director derived an improper personal benefit.

Table of Contents

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior, except in the situations described above.

Our Bylaws provide that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director, officer or trustee. We will reimburse the expenses, including attorneys' fees, incurred by a person indemnified by this provision. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least sixty-six and two-thirds percent (66-2/3%) of the total voting power of all of our outstanding voting stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Odyssey Transfer and Trust Company. The transfer agent and registrar's address is 860 Blue Gentian Rd., Suite 320, Eagan, MN 55121.

The Nasdaq Global Select Market Listing

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

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of June 30, 2026, and assuming (i) the issuance of 9,375,000 shares in this offering, (ii) the automatic conversion of all of our outstanding shares of convertible preferred stock into 17,971,324 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the closing of this offering, (iii) no exercise of the underwriters' option to purchase additional shares of common stock and (iv) no exercise of outstanding options, we will have outstanding an aggregate of 29,078,600 shares of common stock following the closing of this offering.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 19,703,600 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

Lock-Up Agreements

We, our officers, directors, and substantially all of our securityholders, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, among other things and subject to certain exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, 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, request or demand that we file a registration statement related to our common stock, or exercise any right with respect to the registration of any of such securities, or file or cause to be filed any registration statement in connection therewith, under the Securities Act, or enter into any swap or any other agreement or any transaction that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock, without the prior written consent of Leerink Partners LLC, Piper Sandler & Co., Stifel, Nicolaus & Company, Incorporated and UBS Securities LLC.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 10b5-1 Trading Plans

Following the closing of this offering, certain of our officers, directors, and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director, or stockholder when entering into the plan, without further direction from such officer, director, or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director, or stockholder in connection with this offering.

Table of Contents

Rule 144

Affiliate Resales of Restricted Securities

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, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, and who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of 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 290,786 shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

An "affiliate" is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with an issuer. Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

Non-Affiliate Resales of Restricted Securities

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, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701 as currently in effect, any of an issuer's employees, directors, officers, consultants, or advisors who purchase shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act are entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements. However, substantially all Rule 701 shares are subject to lock-up agreements as described above and will become eligible for sale in compliance with Rule 144 only upon the expiration of the restrictions set forth in those agreements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Table of Contents

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the closing of this offering, holders of 18,956,358 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering and 985,034 shares of common stock held by certain key holders, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by our affiliates. See the section titled “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreements described above.

Table of Contents

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax provisions of the Code. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "foreign controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

Table of Contents

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying cash dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described in the subsection titled "—Sale or Other Taxable Disposition" below.

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other intermediary, the Non-U.S. Holder will be required to provide appropriate documentation to the intermediary, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder 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, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Table of Contents

Sale or Other Taxable Disposition

Subject to the discussion below of backup withholding and withholding under FATCA (defined below), a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is 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, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC) for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will be subject to backup withholding or information reporting unless the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Table of Contents

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the United States Department of Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Non-U.S. Holders typically will be required to furnish certifications (generally on the applicable IRS Form W-8) or other documentation to provide the information required by FATCA or to establish compliance with or an exemption from withholding under FATCA. FATCA withholding may apply where payments are made through a non-U.S. intermediary that is not FATCA compliant, even where the Non-U.S. Holder satisfies the holder's own FATCA obligations.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies currently to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, proposed Treasury Regulations would eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. There can be no assurance that the proposed Treasury Regulations will be finalized in their present form.

The United States and a number of other jurisdictions have entered into intergovernmental agreements to facilitate the implementation of FATCA. Any applicable intergovernmental agreement may alter one or more of the FATCA information reporting and withholding requirements. Prospective investors should consult their own tax advisors regarding the potential application of withholding under FATCA to an investment in our common stock, including the applicability of any intergovernmental agreements.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Table of Contents

UNDERWRITING

Leerink Partners LLC, Piper Sandler & Co., Stifel, Nicolaus & Company, Incorporated, UBS Securities LLC and Oppenheimer & Co. Inc. are acting as representatives of each of the underwriters named below and as joint bookrunning managers for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Leerink Partners LLC	3,281,250
Piper Sandler & Co.	2,343,750
Stifel, Nicolaus & Company, Incorporated	2,343,750
UBS Securities LLC	937,500
Oppenheimer & Co. Inc.	468,750
Total	9,375,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and subject to other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the initial public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.63 per share. After the initial offering of the shares, the public offering price, concession or any other term of this offering may be changed by the representatives.

The following table shows the initial public offering price, underwriting discounts and commissions and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

		Total	
	Per Share	Without Option	With Option
Initial public offering price	$ 15.00	$ 140,625,000	$ 161,718,750
Underwriting discounts and commissions	$ 1.05	$ 9,843,750	$ 11,320,312
Proceeds, before expenses, to us	$ 13.95	$ 130,781,250	$ 150,398,438

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $5.0 million. We also have agreed to reimburse the underwriters for up to $45,000 for their FINRA counsel fee.

Table of Contents

Over-Allotment Option

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,406,250 additional shares at the initial public offering price, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to the conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and substantially all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Leerink Partners LLC, Piper Sandler & Co., Stifel, Nicolaus & Company, Incorporated and UBS Securities LLC on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant for the sale of any common stock;
- otherwise dispose of or transfer any common stock;
- request or demand that we file a registration statement related to the common stock; or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock, whether any such swap, agreement or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

The lock-up provisions apply to common stock and to securities convertible into or exchangeable or exercisable for common stock. They also apply to common stock owned now or acquired later by the person executing the lock-up agreement or for which the person executing the lock-up agreement later acquires the power of disposition.

Nasdaq Global Select Market Listing

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

Determination of Offering Price

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

Table of Contents

An active trading market for the shares may not develop. It is also possible that after this offering, our common stock will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' over-allotment option described above. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares 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 over-allotment option granted to them under the underwriting agreement described above. "Naked" short sales are sales in excess of such over-allotment option. 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 our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' 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. The underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

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. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their 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. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their 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. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant State) no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the EU Prospectus Regulation, except that shares may be offered to the public in that Relevant State at any time:

A. to any qualified investor as defined under Article 2 of the EU Prospectus Regulation;

B. to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the EU Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

C. in any other circumstances falling within Article 1(4) of the EU Prospectus Regulation,

provided that no such offer of shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the EU Prospectus Regulation, supplement a prospectus pursuant to Article 23 of the EU Prospectus Regulation or publish an Annex IX document pursuant to Article 1(4) of the EU Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "EU Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom, except that the shares may be offered to the public in the United Kingdom at any time:

A. where the offer is conditional on the admission of the shares to trading on the London Stock Exchange plc's main market (in reliance on the exception in paragraph 6(a) of Schedule 1 of the POATR);

B. to any qualified investor as defined under paragraph 15 of Schedule 1 of the POATR;

C. to fewer than 150 persons (other than qualified investors as defined under paragraph 15 of Schedule 1 of the POATR), subject to obtaining the prior consent of the representatives for any such offer; or

D. in any other circumstances falling within Part 1 of Schedule 1 of the POATR.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication to any person which presents sufficient information on: (a) the shares to be offered; and (b) the terms on which they are to be offered, to enable an investor to decide to buy or subscribe for the shares and the expressions "POATR" means the Public Offers and Admissions to Trading Regulations 2024.

Each person in the United Kingdom who receives any communication in respect of, or who acquires any of our shares under the offers to the public contemplated in this prospectus, or to whom our shares are otherwise made available, will be deemed to have represented, warranted, acknowledged and agreed to and with us, the representatives, and their respective affiliates that it meets the criteria outlined in this section.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Australia

This prospectus:

A. does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);

B. has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC) as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and

C. may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (Exempt Investors).

The shares of common stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares of common stock may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares of common stock may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares of common stock, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares of common stock under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares of common stock you undertake to us that you will not, for a period of 12 months from the date of issue of the shares of common stock, offer, transfer, assign or otherwise alienate those shares of common stock to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Hong Kong

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the SFO) of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the CO) or which do not constitute an offer to

Table of Contents

the public within the meaning of the CO. No advertisement, invitation or document relating to the common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 to do so under the securities laws of Hong Kong) other than with respect to shares of common stock 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 thereunder.

Notice to Prospective Investors in Japan

The shares of common stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the common stock nor any interest therein may be offered or sold, 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 a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore), as modified or amended from time to time (the SFA) pursuant to Section 274 of the SFA; (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

A. 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

B. 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 or securities-based derivatives contract (each term as defined in Section 2(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 common stock pursuant to an offer made under Section 275 of the SFA except:

A. 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;

B. where no consideration is or will be given for the transfer;

C. as specified in Section 276(7) of the SFA; or

D. as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification - Solely for the purposes of its obligations pursuant to sections 309B(1)(a) and 309B(1)(c) of the SFA, the company has determined, and hereby notifies all relevant persons (as defined in Section 309A of the SFA) that the shares of common stock are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to Prospective Investors in Switzerland

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and 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 document nor any other offering or marketing material relating to the shares of common stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the company, the shares of common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares of common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares of common stock.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the Israeli 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 (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," 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.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by DLA Piper LLP (US), San Diego, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2025 and 2024, and for each of the two years in the period ended December 31, 2025, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are not currently subject to the information and periodic and current reporting requirements of the Exchange Act. Upon the closing of this offering, we became subject to the information and periodic and current reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements, and other information with the SEC. The SEC maintains a website at *www.sec.gov* that contains reports, proxy statements, and other information regarding companies that file electronically with it. Our periodic and current reports, proxy statements and other information will be available at *www.sec.gov*.

We also maintain a website at *www.aspenneuroscience.com*. Upon the closing of this offering, you may access our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

Table of Contents

Aspen Neuroscience, Inc.

Index to Financial Statements

Audited Financial Statements as of December 31, 2025 and 2024 and for the Years Ended December 31, 2025 and 2024

	Page
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Comprehensive Loss	F-5
Statements of Convertible Preferred Stock and Stockholders' Deficit	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

Unaudited Financial Statements as of June 30, 2026 and December 31, 2025 and for the Six Months Ended June 30, 2026 and 2025

	Page
Balance Sheets	F-26
Statements of Operations	F-27
Statements of Comprehensive Loss	F-28
Statements of Convertible Preferred Stock and Stockholders' Deficit	F-29
Statements of Cash Flows	F-30
Notes to Unaudited Financial Statements	F-31

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Aspen Neuroscience, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Aspen Neuroscience, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

San Diego, California
March 30, 2026
except for the third paragraph of Note 13, as to which the date is
October 26, 2026

Table of Contents

Aspen Neuroscience, Inc.

Balance Sheets
(in thousands, except share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 82,097	$ 15,221
Marketable securities	28,602	42,461
Prepaid expenses and other current assets	1,687	1,908
Total current assets	112,386	59,590
Operating lease right-of-use assets	8,532	10,852
Property and equipment, net	18,900	12,290
Restricted cash	622	622
Other noncurrent assets	3,223	6,857
Total assets	$ 143,663	$ 90,211
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,640	$ 853
Accrued expenses	7,605	8,126
Operating lease liabilities, current	3,532	3,429
Other current liabilities	486	1,630
Total current liabilities	14,263	14,038
Operating lease liabilities, noncurrent	7,669	10,400
Other noncurrent liabilities	—	20
Commitments and contingencies		
Series Seed convertible preferred stock, $0.0001 par value; 8,323,862 shares authorized, issued and outstanding at December 31, 2025 and 2024; $4,500 aggregate liquidation preference at December 31, 2025 and 2024	4,445	4,445
Series Seed-2 convertible preferred stock, $0.0001 par value; 1,966,511 shares authorized, issued and outstanding at December 31, 2025 and 2024; $2,025 aggregate liquidation preference at December 31, 2025 and 2024	2,008	2,008
Series A-1 convertible preferred stock, $0.0001 par value; 20,631,861 shares authorized, issued and outstanding at December 31, 2025 and 2024; $35,000 aggregate liquidation preference at December 31, 2025 and 2024	34,843	34,843
Series A-2 convertible preferred stock, $0.0001 par value; 19,804,932 shares authorized, issued and outstanding at December 31, 2025 and 2024; $35,000 aggregate liquidation preference at December 31, 2025 and 2024	34,986	34,986
Series B convertible preferred stock, $0.0001 par value; 50,701,812 and 51,530,454 shares authorized at December 31, 2025 and 2024, respectively; 50,693,198 and 50,701,812 shares issued and outstanding at December 31, 2025 and 2024, respectively; $147,563 and $147,588 aggregate liquidation preference at December 31, 2025 and 2024	147,173	147,198
Series C convertible preferred stock, $0.0001 par value; 76,173,492 shares authorized, issued and outstanding at December 31, 2025; $115,624 aggregate liquidation preference at December 31, 2025; no Series C convertible preferred stock was authorized, issued or outstanding at December 31, 2024	115,353	—
Stockholders' deficit:		
Common stock, $0.0001 par value; 228,898,561 and 137,843,464 shares authorized at December 31, 2025 and 2024, respectively; 1,696,796 and 1,662,716 shares issued at December 31, 2025 and 2024, respectively; 1,074,089 and 1,014,267 shares outstanding at December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	11,250	8,518
Accumulated other comprehensive income	13	39
Accumulated deficit	(228,340)	(166,284)
Total stockholders' deficit	(217,077)	(157,727)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 143,663	$ 90,211

The accompanying notes are an integral part of these financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 41,833	$ 35,593
General and administrative	17,472	17,865
Total operating expenses	59,305	53,458
Loss from operations	(59,305)	(53,458)
Other income (loss):		
Interest income	1,793	4,397
Other (loss) income, net	(4,544)	504
Total other (loss) income, net	(2,751)	4,901
Net loss	$ (62,056)	$ (48,557)
Net loss per common share:		
Net loss per common share, basic and diluted	$ (59.43)	$ (51.81)
Weighted-average shares used to calculate net loss per common share, basic and diluted	1,044,175	937,224

The accompanying notes are an integral part of these financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2025	2024
Net loss	$ (62,056)	$ (48,557)
Other comprehensive loss:		
Unrealized loss on marketable securities	(26)	(398)
Comprehensive loss	$ (62,082)	$ (48,955)

The accompanying notes are an integral part of these financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	101,428,978	$ 223,480	900,420	$ —	$ 5,253	$ 437	$ (117,727)	$ (112,037)
Vesting of restricted stock	—	—	3,795	—	91	—	—	91
Exercise of stock options	—	—	110,052	—	467	—	—	467
Stock-based compensation	—	—	—	—	2,707	—	—	2,707
Unrealized loss on marketable securities	—	—	—	—	—	(398)	—	(398)
Net loss	—	—	—	—	—	—	(48,557)	(48,557)
Balance at December 31, 2024	101,428,978	$ 223,480	1,014,267	$ —	$ 8,518	$ 39	$ (166,284)	$ (157,727)
Issuance of Series C preferred stock, net of issuance costs of $271	76,173,492	115,353	—	—		—	—	—
Conversion of preferred to common stock	(8,614)	(25)	88	—	25	—	—	25
Exercise of stock options	—	—	33,989	—	173	—	—	173
Vesting of restricted stock	—	—	25,745	—	17	—	—	17
Stock-based compensation	—	—	—	—	2,517	—	—	2,517
Unrealized loss on marketable securities	—	—	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	—	—	(62,056)	(62,056)
Balance at December 31, 2025	177,593,856	$ 338,808	1,074,089	$ —	$ 11,250	$ 13	$ (228,340)	$ (217,077)

The accompanying notes are an integral part of these financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	2024
Operating Activities		
Net loss	$ (62,056)	$ (48,557)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	2,517	2,707
Amortization of right-of-use lease assets	2,321	2,151
Depreciation	1,637	1,362
Accretion of discounts and amortization of premiums on short-term investments, net	(53)	(1,960)
Loss (gain) from change in fair value of convertible note receivable	4,552	(496)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	220	(142)
Other noncurrent assets	454	(299)
Accounts payable	1,788	(304)
Accrued expenses and other current liabilities	(1,495)	3,779
Noncurrent liabilities	(2,732)	(2,403)
Net cash used in operating activities	(52,847)	(44,162)
Investing Activities		
Purchases of marketable securities	(33,613)	(74,886)
Purchase of convertible note	—	(5,000)
Maturities of marketable securities	47,500	103,101
Purchases of property and equipment	(9,690)	(2,584)
Net cash provided by investing activities	4,197	20,631
Financing Activities		
Proceeds from exercise of stock options	173	467
Payment of debt issuance costs	—	(10)
Proceeds from issuance of Series C Preferred Stock, net of issuance costs	115,353	—
Net cash provided by financing activities	115,526	457
Net increase (decrease) in cash, cash equivalents and restricted cash	66,876	(23,074)
Cash, cash equivalents and restricted cash at beginning of year	15,843	38,917
Cash, cash equivalents and restricted cash at end of year	$ 82,719	$ 15,843
Supplemental Disclosure for Non-cash Activities		
Change in purchases of property and equipment included in accrued expenses	(69)	41
Non-cash adjustment to reduce right-of-use assets and lease liabilities due to lease termination	—	142

The accompanying notes are an integral part of these financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Notes to Financial Statements

1. Organization and Basis of Presentation

Description of Business

Aspen Neuroscience, Inc. ("Aspen" or "the Company") is a clinical-stage, regenerative medicine biotechnology company focused on developing autologous induced-pluripotent stem cell ("iPSC")-derived therapies to initially address neurodegenerative diseases with high unmet medical need. The Company's lead program, sasineprocel, is an investigational autologous iPSC-based therapy for Parkinson's disease designed to replace a patient's lost dopamine neurons with dopaminergic neuron precursor cells. Aspen is headquartered in San Diego, California, and was originally incorporated in Delaware on May 18, 2018.

Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as found in the Accounting Standards Codification ("ASC") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Emerging Growth Company Status

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Liquidity and Capital Resources

From inception through December 31, 2025, the Company has devoted substantially all of its efforts to conducting product research and development, developing intellectual property, raising capital and entering into licensing agreements. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has incurred net losses and negative cash flows from operating activities since inception and had an accumulated deficit of $228.3 million as of December 31, 2025.

The Company expects to continue to incur net losses into the foreseeable future as it continues the development of its pipeline and expands its product manufacturing efforts. As a result, the Company will need to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to meet its capital requirements and fund its operations through at least twelve months from the date of the issuance of these financial statements. Future capital requirements will depend on many factors, including the timing and extent of the Company's spending on its operations, and there can be no assurance that the Company will be successful in obtaining additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. The failure to obtain sufficient funds on acceptable terms and in a timely manner could require the Company to make significant spending reductions in its future operations including suspending or curtailing planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Table of Contents

Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for research and development expenses, valuation of stock-based awards, fair value of convertible promissory note receivable and incremental borrowing rate used for calculating operating lease liabilities. Management evaluates its estimates on an ongoing basis. Although these 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents primarily represent funds invested in readily available money market funds. The Company records standby letters of credit related to the Company's leases as restricted cash.

Investments in Marketable Securities, Available-for-Sale

The Company classifies its investments in securities as available-for-sale because, for accounting purposes, they are not considered to be either held-to-maturity securities or trading securities. They are not considered to be held-to-maturity securities because the Company does not have the positive intent to hold those securities to maturity. They are not considered trading securities because they are not acquired with the intent of selling them within hours or days. The Company's investments in securities are classified as current as they are available to use to fund current operations, and the Company has the ability and intent to do so. Short-term investments are carried at fair value with the unrealized gains and losses included in other comprehensive income as a component of stockholders' equity until realized. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity and recorded as interest income. Realized gains and losses are determined using the specific identification method and are included in other income (loss).

Decreases in fair value attributable to credit loss are recorded directly to earnings with a corresponding allowance for credit losses, limited to the amount that the fair value is less than the amortized cost basis. If the credit quality subsequently improves, the allowance is reversed up to a maximum of the previously recorded credit losses. When the Company intends to sell an impaired available-for-sale debt security, or if it is more likely than not that the Company will be required to sell the security prior to recovering the amortized cost basis, the entire fair value adjustment will immediately be recognized in earnings with no corresponding allowance for credit losses.

Fair Value of Financial Instruments

The carrying amounts of all cash equivalents, prepaid expenses and other current assets, accounts payable and accrued and other current liabilities are reasonable estimates of their fair value because of the short-term nature of these assets and liabilities. Investment securities are reported at their estimated fair value based on quoted market prices for identical or similar instruments.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured major 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 institution in which those deposits are held.

Property and Equipment, net

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years, or the remaining term of the lease for leasehold improvements, whichever is shorter) and generally consist of laboratory equipment, computer and office equipment, furniture and fixtures, and leasehold improvements.

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. If impairment indicators are identified, the Company first performs a recoverability test by comparing the estimated future undiscounted cash flows associated with the asset group to its carrying amount. If the future undiscounted cash flows are less than the carrying amount, an impairment loss is measured based on the excess over the carrying amount of the asset's fair value. The Company did not recognize any impairment losses for the years ended December 31, 2025 and 2024.

Convertible Promissory Notes Receivable

As permitted under Accounting Standards Codification ("ASC") 825, Financial Instruments, ("ASC 825"), the Company has elected the fair value option to account for its convertible promissory note receivable. In accordance with ASC 825, the Company records the convertible promissory note receivable at fair value with changes in fair value recorded in other income (loss), net in the statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory note receivable were recognized in earnings as incurred.

Leases

The Company leases its office, laboratory and manufacturing facilities. If a lease is identified in an arrangement, the Company determines whether the lease should be classified as a finance or operating lease and recognizes a right-of-use ("ROU") asset and liability on its balance sheets. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months. Lease payments for short-term leases are recorded in operating expense on a straight-line basis over the lease term and variable lease payments are recorded in the period in which the obligation for those payments is incurred. The Company currently does not have any finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company includes lease and non-lease components as a single lease component when determining lease payments. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Convertible Preferred Stock

The Company's convertible preferred stock is classified as temporary equity and excluded from stockholders' deficit as the potential redemption of such stock is not solely within the Company's control. The carrying value of the convertible preferred stock is not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with the Company's research and development activities, including the clinical development of its product candidates. Research and development costs are expensed as incurred.

Table of Contents

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, clinical research organizations, and clinical site agreements in connection with conducting clinical and preclinical 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 clinical and preclinical study expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the study as measured by the timing of various aspects of the study or related activities. The Company determines accrual and prepaid estimates through review of the underlying contracts along with preparation of financial models taking into account correspondence with clinical and other key personnel and third-party service providers as to the progress of the study or other services being conducted. During the course of the study, the Company adjusts its expense recognition if actual results differ from its estimates. To date, there have been no material differences between the Company's estimates of such expenses and the amounts actually incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of 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 valuation approved by the Company's Board of Directors. The Company recognizes forfeitures for all awards as such forfeitures occur.

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 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.

The Company maintains 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 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. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties.

Other Comprehensive Income (Loss)

Other comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive income (loss) includes unrealized gains or losses on the Company's available-for-sale debt securities.

Segment Reporting

The Company's chief operating decision maker ("CODM") is the Company's Chief Executive Officer. The CODM is assisted in his responsibilities of making decisions regarding resource allocation and performance assessment by the leadership team, consisting of executive officers and vice presidents.

The Company views its operations and manages its business as one operating segment, focused on developing autologous iPSC-derived therapies to initially address neurodegenerative diseases with high unmet medical need.

Segment loss is measured as the Company's net loss as reported on the Company's statements of operations. The Company monitors its cash, cash equivalents, and marketable securities as reported on the Company's balance sheets to determine funding for its research and development programs. When evaluating the Company's financial performance, the CODM reviews total expenses by certain categories and makes decisions using this information.

Significant segment expenses which are regularly reported to the CODM for purposes of making decisions regarding the allocation of resources are included within the table below and are reconciled to net loss (in thousands):

	Year Ended December 31,	
	2025	2024
Salaries, bonuses and benefits	$ 26,799	$ 24,784
Cell-therapy development and production costs	14,497	11,485
Equipment and facilities costs	8,440	7,926
Other[(1)]	12,320	4,362
Net loss	$ (62,056)	$ (48,557)

(1) Other includes stock-based compensation, depreciation, interest income, and other (loss) income.

Recent Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09, Improvements to Income Tax Disclosures, which does not change accounting for income taxes but requires new disclosures focusing on the effective rate reconciliation and taxes paid. The Company adopted the standard and applied the disclosure requirements on a prospective basis for the year ended December 31, 2025. Adoption of this ASU did not have a material impact on the financial statements and related disclosures.

Recently issued accounting pronouncements not yet adopted

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which establishes guidance on the recognition, measurement, presentation, and disclosure of government grants received by business entities. The standard is effective for public business entities for annual reporting periods beginning after December 15, 2028, including interim periods within those annual reporting periods, and for all other entities for annual reporting periods beginning after December 15, 2029, including interim periods within those annual reporting periods. Early adoption is permitted. The standard may be adopted using a modified prospective, modified retrospective, or full retrospective approach. The Company is currently evaluating the impact of adoption of this standard on its financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220 -40): Disaggregation of Income Statement Expenses, which is intended to enhance expense disclosures by requiring additional information about specific expense categories in the notes to the financial statements. The standard is effective, as clarified by ASU 2025-01, for annual periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be adopted prospectively or retrospectively. The Company is currently evaluating the impact of the standard on its financial statements and related disclosures.

2. 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 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).

Level 1 includes money market funds and U.S. treasuries. Level 2 includes corporate bonds and asset-backed securities.

The Company obtains the fair value of its Level 2 investments from a professional pricing service and validates the fair value of its Level 2 investments by understanding the pricing model used by the professional pricing service and comparing that fair value to the fair value based on observable market prices.

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 did not have any securities that were in a material unrealized loss position.

The following tables present the major security types that the Company held as of December 31, 2025 and 2024 regularly measured and carried at fair value (in thousands):

	December 31, 2025				
	Amortized Cost	Unrealized Gains (Losses)	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Level 1					
Cash	$ 507	$ —	$ 507	$ 507	$ —
Money market funds	34,441	—	34,441	34,441	—
U.S. treasuries	71,034	6	71,040	47,149	23,891
Level 1 total	105,982	6	105,988	82,097	23,891
Level 2					
Corporate fixed income securities	3,444	4	3,448	—	3,448
Asset backed securities	1,260	3	1,263	—	1,263
Level 2 total	4,704	7	4,711	—	4,711
Total	$ 110,686	$ 13	$ 110,699	$ 82,097	$ 28,602

Table of Contents

	December 31, 2024				
	Amortized Cost	Unrealized Gains (Losses)	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Level 1					
Cash	$ 7,835	$ —	$ 7,835	$ 7,835	$ —
Money market funds	7,386	—	7,386	7,386	—
U.S. treasuries	15,502	14	15,516	—	15,516
Level 1 total	30,723	14	30,737	15,221	15,516
Level 2					
Corporate fixed income securities	20,753	15	20,768	—	20,768
Asset backed securities	6,167	10	6,177	—	6,177
Level 2 total	26,920	25	26,945	—	26,945
Total	$ 57,643	$ 39	$ 57,682	$ 15,221	$ 42,461

Contractual maturities of fixed income securities as of December 31, 2025 and 2024 were as follows (in thousands):

	December 31,	
	2025	2024
	Estimated Fair Value	Estimated Fair Value
Due within one year	$ 27,339	$ 33,658
One to two years	803	5,117
More than two years	460	3,686
Total	$ 28,602	$ 42,461

The following table presents a reconciliation of assets that were measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Balance at December 31, 2024	Purchase of convertible promissory note	Change in fair value included in other income (loss)	Balance at December 31, 2025
Level 3				
Cell X Convertible Note	$ 5,496	$ —	$ (4,552)	$ 944
Total	$ 5,496	$ —	$ (4,552)	$ 944

	Balance at December 31, 2023	Purchase of convertible promissory note	Change in fair value included in other income (loss)	Balance at December 31, 2024
Level 3				
Cell X Convertible Note	$ —	$ 5,000	$ 496	$ 5,496
Total	$ —	$ 5,000	$ 496	$ 5,496

The Cell X Convertible Note is recorded in other noncurrent assets on the balance sheets and is described in Note 7 of these financial statements. The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the Cell X Convertible Note as of December 31, 2025:

Key unobservable inputs	Range
Estimated time to liquidity	2–3 years
Volatility	72.5%
Discount rate	26.6%

There are significant judgments, assumptions and estimates inherent in the determination of the fair value of the Cell X Convertible Note. These include determining a valuation method and selecting possible outcomes available to the Company, including the timing and expected future investment returns for such scenarios. The related judgments, assumptions and estimates are highly interrelated, and changes in any one assumption could necessitate changes in another. Any changes in the probability of a particular outcome would require a related change to the probability of another outcome.

The fair value of the Cell X Convertible Note was estimated using a scenario-based analysis that estimated the fair value of the note based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the Company as the noteholder, including settlement, a qualified equity financing, corporate transactions and dissolution scenarios.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued compensation	5,652	5,615
Accrued research	1,816	2,089
Other accrued expenses	137	422
Total accrued expenses	7,605	8,126

	December 31,	
	2025	2024
Deferred CIRM Award	377	1,479
Other current liabilities	109	151
Total other current liabilities	486	1,630

4. Property and Equipment, net

Property and equipment, net consist of the following (in thousands):

	Estimated Useful Lives	December 31,	
	(in years)	2025	2024
Lab equipment	3 to10	$ 7,739	$ 6,300
Leasehold improvements	The lesser of the remaining useful of the asset or the remaining lease term	5,653	5,653
Furniture and fixtures	3 to10	845	786
Computer and software	3 to 7	512	467
Vehicle	5	42	42
Construction in progress		8,645	1,941
Total property and equipment, gross		23,436	15,189
Less: accumulated depreciation		(4,536)	(2,899)
Total property and equipment, net		$ 18,900	$ 12,290

The Company recorded depreciation expense of $1.6 million and $1.4 million for the years ended December 31, 2025 and 2024, respectively.

5. Other Noncurrent Assets

Other noncurrent assets consist of the following (in thousands):

	December 31,	
	2025	2024
Prepaid equipment	$ 2,221	$ 848
Convertible promissory note receivable	944	5,496
Deferred asset costs	58	301
Deferred debt issuance costs	—	212
Total other noncurrent assets	$ 3,223	$ 6,857

6. Convertible Preferred Stock and Stockholders' Deficit

The Company's convertible preferred stock has been classified as temporary equity on the accompanying balance sheets. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock can cause its redemption. Because these change-in-control events are not considered probable for accounting purposes, the Company has not adjusted the carrying values of the convertible preferred stock to redemption value.

In various closings from October 2025 to November 2025, the Company issued and sold to investors in private placements an aggregate of 76,173,492 shares of Series C convertible preferred stock at a per share purchase price of $1.5179, and the Company received gross proceeds of approximately $115.6 million.

Dividends

Each holder of the Company's Series C, Series B, Series A (Series A-1 and Series A-2 combined as a separate class) and Series Seed (Series Seed and Series Seed-2 combined as a separate class) convertible preferred stock is entitled to receive non-cumulative dividends, when and if declared by the Company's Board of Directors. No dividends have been declared to date.

Series C preferred stock has priority dividend rights over all other classes of capital stock, and all other series of preferred stock rank *pari passu* with one another and senior to common stock with respect to dividends.

Liquidation Preferences

In the event of any liquidation, dissolution or winding up of the Company, the holders of the convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share equal to the original issue price plus declared but unpaid dividends.

The stockholders of the Series C preferred stock have liquidation preferences over all other preferred stockholders. The stockholders of Series A-1 and Series A-2 Preferred Stock have liquidation preferences over the stockholders of the Series Seed Preferred Stock.

Conversion

Each share of convertible preferred stock is convertible at the option of the holder, at any time, into the number of shares of common stock determined by dividing the applicable purchase price ($0.540614, $1.029742, $1.696405, $1.767236, $2.9109, and $1.5179 for the Series Seed, Series Seed-2, Series A-1, Series A-2, Series B, and Series C, respectively) by the applicable conversion price at the time of conversion.

Each share of convertible preferred stock will be automatically converted into common stock immediately upon (i) the closing of a firm commitment underwritten initial public offering at a price of at least $30.00 per share resulting in at least $50.0 million of gross proceeds to the Company or (ii) the approval, by vote or written consent, of the holders of a majority of the outstanding shares of preferred stock (voting together as a single class on an as-converted basis), together with the holders of a majority of shares of outstanding Series C preferred stock, and a majority of shares of outstanding Series B preferred stock.

Voting

The holders of convertible preferred stock are entitled to one vote for each share of common stock into which such shares of convertible preferred stock could then be converted; and with respect to such vote, such holders shall have full voting rights and powers equal to the voting rights and powers of the holders of the common stock.

Redemption

The convertible preferred stock is not explicitly redeemable except in the event of certain effected deemed liquidation events.

Stock Options

In 2018, the Company adopted the 2018 Stock Plan (the "Plan"). The Plan provides for the grant of incentive stock options, non-statutory stock options, and restricted stock awards to directors, employees and consultants of the Company. Through December 31, 2025, the Company has limited its grants under the Plan solely to stock options. The Plan allows for the early exercise of stock options to plan participants subject to the right of repurchase by the Company at the original purchase price upon any voluntary or involuntary separation of an employee from the Company. Shares subject to the Company's right to repurchase are not deemed outstanding for accounting purposes until those shares vest.

As of December 31, 2025, the total number of shares authorized under the Plan was 4,163,709, and the number of shares available for issuance under the Plan was 201,877.

Stock options granted under the Plan are exercisable based on vesting schedules determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option is determined by the Board of Directors based on the estimated fair value of the Company's stock on the date of the option grant. Option grants generally vest either (a) monthly over four years, or (b) 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years.

A summary of the Company's stock option activity under the Plan is as follows:

	Number of Options	Weighted-average Exercise Price (per share)	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	1,459,603	$ 7.12		
Granted	1,494,216	5.93		
Exercised	(33,989)	5.04		
Canceled	(99,555)	7.02		
Outstanding at December 31, 2025	2,820,275	$ 6.53	8.54	$ 6,191
Exercisable at December 31, 2025	1,057,766	$ 6.82	6.89	$ 1,935

Options outstanding as of December 31, 2025 consist of options vested and expected to vest. Aggregate intrinsic value in the table above is the total in-the-money value of the options above as of December 31, 2025 based on the Company's latest estimated fair value of its common stock in 2025.

The intrinsic value of options exercised during the years ended December 31, 2025 and 2024, calculated based on the Company's latest estimated fair value of its common stock in 2025 and 2024, respectively, was $0.1 million and $0.2 million, respectively.

The aggregate fair value of shares vested during the year ended December 31, 2025 and 2024 was $2.2 million and $2.1 million, respectively. As of December 31, 2025, there were 1.1 million options vested and outstanding.

The weighted-average grant date fair value of employee option grants during the years ended December 31, 2025 and 2024 was $7.22 per share and $6.43 per share, respectively.

In 2019, the Company amended the Plan to allow its directors and officers to early exercise their stock options by delivery of promissory notes, which provide the Company first-priority security interest in the underlying shares exercised through such promissory notes ("Promissory Notes"). In 2021 and 2022, certain directors and officers of the Company early exercised their stock options using Promissory Notes. These Promissory Notes accrue interest at a rate of 2% per year. For accounting purposes, Promissory Notes are treated as non-recourse as the Company does not intend to pursue cash collection in the event of default. Accordingly, the resulting exercises of the options were determined to be non-substantive, and the Company has not recorded the Promissory Notes or related accrued interest on its balance sheets. For this reason, the shares are not considered to be outstanding until the Promissory Notes are repaid. The principal balance and accrued interest of the Promissory Notes as of December 31, 2025 and 2024 was $2.3 million and $2.4 million, respectively. The number of shares subject to Promissory Notes was 622,707 and 643,494 as of December 31, 2025 and 2024, respectively.

In August 2024, an officer of the Company sold 50,293 shares of common stock to a preferred shareholder of the Company (the "Buyer") that were previously early exercised through a Promissory Note and paid the outstanding Promissory Note balance of $0.2 million to the Company. The amount paid by the Buyer in excess of fair value of the Company's common stock at the date of the sale was recorded to stock-based compensation expense during the year ended December 31, 2024.

In December 2024, the Company entered into an agreement to repurchase 196,821 shares of common stock for $1.6 million issued to the Chief Executive Officer and Director of the Company, which was used to cancel principal and interest of $1.6 million on an outstanding Promissory Note for the early exercise of stock options. Concurrently, the Company granted 196,820 new stock option awards with the same vesting terms. The transaction was considered an option modification under ASC 718, which was recorded to stock-based compensation expense during the year ended December 31, 2024.

Stock-based Compensation Expense

The following table summarizes stock-based compensation recognized in the Company's statements of operations (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 1,178	$ 966
General and administrative	1,339	1,741
Total stock-based compensation	$ 2,517	$ 2,707

As of December 31, 2025, total unrecognized stock-based compensation cost was $12.4 million, which is expected to be recognized as expense over a weighted average period of 3.2 years.

Stock Option Valuation

The fair value of the Company's stock option awards is estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Year Ended December 31,	
	2025	2024
Risk-free rate of interest	3.7%–4.1%	3.5% –4.3%
Expected term (years)	5.95–6.02	5.95–6.10
Expected stock price volatility	96.3%–98.5%	94.0%–96.4%
Dividend yield	—	—

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 term (years). 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, which uses the average of the time-to-vesting and the contractual term of the options.

Expected stock price 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.

Dividend yield. The expected dividend assumption is based on the Company's history and expectation of dividend payments. The Company has not paid and does not intend to pay dividends.

7. License Agreements

TSRI License Agreement

In October 2018, the Company was assigned an exclusive license agreement by Summit for Stem Cell Foundation with the Scripps Research Institute ("TSRI") under which Aspen acquired the exclusive license to intellectual property, which allows the Company to substantially facilitate the development of the licensed intellectual property (the "TSRI License Agreement"). The TSRI License Agreement includes the payment of royalties equal to a low single digit percentage on future net sales of licensed products. If the Company sublicenses a product under the TSRI License Agreement, the Company is obligated to pay TSRI a royalty of a mid-single-digit percentage of sublicensing consideration. Payments related to the TSRI License Agreement are made in the period when the contingency is resolved, and the amounts become payable. No amounts have been payable under this agreement.

AJ License Agreement

In September 2019, the Company entered into a non-exclusive license agreement with iPS Academia Japan, Inc. ("the AJ License Agreement") pursuant to which iPS Academia Japan, Inc. granted the Company a license under the licensed patents for the development, manufacture, and sale of licensed products. Pursuant to the AJ License Agreement, the Company is obligated to pay iPS Academia Japan, Inc. an upfront fee of $60,000 and annual maintenance fees of $25,000 until and including the calendar year in which the Company obtains approval of a first new drug application of a licensed product. The Company is obligated to pay future milestone payments up to $135,000 upon the successful achievement of developmental milestones, and up to $1.1 million when certain net sales thresholds of a licensed product are met. The Company is obligated to pay future royalty payments in the low single digit percentage of net sales of licensed products. We will also be subject to an annual minimum royalty of $25,000 following the first approval of a licensed product. The Company recognizes the expense of the milestones when payable.

The AJ License Agreement contains additional customary representations and warranties, covenants, indemnifications and insurance and confidentiality provisions for agreements of its type. The AJ License Agreement may be terminated upon mutual consent of both parties. Unless terminated in accordance with its terms, the AJ License Agreement continues until the expiration, revocation or invalidation of the last patents or the abandonment of the last patent application included within the licensed patents and technology.

Payments related to this license agreement are expensed in the period when the contingency is resolved, and the amounts become payable. The Company incurred expenses of $235,000 and $25,000 under this agreement during the years ended December 31, 2025 and 2024.

Sumitomo License Agreement

In December 2023, the Company entered into a non-exclusive license agreement with Sumitomo Pharma Co., Ltd. ("the Sumitomo License Agreement") with the Company to obtain a non-exclusive sublicense for certain rights granted by ID Pharma to Sumitomo under the original license agreement between Sumitomo and ID Pharma. the Company is obligated to pay Sumitomo Pharma Co., Ltd. an upfront fee of ¥40.0 million and annual license fees of ¥6.0 million. The Company is obligated to pay future development milestone payments up to ¥125.0 million per licensed product per region for up to three regions upon the successful achievement of each developmental milestone, and up to ¥1.85 billion per licensed product when certain net sales thresholds of a licensed product are met. The Company is obligated to pay future royalty payments in the low single digit percentage of net sales of licensed products. The Company incurred expense of $42,000 and $41,000 during the years ended December 31, 2025 and 2024.

Cell X License Agreement

In January 2024, Cell X Technologies, Inc. ("Cell X") and the Company entered into a Collaboration and License Agreement upon which Cell X granted licenses to the Company to develop, practice, make, have made, use, sell, offer to sell, import and commercialize Licensed Products in the Licensed Field in the Territory as defined and more fully set forth in the Cell X agreement. In connection with such licenses, the Company and Cell X also agreed to collaborate for the purpose of improving the Cell X platform technology for use by the Company to develop, practice, make, have made, use, sell, offer to sell, import and commercialize licensed products in the licensed field. The Company paid Cell X an upfront fee of $250,000 and is obligated to pay future development milestone payments up to $30.5 million, and additional potential license fees if the Company pursues the technology for certain additional indications of up to $15.5 million. The Company paid the $250,000 upfront fee in 2024, which was included as a component of research and development expenses in the statement of operations.

In January 2024, the Company and Cell X entered a Secured Convertible Promissory Note Purchase Agreement whereby the Company agreed to purchase, and Cell X agreed to sell and issue, a convertible promissory note ("Cell X Convertible Note") with an original principal amount equal to $5.0 million and an 8% annual interest rate. The outstanding amount shall automatically convert into shares of Cell X's preferred stock (the "Conversion Stock") upon a qualified financing and provides an optional conversion upon a non-qualified equity financing. The principal and accrued interest are due and payable upon the earliest to occur of (i) the 24-month anniversary of the agreement, (ii) a change in control of Cell X or (iii) the occurrence of an event of default, as defined in the agreement. The Company purchased the $5.0 million note in 2024 and elected the fair value option for the note. The fair value of the Cell X Convertible Note was $0.9 million and $5.5 million as of December 31, 2025 and December 31, 2024, respectively, which is included in other noncurrent assets on the balance sheets. The Company recorded through other income (loss) a $4.5 million loss during the year ended December 31, 2025 and recorded a gain of $0.5 million during the year ended December 31, 2024 resulting from the change in fair value of the Cell X Convertible Note (see Note 2).

8. Loan and Security Agreement

In December 2022, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with a lender (the "Lender"). Under the Loan Agreement, the Company was permitted to borrow $15.0 million at the inception of the Loan Agreement and up to an additional $25.0 million from three additional tranches at the Company's option subject to achievement of certain clinical milestones.

In connection with the Loan Agreement, the Company issued the Lender a warrant (the "Lender Warrant") to purchase 13,333 shares of the Company's common stock as of the date of the agreement at an exercise price of $7,71 per share and expiring on December 20, 2032. The Company recorded $0.1 million as a component of additional paid-in capital within stockholders' deficit upon issuing the Lender Warrant.

In November 2024, the Company entered into a Warrant Purchase Agreement with the Lender to allow for the purchase of 4,445 shares of common stock at an exercise price of $7.71 per share. The Company recorded $34,000 as a component of additional paid-in capital within stockholders' deficit related to the Lender Warrant.

In November 2025, the Loan Agreement expired undrawn, and the Company has no debt obligations under the Loan Agreement as of December 31, 2025.

9. California Institute for Regenerative Medicine Award

In March 2024, the California Institute for Regenerative Medicine (the "CIRM") issued an award to the Company for $8.0 million to co-sponsor a Phase 1/2a dose escalation study of the Company's lead product candidate, sasineprocel, in sporadic Parkinson's disease (the "Award"). The Company is eligible to receive seven disbursements in varying amounts, with one disbursement receivable upon the execution of the Award, and six disbursements receivable upon the completion of certain milestones throughout the project period of the Award, which is estimated to be from April 2024 to September 2026 (the "Award Period").

Following the conclusion of the Award Period, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. If the Company does not elect to treat the Award as a loan within 10 years of the award date, the Award will be considered a grant, and the Company will be obligated to pay CIRM, on a quarterly basis, a low single-digit royalty on commercial sales of sasineprocel until such aggregate royalty payments equal nine times the total amount awarded to the Company under the Award. If the Company elects to treat the Award as a loan, the Company is obligated to repay the Award within ten business days of making the election at an amount based on a specified percentage of the Award (ranging from 80% to 100%, plus, in certain cases, interest up to an annual percentage rate of 10% plus LIBOR), with the applicable amounts based on the phase of development of sasineprocel at the time the election is made

The Company has elected for accounting purposes to treat the Award as a direct research and development arrangement in accordance with ASC 730-20, *Research and Development—Research and Development Arrangements*, as the Company does not intend to repay the Award other than by way of royalty payments on potential future sales of sasineprocel. The Award is recognized as an offset to research and development expenses as costs related to the project are incurred as the Company has concluded that the research and development risk is substantive and it is not yet probable that development will be successful. A deferred liability is recorded when the cash disbursements under the Award exceed the related research and development expenses incurred through such date.

During the year ended December 31, 2025, the Company received two cash disbursements under the award totaling $1.7 million. During the year ended December 31, 2024, the Company received three cash disbursements under the award totaling $5.7 million. The Company recognized $2.8 million and $4.2 million as an offset to research and development expense for the years ended December 31, 2025 and December 31, 2024, respectively, and $0.4 million and $1.5 million was deferred and recorded in other current liabilities as of December 31, 2025 and December 31, 2024, respectively.

Table of Contents

10. Commitments and Contingencies

Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the balance sheets. These leases have terms varying from approximately three to ten years, with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise the options. The leases are subject to additional variable costs, including common area maintenance, property taxes, property insurance, and utilities. Variable costs are recognized as expense as incurred.

During the year ended December 31, 2025, the Company incurred $4.9 million of lease expense; $1.7 million was related to variable costs, and $3.2 million was related to straight-line operating lease expense.

During the year ended December 31, 2024, the Company incurred $4.9 million of lease expense; $1.6 million was related to variable lease costs, and $3.3 million was related to straight-line operating lease expense.

As of December 31, 2025, maturities of the Company's operating leases were as follows (in thousands):

Minimum lease payments for the year ending December 31,	
2026	3,653
2027	3,051
2028	1,392
2029	1,434
2030	1,477
Thereafter	2,430
Total future minimum lease payments	13,437
Less: present value discount	(2,236)
Total operating lease liabilities	11,201
Less: current portion	(3,532)
Lease liabilities, noncurrent	$ 7,669
Weighted-average remaining lease term (in years)	2.34
Weighted-average incremental borrowing rate	7.70%

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business. The Company believes there is no litigation pending that could have, individually, or in the aggregate, have a material adverse effect on the results of its operations, financial condition or cash flows.

11. Income Taxes

The Company had no provision for income taxes for the years ended December 31, 2025 and 2024, due to its history of operating losses.

The Company did not record a current or deferred income tax expense or benefit for the years ended December 31, 2025 and 2024 due to the Company's net and comprehensive losses and increases in its deferred tax asset valuation allowance. Additionally, the Company did not pay federal or state cash income taxes or have cash income tax refunded for the year ended December 31, 2025.

The reconciliation from the statutory federal income tax rate to the Company's effective income tax rate, applying ASU 2023-09 prospectively, is as follows (amounts in thousands):

	Year Ended December 31, 2025	
	Amount	%
Income taxes (benefit) at statutory federal rate	(13,032)	21.0%
State and local taxes, net of federal income tax effect	(1,872)	3.0%
Tax credits		
Research and development credits	(2,351)	3.8%
Changes in valuation allowance	14,589	-23.5%
Nontaxable or nondeductible items		
Other	401	-0.6%
Changes in unrecognized tax benefits	2,265	-3.7%
Provision for income taxes	—	0.0%

The state that contributed to more than 50% of the tax effect for state and local taxes was California for the year ended December 31, 2025.

The reconciliation from the statutory federal income tax rate to the Company's effective income tax rate, applying ASC 740 prior to the adoption of ASU 2023-09, is as follows (amounts in thousands):

	Year Ended December 31, 2024	
	Amount	%
Expected tax benefit at statutory rate	(10,197)	21.0%
State income tax, net of federal benefit	(1,983)	4.1%
Permanent items and other	484	-1.0%
Research credits	(1,827)	3.8%
Change in valuation allowance	13,523	-27.9%
Provision for income taxes	—	0.0%

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2025 and 2024, respectively, are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	44,408	26,728
Research and development credits	8,910	6,122
Lease liability	2,858	3,515
Capitalized research expenses	12,138	16,044
Other	2,030	750
Total deferred tax assets	70,344	53,159
Valuation allowance	(66,288)	(48,326)
Deferred tax assets, net of valuation allowance	4,056	4,833
Deferred tax liabilities:		
Fixed assets	(1,876)	(2,065)
Right-of-use lease assets	(2,177)	(2,758)
Other	(3)	(10)
Total deferred tax liabilities	(4,056)	(4,833)
Net deferred tax assets	—	—

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 $66.3 million as of December 31, 2025 as management cannot conclude that it is more likely than not that certain deferred tax assets will be realized primarily due to the history of losses from inception. The Company increased its valuation allowance by $18.0 million during the year ended December 31, 2025.

As of December 31, 2025, the Company has federal and state net operating loss ("NOL") carryforwards of approximately $161.5 million and $194.5 million, respectively. For tax purposes, federal NOLs generated after December 31, 2017 can be carried forward indefinitely but are limited to 80% utilization against future taxable income each year starting with the taxable year beginning January 1, 2021. Of the amount of federal NOL carryforwards, all $161.5 million can be carried forward indefinitely. Unless previously utilized, the state NOL carryforwards will begin to expire in 2038.

As of December 31, 2025, the Company has federal and California research and development tax credit carryforwards of $6.9 million and $4.9 million, respectively. The federal research and development tax credit carryforwards begin to expire in 2040 unless previously utilized, and the California research and development tax credit carryforwards are available indefinitely.

Pursuant to the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's NOL and research and development credit carryforwards may be limited in the event a cumulative change in ownership by certain shareholders of more than 50 percentage points occurs within a three-year period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance.

On July 4, 2025, the U.S. President signed into law H.R.1, the legislation commonly known as the One Big Beautiful Bill Act ("OBBBA"). This legislation extended, modified, or made permanent many of the tax provisions which were initially enacted as part of the Tax Cuts and Jobs Act ("TCJA") of 2017. The OBBBA contains a number of tax provisions including, but not limited to, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest, bonus depreciation modifications, as well as international tax provision modifications. These tax provisions apply to either tax years beginning after December 31, 2025 or December 31, 2024. The Company has reflected the effect of OBBBA within the provision for income taxes and the deferred taxes as of December 31, 2025.

Uncertain tax positions are evaluated based on the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based on new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, on resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Beginning balance at January 1	3,050	885
Additions related to current year positions	2,776	2,165
Additions related to prior year positions	11	—
Ending balance at December 31	5,837	3,050

These unrecognized tax benefits are not expected to change within the next twelve months. Due to the existence of the valuation allowance, future recognition of previously unrecognized tax benefits will not impact the Company's effective tax rate. The Company is subject to taxation in the United States and California. All of the Company's tax years from inception are subject to examination by federal and state tax authorities. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense.

The Company had no accrued interest or penalties related to income tax matters in the Company's balance sheets at December 31, 2025 or 2024 and has not recognized interest or penalties in the Company's statement of operations and comprehensive loss for the year ended December 31, 2025. The Company is not currently under examination by any federal, state or local tax authority.

12. Net Loss per Share

In periods of net loss, basic and diluted net loss per share are calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding.

Convertible preferred stock are considered participating securities; however, they were excluded from the computation of basic net loss per share because there is no contractual obligation for the holders to share in the losses of the Company. Options outstanding, common stock issued subject to Promissory Notes, Lender Warrants, and common stock subject to repurchase due to being early exercised and unvested, were excluded from the computation of net loss per share because including them would have had an anti-dilutive effect.

The following table summarizes issued securities excluded from the calculation of net loss per share:

	December 31,	
	2025	2024
Issued securities excluded from the calculation of net loss per share:		
Convertible preferred stock, as converted	17,971,324	10,263,067
Options outstanding	2,820,275	1,459,603
Common stock subject to Promissory Notes	622,707	643,494
Lender Warrants	17,778	17,778
Other common stock subject to repurchase	—	4,955
Total	21,432,084	12,388,897

13. Subsequent Events

For the financial statements as of and for the year ended December 31, 2025, the Company evaluated subsequent events through March 30, 2026, the date on which these financial statements were issued. The Company further evaluated subsequent events through October 26, 2026 and has determined that, other than the events described below, there were no further subsequent events requiring disclosure in these financial statements.

In January 2026, the Company and Cell X amended the Cell X Convertible Note to extend the maturity date to February 2026, or such later date approved by the Company and Cell X. In February 2026, the Company and Cell X extended the maturity date to March 2026, and in March 2026, the Company and Cell X extended the maturity date to April 13, 2026.

Reverse Stock Split

On October 22, 2026, the board of directors and stockholders of the Company approved, and on October 23, 2026, the Company effected, a reverse stock split of the shares of the Company's outstanding common stock at a ratio of 1-for-9.8821 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, options to purchase common stock, warrants, share amounts, per share amounts, and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The shares of common stock underlying outstanding stock options and warrants were proportionately reduced, and the respective exercise prices were proportionately increased. In addition, the conversion ratios for each series of the Company's convertible preferred stock, which will convert into shares of common stock upon the closing of the Company's IPO, were proportionally adjusted.

Table of Contents

Aspen Neuroscience, Inc.

Balance Sheets
(in thousands, except share data)

	June 30, 2026 (Unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 21,287	$ 82,097
Marketable securities	51,090	28,602
Prepaid expenses and other current assets	2,218	1,687
Total current assets	74,595	112,386
Operating lease right-of-use assets	7,292	8,532
Property and equipment, net	22,029	18,900
Restricted cash	622	622
Other noncurrent assets	5,737	3,223
Total assets	$ 110,275	$ 143,663
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,536	$ 2,640
Accrued expenses	7,100	7,605
Operating lease liabilities, current	3,583	3,532
Other current liabilities	133	486
Total current liabilities	16,352	14,263
Operating lease liabilities, noncurrent	6,188	7,669
Commitments and contingencies		
Series Seed convertible preferred stock, $0.0001 par value; 8,323,862 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $4,500 aggregate liquidation preference at June 30, 2026 and December 31, 2025	4,445	4,445
Series Seed-2 convertible preferred stock, $0.0001 par value; 1,966,511 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $2,025 aggregate liquidation preference at June 30, 2026 and December 31, 2025	2,008	2,008
Series A-1 convertible preferred stock, $0.0001 par value; 20,631,861 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $35,000 aggregate liquidation preference at June 30, 2026 and December 31, 2025	34,843	34,843
Series A-2 convertible preferred stock, $0.0001 par value; 19,804,932 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $35,000 aggregate liquidation preference at June 30, 2026 and December 31, 2025	34,986	34,986
Series B convertible preferred stock, $0.0001 par value; 50,701,812 shares authorized at June 30, 2026 and December 31, 2025; 50,693,198 shares issued and outstanding at June 30, 2026 and December 31, 2025; $147,563 aggregate liquidation preference at June 30, 2026 and December 31, 2025	147,173	147,173
Series C convertible preferred stock, $0.0001 par value; 76,173,492 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $115,624 aggregate liquidation preference at June 30, 2026 and December 31, 2025	115,353	115,353
Stockholders' deficit:		
Common stock, $0.0001 par value; 228,898,561 shares authorized at June 30, 2026 and December 31, 2025; 1,732,276 and 1,696,796 shares issued at June 30, 2026 and December 31, 2025, respectively; 1,109,569 and 1,074,089 shares outstanding at June 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	13,855	11,250
Accumulated other comprehensive (loss) income	(42)	13
Accumulated deficit	(264,886)	(228,340)
Total stockholders' deficit	(251,073)	(217,077)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 110,275	$ 143,663

The accompanying notes are an integral part of these unaudited financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Six Months Ended June 30,	
	2026	2025
Operating expenses:		
Research and development	$ 28,454	$ 20,812
General and administrative	9,764	10,074
Total operating expenses	38,218	30,886
Loss from operations	(38,218)	(30,886)
Other income (loss):		
Interest income	1,670	858
Other income (loss), net	2	(1,731)
Total other income (loss), net	1,672	(873)
Net loss	$ (36,546)	$ (31,759)
Net loss per common share:		
Net loss per common share, basic and diluted	$ (33.39)	$ (30.73)
Weighted-average shares used to calculate net loss per common share, basic and diluted	1,094,550	1,033,651

The accompanying notes are an integral part of these unaudited financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2026	2025
Net loss	$ (36,546)	$ (31,759)
Other comprehensive loss:		
Unrealized loss on marketable securities	(55)	(32)
Comprehensive loss	$ (36,601)	$ (31,791)

The accompanying notes are an integral part of these unaudited financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2025	177,593,856	$ 338,808	1,074,089	$ —	$ 11,250	$ 13	$ (228,340)	$ (217,077)
Exercise of stock options	—	—	35,480	—	122	—	—	122
Stock-based compensation	—	—	—	—	2,483	—	—	2,483
Unrealized loss on marketable securities	—	—	—	—	—	(55)	—	(55)
Net loss	—	—	—	—	—	—	(36,546)	(36,546)
Balance at June 30, 2026	177,593,856	$ 338,808	1,109,569	$ —	$ 13,855	$ (42)	$ (264,886)	$ (251,073)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	101,428,978	$ 223,480	1,014,267	$ —	$ 8,518	$ 39	$ (166,284)	$ (157,727)
Exercise of stock options	—	—	7,886	—	50	—	—	50
Vesting of restricted stock	—	—	24,796	—	14	—	—	14
Stock-based compensation	—	—	—	—	1,220	—	—	1,220
Unrealized loss on marketable securities	—	—	—	—	—	(32)	—	(32)
Net loss	—	—	—	—	—	—	(31,759)	(31,759)
Balance at June 30, 2025	101,428,978	$ 223,480	1,046,949	$ —	$ 9,802	$ 7	$ (198,043)	$ (188,234)

The accompanying notes are an integral part of these unaudited financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Statements of Cash Flows
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2026	2025
Operating Activities		
Net loss	$ (36,546)	$ (31,759)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock-based compensation	2,483	1,220
Amortization of right-of-use lease assets	1,239	1,140
Depreciation	881	804
Accretion of discounts and amortization of premiums on short-term investments, net	(748)	43
(Gain) loss from change in fair value of convertible note receivable	(2)	1,737
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(532)	(1,712)
Other noncurrent assets	(33)	121
Accounts payable	1,637	525
Accrued expenses and other current liabilities	(1,402)	(1,410)
Noncurrent liabilities	(1,482)	(1,328)
Net cash used in operating activities	(34,505)	(30,619)
Investing Activities		
Purchases of marketable securities	(55,571)	(9,824)
Maturities of marketable securities	33,777	38,312
Purchases of property and equipment	(3,819)	(3,732)
Net cash (used in) provided by investing activities	(25,613)	24,756
Financing Activities		
Proceeds from exercise of stock options	122	50
Payment of deferred offering costs	(814)	—
Net cash (used in) provided by financing activities	(692)	50
Net decrease in cash, cash equivalents and restricted cash	(60,810)	(5,813)
Cash, cash equivalents and restricted cash at beginning of year	82,719	15,843
Cash, cash equivalents and restricted cash at end of year	$ 21,909	$ 10,030
Supplemental Disclosure for Non-cash Activities		
Deferred offering costs included in accounts payable and accrued expenses	1,681	—
Change in purchases of property and equipment included in accrued expenses	174	668

The accompanying notes are an integral part of these unaudited financial statements.

Table of Contents

Aspen Neuroscience, Inc.

Notes to Unaudited Financial Statements

1. Organization and Basis of Presentation

Description of Business

Aspen Neuroscience, Inc. ("Aspen" or "the Company") is a clinical-stage, regenerative medicine biotechnology company focused on developing autologous induced-pluripotent stem cell ("iPSC")-derived therapies to initially address neurodegenerative diseases with high unmet medical need. The Company's lead program, sasineprocel, is an investigational autologous iPSC-based therapy for Parkinson's disease designed to replace a patient's lost dopamine neurons with dopaminergic neuron precursor cells. Aspen is headquartered in San Diego, California, and was originally incorporated in Delaware on May 18, 2018.

Basis of Presentation

The Company's unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") applicable to interim financial information. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and pursuant to the rules and regulations of the SEC.

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period. These unaudited financial statements should be read in conjunction with the Company's audited financial statements and accompanying notes for the years ended December 31, 2025 and 2024.

Emerging Growth Company Status

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these unaudited financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Liquidity and Capital Resources

From inception through June 30, 2026, the Company has devoted substantially all of its efforts to conducting product research and development, developing intellectual property, raising capital and entering into licensing agreements. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has incurred net losses and negative cash flows from operating activities since inception and had an accumulated deficit of $264.9 million as of June 30, 2026. The Company expects to continue to incur net losses into the foreseeable future as it continues the development of its pipeline and expands its product manufacturing efforts. As a result, the Company will need to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

The accompanying unaudited financial statements have been prepared on a basis that assumes the Company will continue as a going concern. As of June 30, 2026, the Company had cash, cash equivalents and marketable securities of $72.4 million. Based on its current operating plan and without giving effect to any proceeds from any

financing transaction, the Company believes that its existing cash, cash equivalents and marketable securities will not be sufficient to fund its operations for the 12 months following the date of issuance of these unaudited financial statements. Accordingly, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that these unaudited financial statements are issued. The unaudited financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from this uncertainty.

Future capital requirements will depend on many factors, including the timing and extent of the Company's spending on its operations, and there can be no assurance that the Company will be successful in obtaining additional funding, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. The failure to obtain sufficient funds on acceptable terms and in a timely manner could require the Company to make significant spending reductions in its future operations including suspending or curtailing planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Use of Estimates

The preparation of the Company's unaudited financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent liabilities in the Company's unaudited financial statements and accompanying notes. The most significant estimates in the Company's unaudited financial statements relate to accruals for research and development expenses, valuation of stock-based awards, fair value of convertible promissory note receivable and incremental borrowing rate used for calculating operating lease liabilities. Management evaluates its estimates on an ongoing basis. Although these 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.

Summary of Significant Accounting Policies

During the six months ended June 30, 2026, there were no changes to the Company's significant accounting policies as described in Note 1 to the audited financial statements for the year ended December 31, 2025.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash, cash equivalents and marketable securities. The Company maintains deposits in federally insured major 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 institution in which those deposits are held.

Segment Reporting

The Company's chief operating decision maker ("CODM") is the Company's Chief Executive Officer. The CODM is assisted in his responsibilities of making decisions regarding resource allocation and performance assessment by the leadership team, consisting of executive officers and vice presidents.

The Company views its operations and manages its business as one operating segment, focused on developing autologous iPSC-derived therapies to initially address neurodegenerative diseases with high unmet medical need.

Segment loss is measured as the Company's net loss as reported on the Company's statements of operations. The Company monitors its cash, cash equivalents, and marketable securities as reported on the Company's balance sheets to determine funding for its research and development programs. When evaluating the Company's financial performance, the CODM reviews total expenses by certain categories and makes decisions using this information.

Significant segment expenses which are regularly reported to the CODM for purposes of making decisions regarding the allocation of resources are included within the table below and are reconciled to net loss (in thousands):

	Six Months Ended June 30,	
	2026	2025
Salaries, bonuses and benefits	$ 15,663	$ 13,678
Cell-therapy development and production costs	11,706	7,656
Equipment and facilities costs	4,746	4,247
Other[(1)]	4,431	6,178
Net loss	$ (36,546)	$ (31,759)

[(1)] Other includes stock-based compensation, depreciation, interest income, and other income (loss).

Recent Accounting Pronouncements

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which establishes guidance on the recognition, measurement, presentation, and disclosure of government grants received by business entities. The standard is effective for public business entities for annual reporting periods beginning after December 15, 2028, including interim periods within those annual reporting periods, and for all other entities for annual reporting periods beginning after December 15, 2029, including interim periods within those annual reporting periods. Early adoption is permitted. The standard may be adopted using a modified prospective, modified retrospective, or full retrospective approach. The Company is currently evaluating the impact of adoption of this standard on its financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which is intended to enhance expense disclosures by requiring additional information about specific expense categories in the notes to the financial statements. The standard is effective, as clarified by ASU 2025-01, for annual periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be adopted prospectively or retrospectively. The Company is currently evaluating the impact of the standard on its financial statements and related disclosures.

2. 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 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).

Level 1 includes money market funds and U.S. treasuries. Level 2 includes corporate bonds and asset-backed securities.

The Company obtains the fair value of its Level 2 investments from a professional pricing service and validates the fair value of its Level 2 investments by understanding the pricing model used by the professional pricing service and comparing that fair value to the fair value based on observable market prices.

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 did not have any securities that were in a material unrealized loss position.

The following tables present the major security types that the Company held as of June 30, 2026 and December 31, 2025 regularly measured and carried at fair value (in thousands):

	June 30, 2026				
	Amortized Cost	Unrealized Gains (Losses)	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Level 1					
Cash	$ 721	$ —	$ 721	$ 721	$ —
Money market funds	20,566	—	20,566	20,566	—
U.S. treasuries	50,556	(42)	50,514	—	50,514
Level 1 total	71,843	(42)	71,801	21,287	50,514
Level 2					
Corporate fixed income securities	299	—	299	—	299
Asset backed securities	277	—	277	—	277
Level 2 total	576	—	576	—	576
Total	$ 72,419	$ (42)	$ 72,377	$ 21,287	$ 51,090

	December 31, 2025				
	Amortized Cost	Unrealized Gains (Losses)	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Level 1					
Cash	$ 507	$ —	$ 507	$ 507	$ —
Money market funds	34,441	—	34,441	34,441	—
U.S. treasuries	71,034	6	71,040	47,149	23,891
Level 1 total	105,982	6	105,988	82,097	23,891
Level 2					
Corporate fixed income securities	3,444	4	3,448	—	3,448
Asset backed securities	1,260	3	1,263	—	1,263
Level 2 total	4,704	7	4,711	—	4,711
Total	$ 110,686	$ 13	$ 110,699	$ 82,097	$ 28,602

The estimated fair value of contractual maturities of fixed income securities as of June 30, 2026 and December 31, 2025 were as follows (in thousands):

	June 30, 2026	December 31, 2025
Due within one year	$ 50,845	$ 27,339
One to two years	245	803
More than two years	—	460
Total	$ 51,090	$ 28,602

The following table presents a reconciliation of assets that were measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Balance at December 31, 2025	Change in fair value included in other income (loss)	Balance at June 30, 2026
Level 3			
Cell X Convertible Note	$ 944	$ 2	$ 946
Total	$ 944	$ 2	$ 946

The Cell X Convertible Note is recorded in other noncurrent assets on the balance sheets and is described in Note 7 of these unaudited financial statements. The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the Cell X Convertible Note as of June 30, 2026:

Key unobservable inputs	Range
Estimated time to liquidity	1.5–2.5 years
Volatility	70.0%
Discount rate	29.3%

There are significant judgments, assumptions and estimates inherent in the determination of the fair value of the Cell X Convertible Note. These include determining a valuation method and selecting possible outcomes available to the Company, including the timing and expected future investment returns for such scenarios. The related judgments, assumptions and estimates are highly interrelated, and changes in any one assumption could necessitate changes in another. Any changes in the probability of a particular outcome would require a related change to the probability of another outcome.

The fair value of the Cell X Convertible Note was estimated using a scenario-based analysis that estimated the fair value of the note based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the Company as the noteholder, including settlement, a qualified equity financing, corporate transactions and dissolution scenarios.

3. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Accrued compensation	$ 4,094	$ 5,652
Accrued research	2,428	1,816
Other accrued expenses	578	137
Total accrued expenses	$ 7,100	$ 7,605

4. Property and Equipment, net

Property and equipment, net consist of the following (in thousands):

	Estimated Useful Lives (in years)	June 30, 2026	December 31, 2025
Lab equipment	3 to 10	$ 9,332	$ 7,739
Leasehold improvements	The lesser of the remaining useful of the asset or the remaining lease term	5,652	5,653
Furniture and fixtures	3 to 10	857	845
Computer and software	3 to 7	521	512
Vehicle	5	42	42
Construction in progress		11,042	8,645
Total property and equipment, gross		27,446	23,436
Less: accumulated depreciation		(5,417)	(4,536)
Total property and equipment, net		$ 22,029	$ 18,900

The Company recorded depreciation expense of $0.9 million and $0.8 million for the six months ended June 30, 2026 and 2025, respectively. The Company did not recognize any impairment losses for the six months ended June 30, 2026 and 2025.

5. Other Noncurrent Assets

Other noncurrent assets consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Deferred offering costs	$ 2,495	$ -
Prepaid equipment	2,204	2,221
Cell X Convertible Note	946	944
Deferred asset costs	92	58
Total other noncurrent assets	$ 5,737	$ 3,223

6. Convertible Preferred Stock and Stockholders' Deficit

The Company's convertible preferred stock has been classified as temporary equity on the accompanying balance sheets. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock can cause its redemption. Because these change-in-control events are not considered probable for accounting purposes, the Company has not adjusted the carrying values of the convertible preferred stock to redemption value.

Dividends

Each holder of the Company's Series C, Series B, Series A (Series A-1 and Series A-2 combined as a separate class) and Series Seed (Series Seed and Series Seed-2 combined as a separate class) convertible preferred stock is entitled to receive non-cumulative dividends, when and if declared by the Company's Board of Directors. No dividends have been declared to date.

Series C preferred stock has priority dividend rights over all other classes of capital stock, and all other series of preferred stock rank *pari passu* with one another and senior to common stock with respect to dividends.

Liquidation Preferences

In the event of any liquidation, dissolution or winding up of the Company, the holders of the convertible preferred stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share equal to the original issue price plus declared but unpaid dividends.

The stockholders of the Series C preferred stock have liquidation preferences over all other preferred stockholders. The stockholders of Series A-1 and Series A-2 Preferred Stock have liquidation preferences over the stockholders of the Series Seed Preferred Stock.

Conversion

Each share of convertible preferred stock is convertible at the option of the holder, at any time, into the number of shares of common stock determined by dividing the applicable purchase price ($0.540614, $1.029742, $1.696405, $1.767236, $2.9109, and $1.5179 for the Series Seed, Series Seed-2, Series A-1, Series A-2, Series B, and Series C, respectively) by the applicable conversion price at the time of conversion.

Each share of convertible preferred stock will be automatically converted into common stock immediately upon (i) the closing of a firm commitment underwritten initial public offering at a price of at least $30.00 per share resulting in at least $50.0 million of gross proceeds to the Company or (ii) the approval, by vote or written consent, of the holders of a majority of the outstanding shares of preferred stock (voting together as a single class on an as-converted basis), together with the holders of a majority of shares of outstanding Series C preferred stock, and a majority of shares of outstanding Series B preferred stock.

Voting

The holders of convertible preferred stock are entitled to one vote for each share of common stock into which such shares of convertible preferred stock could then be converted; and with respect to such vote, such holders shall have full voting rights and powers equal to the voting rights and powers of the holders of the common stock.

Redemption

The convertible preferred stock is not explicitly redeemable except in the event of certain effected deemed liquidation events.

Stock Options

In 2018, the Company adopted the 2018 Stock Plan (the “Plan”). The Plan provides for the grant of incentive stock options, non-statutory stock options, and restricted stock awards to directors, employees and consultants of the Company. Through June 30, 2026, the Company has limited its grants under the Plan solely to stock options. The Plan allows for the early exercise of stock options to plan participants subject to the right of repurchase by the Company at the original purchase price upon any voluntary or involuntary separation of an employee from the Company. Shares subject to the Company’s right to repurchase are not deemed outstanding for accounting purposes until those shares vest.

As of June 30, 2026, the total number of shares authorized under the Plan was 4,264,902, and the number of shares available for issuance under the Plan was 44,106.

Stock options granted under the Plan are exercisable based on vesting schedules determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option is determined by the Board of Directors based on the estimated fair value of the Company’s stock on the date of the option grant. Option grants generally vest either (a) monthly over four years, or (b) 25% on the first anniversary of the original vesting commencement date, with the balance vesting monthly over the remaining three years.

A summary of the Company's stock option activity under the Plan is as follows:

	Number of Options	Weighted-average Exercise Price (per share)	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	2,820,275	$ 6.53		
Granted	286,629	8.90		
Exercised	(35,480)	3.57		
Canceled	(27,927)	7.93		
Outstanding at June 30, 2026	3,043,497	$ 6.75	8.25	$ 9,240
Exercisable at June 30, 2026	1,344,458	$ 6.95	6.94	$ 3,809

Options outstanding as of June 30, 2026 consist of options vested and expected to vest. Aggregate intrinsic value in the table above is the total in-the-money value of the options above as of June 30, 2026 based on the Company's latest estimated fair value of its common stock in 2026.

The intrinsic value of options exercised during the six months ended June 30, 2026 and 2025, calculated based on the Company's latest estimated fair value of its common stock in 2026 and 2025, respectively, was $0.2 million and $19,000, respectively.

The aggregate fair value of shares vested during the six months ended June 30, 2026 and 2025 was $1.8 million and $1.0 million, respectively. As of June 30, 2026, there were 1.3 million options vested and outstanding.

The weighted-average grant date fair value of employee option grants during the six months ended June 30, 2026 and 2025 was $7.57 per share and $6.98 per share, respectively.

In 2019, the Company amended the Plan to allow its directors and officers to early exercise their stock options by delivery of promissory notes, which provide the Company first-priority security interest in the underlying shares exercised through such promissory notes ("Promissory Notes"). In 2021 and 2022, certain directors and officers of the Company early exercised their stock options using Promissory Notes. These Promissory Notes accrue interest at a rate of 2% per year. For accounting purposes, Promissory Notes are treated as non-recourse as the Company does not intend to pursue cash collection in the event of default. Accordingly, the resulting exercises of the options were determined to be non-substantive, and the Company has not recorded the Promissory Notes or related accrued interest on its balance sheets. For this reason, the shares are not considered to be outstanding until the Promissory Notes are repaid. The principal balance and accrued interest of the Promissory Notes was $2.4 million and $2.3 million as of June 30, 2026 and December 31, 2025, respectively. The number of shares subject to Promissory Notes was 622,707 as of June 30, 2026 and December 31, 2025.

Stock-based Compensation Expense

The following table summarizes stock-based compensation recognized in the Company's statements of operations (in thousands):

	Six Months Ended June 30,	
	2026	2025
Research and development	$ 1,251	$ 536
General and administrative	1,232	684
Total stock-based compensation	$ 2,483	$ 1,220

As of June 30, 2026, total unrecognized stock-based compensation cost was $12.0 million, which is expected to be recognized as expense over a weighted average period of 3.2 years.

Stock Option Valuation

The fair value of the Company's stock option awards is estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Six Months Ended June 30,	
	2026	2025
Risk-free rate of interest	3.9% –4.2%	4.1% –4.2%
Expected term (years)	5.97–6.08	5.94–6.07
Expected stock price volatility	94.0%–96.8%	98.4%–98.7%

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 term (years). 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, which uses the average of the time-to-vesting and the contractual term of the options.

Expected stock price 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.

Dividend yield. The Company used a dividend yield assumption of 0% based on the Company's history and expectation of dividend payments. The Company has not paid and does not intend to pay dividends.

7. License Agreements

TSRI License Agreement

In October 2018, the Company was assigned an exclusive license agreement by Summit for Stem Cell Foundation with the Scripps Research Institute ("TSRI") under which Aspen acquired the exclusive license to intellectual property, which allows the Company to substantially facilitate the development of the licensed intellectual property (the "TSRI License Agreement"). The TSRI License Agreement includes the payment of royalties equal to a low single digit percentage on future net sales of licensed products. If the Company sublicenses a product under the TSRI License Agreement, the Company is obligated to pay TSRI a royalty of a mid-single-digit percentage of sublicensing consideration. Payments related to the TSRI License Agreement are made in the period when the contingency is resolved, and the amounts become payable. No amounts have been payable under this agreement.

AJ License Agreement

In September 2019, the Company entered into a non-exclusive license agreement with iPS Academia Japan, Inc. ("the AJ License Agreement") pursuant to which iPS Academia Japan, Inc. granted the Company a license under the licensed patents for the development, manufacture, and sale of licensed products. Pursuant to the AJ License Agreement, the Company is obligated to pay iPS Academia Japan, Inc. an upfront fee of $60,000 and annual maintenance fees of $25,000 until and including the calendar year in which the Company obtains approval of a first new drug application of a licensed product. The Company is obligated to pay future milestone payments up to $135,000 upon the successful achievement of developmental milestones, and up to $1.1 million when certain net sales thresholds of a licensed product are met. The Company is obligated to pay future royalty payments in the low single digit percentage of net sales of licensed products. We will also be subject to an annual minimum royalty of $25,000 following the first approval of a licensed product. The Company recognizes the expense of the milestones when payable.

The AJ License Agreement contains additional customary representations and warranties, covenants, indemnifications and insurance and confidentiality provisions for agreements of its type. The AJ License Agreement may be terminated upon mutual consent of both parties. Unless terminated in accordance with its terms, the AJ License Agreement continues until the expiration, revocation or invalidation of the last patents or the abandonment of the last patent application included within the licensed patents and technology.

Payments related to this license agreement are expensed in the period when the contingency is resolved, and the amounts become payable. The Company did not incur any expenses under this agreement during the six months ended June 30, 2026 and 2025.

Sumitomo License Agreement

In December 2023, the Company entered into a non-exclusive license agreement with Sumitomo Pharma Co., Ltd. ("the Sumitomo License Agreement") with the Company to obtain a non-exclusive sublicense for certain rights granted by ID Pharma to Sumitomo under the original license agreement between Sumitomo and ID Pharma. the Company is obligated to pay Sumitomo Pharma Co., Ltd. an upfront fee of ¥40.0 million and annual license fees of ¥6.0 million. The Company is obligated to pay future development milestone payments up to ¥125.0 million per licensed product per region for up to three regions upon the successful achievement of each developmental milestone, and up to ¥1.85 billion per licensed product when certain net sales thresholds of a licensed product are met. The Company is obligated to pay future royalty payments in the low single digit percentage of net sales of licensed products. The Company incurred expenses under this agreement of $23,000 and $21,000 during the six months ended June 30, 2026 and 2025, respectively.

Cell X License Agreement

In January 2024, Cell X Technologies, Inc. ("Cell X") and the Company entered into a Collaboration and License Agreement upon which Cell X granted licenses to the Company to develop, practice, make, have made, use, sell, offer to sell, import and commercialize Licensed Products in the Licensed Field in the Territory as defined and more fully set forth in the Cell X agreement. In connection with such licenses, the Company and Cell X also agreed to collaborate for the purpose of improving the Cell X platform technology for use by the Company to develop, practice, make, have made, use, sell, offer to sell, import and commercialize licensed products in the licensed field. The Company paid Cell X an upfront fee of $250,000 and was obligated to pay future development milestone payments up to $30.5 million, and additional potential license fees if the Company pursues the technology for certain additional indications of up to $15.5 million. The Company paid the $250,000 upfront fee in 2024, which was included as a component of research and development expenses in the statement of operations.

In January 2024, the Company and Cell X entered a Secured Convertible Promissory Note Purchase Agreement whereby the Company agreed to purchase, and Cell X agreed to sell and issue, a convertible promissory note ("Cell X Convertible Note") with an original principal amount equal to $5.0 million and an 8% annual interest rate. The outstanding amount shall automatically convert into shares of Cell X's preferred stock (the "Conversion Stock") upon a qualified financing and provides an optional conversion upon a non-qualified equity financing. The principal and accrued interest are due and payable upon the earliest to occur of (i) the maturity date, (ii) a change in control of Cell X or (iii) the occurrence of an event of default, as defined in the agreement. The Company purchased the $5.0 million note in 2024 and elected the fair value option for the note.

The fair value of the Cell X Convertible Note was $0.9 million as of both June 30, 2026 and December 31, 2025, which is included in other noncurrent assets on the balance sheets. The Company recorded a $2,000 gain and a $1.7 million loss during the six months ended June 30, 2026 and 2025, respectively, resulting from the change in fair value of the Cell X Convertible Note (see Note 2).

In January 2026, the Company and Cell X amended the Cell X Convertible Note to extend the maturity date to February 2026, or such later date approved by the Company and Cell X. In February 2026, the Company and Cell X extended the maturity date to March 2026, and in March 2026, the Company and Cell X extended the maturity date to April 13, 2026. Subsequently, the Company and Cell X entered into a series of additional amendments to further extend the maturity date through June 10, 2026. Following June 10, 2026, the maturity was not extended; however, the Company has not called or converted the Cell X Convertible Note through the date these unaudited financial statements were issued.

8. Loan and Security Agreement

In December 2022, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with a lender (the "Lender"). Under the Loan Agreement, the Company was permitted to borrow $15.0 million at the inception of the Loan Agreement and up to an additional $25.0 million from three additional tranches at the Company's option subject to achievement of certain clinical milestones.

In connection with the Loan Agreement, the Company issued the Lender a warrant (the "Lender Warrant") to purchase 13,333 shares of the Company's common stock as of the date of the agreement at an exercise price of $7.71 per share and expiring on December 20, 2032. The Company recorded $0.1 million as a component of additional paid-in capital within stockholders' deficit upon issuing the Lender Warrant.

In November 2024, the Company entered into a Warrant Purchase Agreement with the Lender to allow for the purchase of 4,445 shares of common stock at an exercise price of $7.71 per share. The Company recorded $34,000 as a component of additional paid-in capital within stockholders' deficit related to the Lender Warrant.

In November 2025, the Loan Agreement expired undrawn, and the Company has no debt obligations under the Loan Agreement as of June 30, 2026 and December 31, 2025.

9. California Institute for Regenerative Medicine Award

In March 2024, the California Institute for Regenerative Medicine (the "CIRM") issued an award to the Company for $8.0 million to co-sponsor a Phase 1/2a dose escalation study of the Company's lead product candidate, sasineprocel, in sporadic Parkinson's disease (the "Award"). The Company is eligible to receive seven disbursements in varying amounts, with one disbursement receivable upon the execution of the Award, and six disbursements receivable upon the completion of certain milestones throughout the project period of the Award, which is estimated to be from April 2024 to September 2026 (the "Award Period").

Following the conclusion of the Award Period, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. If the Company does not elect to treat the Award as a loan within 10 years of the award date, the Award will be considered a grant, and the Company will be obligated to pay CIRM, on a quarterly basis, a low single-digit royalty on commercial sales of sasineprocel until such aggregate royalty payments equal nine times the total amount awarded to the Company under the Award. If the Company elects to treat the Award as a loan, the Company is obligated to repay the Award within ten business days of making the election at an amount based on a specified percentage of the Award (ranging from 80% to 100%, plus, in certain cases, interest up to an annual percentage rate of 10% plus LIBOR), with the applicable amounts based on the phase of development of sasineprocel at the time the election is made

The Company has elected for accounting purposes to treat the Award as a direct research and development arrangement in accordance with ASC 730-20, *Research and Development—Research and Development Arrangements*, as the Company does not intend to repay the Award other than by way of royalty payments on potential future sales of sasineprocel. The Award is recognized as an offset to research and development expenses as costs related to the project are incurred as the Company has concluded that the research and development risk is substantive and it is not yet probable that development will be successful. A deferred liability is recorded when the cash disbursements under the Award exceed the related research and development expenses incurred through such date.

During the six months ended June 30, 2026 and 2025, the Company did not receive any cash disbursements under the Award. The Company recognized $0.9 million and $1.0 million as an offset to research and development expense for the six months ended June 30, 2026 and 2025, respectively. The Company recorded no deferred liability as of June 30, 2026 and recorded a deferred liability of $0.4 million in other current liabilities as of December 31, 2025.

Table of Contents

10. Commitments and Contingencies

Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the balance sheets. These leases have terms varying from approximately three to ten years, with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise the options. The leases are subject to additional variable costs, including common area maintenance, property taxes, property insurance, and utilities. Variable costs are recognized as expense as incurred.

During the six months ended June 30, 2026, the Company incurred $2.6 million of lease expense; $1.0 million was related to variable costs, and $1.6 million was related to straight-line operating lease expense. During the six months ended June 30, 2025, the Company incurred $2.3 million of lease expense; $0.7 million was related to variable lease costs, and $1.6 million was related to straight-line operating lease expense.

As of June 30, 2026, maturities of the Company's operating leases in effect as of June 30, 2026 were as follows (in thousands):

Minimum lease payments for the year ending December 31,	
2026 (6 months)	1,844
2027	3,051
2028	1,392
2029	1,434
2030	1,477
Thereafter	2,430
Total future minimum lease payments	11,628
Less: present value discount	(1,857)
Total operating lease liabilities	9,771
Less: current portion	(3,583)
Lease liabilities, noncurrent	$ 6,188
Weighted-average remaining lease term (in years)	4.87
Weighted-average incremental borrowing rate	7.70%

The table above does not include obligations under the Company's new lease described in Note 13.

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business. The Company believes there is no litigation pending that could have, individually, or in the aggregate, have a material adverse effect on the results of its operations, financial condition or cash flows.

11. Income Taxes

During the six months ended June 30, 2026 and 2025, the Company did not record income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items.

The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. As of June 30, 2026, there were no pending tax examinations. All of the Company's tax years from inception are subject to examination by federal and state tax authorities.

12. Net Loss per Share

In periods of net loss, basic and diluted net loss per share are calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding.

Convertible preferred stock are considered participating securities; however, they were excluded from the computation of basic net loss per share because there is no contractual obligation for the holders to share in the losses of the Company. Options outstanding, common stock issued subject to Promissory Notes, Lender Warrants, and common stock subject to repurchase due to being early exercised and unvested, were excluded from the computation of net loss per share because including them would have had an anti-dilutive effect.

The following table summarizes issued securities excluded from the calculation of net loss per share:

	June 30,	
	2026	2025
Issued securities excluded from the calculation of net loss per share:		
Convertible preferred stock, as converted	17,971,324	10,263,910
Options outstanding	3,043,497	1,490,539
Common stock subject to Promissory Notes	622,707	622,707
Lender Warrants	17,778	17,778
Other common stock subject to repurchase	—	949
Total	21,655,306	12,395,883

13. Subsequent Events

For the unaudited financial statements as of and for the six months ended June 30, 2026, the Company evaluated subsequent events through October 9, 2026, the date on which these unaudited financial statements were issued. The Company further evaluated subsequent events through October 26, 2026 and has determined that, other than the events described below, there were no further subsequent events requiring disclosure in these unaudited financial statements.

Promissory Note

In August 2026, the Company's Board of Directors authorized, and the Company completed, the forgiveness of promissory notes held by the Company's Chief Executive Officer, representing approximately $1.9 million of outstanding principal, $0.2 million of accrued interest and 561,646 shares of underlying common stock. In connection with the forgiveness, the Company also amended the vesting schedule applicable to the Chief Executive Officer's November 2025 option grant, extending the vesting period from four to six years for the remaining unvested options.

In September 2026, the Company's Board of Directors authorized, and the Company completed, the forgiveness of promissory notes held by certain members of the Company's Board of Directors, representing approximately $0.2 million of outstanding principal, $23,000 of accrued interest and 61,061 shares of underlying common stock. In connection with the forgiveness, the Company also amended the vesting schedules applicable to such directors' November 2025 option grants, extending the vesting period from four to six years for the remaining unvested options.

Because the promissory notes were treated as substantively nonrecourse for accounting purposes, the Company historically accounted for the arrangements as outstanding stock options and excluded the related shares from basic weighted-average common shares outstanding. The Company accounted for the forgiveness and related changes in award terms as modifications under ASC 718 and expects to recognize an estimated $1.8 million of incremental noncash stock-based compensation expense during the quarter ended September 30, 2026. Following forgiveness, the 529,100 related shares are considered issued and outstanding for accounting purposes and will be included in basic weighted-average common shares outstanding beginning on the applicable forgiveness dates. The remaining 93,607 shares remain subject to performance-based vesting conditions and are not considered outstanding for accounting purposes as they remain subject to forfeiture if performance-based vesting conditions are not satisfied.

Cell X

In August 2026, the Company and Cell X entered into an Amended and Restated Collaboration and License Agreement (the "A&R CLA"), which amends and restates the Collaboration and License Agreement in its entirety and terminates the parties' collaboration program in favor of a fee-for-service arrangement, under which Cell X will provide development and engineering services to the Company pursuant to a separate services agreement.

Prior to the A&R CLA, the Company's rights to certain Cleveland Clinic Foundation ("CCF")-controlled intellectual property were held indirectly, as a sublicense granted by Cell X, which Cell X licensed directly from CCF. In connection with the A&R CLA, this arrangement was changed so that CCF now grants these rights directly to the Company under a new, separate exclusive license agreement between the Company and CCF (the "CCF License"), rather than through a sublicense from Cell X. The CCF License carries its own financial terms separate from the Cell X milestone payments described below.

Under the A&R CLA and CCF License, the Company's licenses to the Cell X platform technology for Parkinson's disease and leukodystrophies (the same indications covered under the original 2024 agreement) were retained, and the prior milestone and license fee structure, which totaled up to $46.0 million ($30.5 million in development milestones plus $15.5 million if the Company pursues the technology for certain additional indications), was replaced with milestone payments of up to $14.9 million. The reduction in milestone payments reflects the Company no longer having an option to expand the exclusive license into additional indications beyond Parkinson's disease and leukodystrophies. The milestone payments retained for Parkinson's disease and leukodystrophies are substantially consistent with the amounts payable under the original 2024 agreement for those same two indications, but are now allocated between Cell X and CCF.

In connection with these agreements, the Company and Cell X executed a side letter providing that, upon satisfaction of specified conditions, the parties will amend the Cell X Convertible Note to extend its maturity date to March 31, 2028, and will terminate its related security agreements. As of the date of issuance of these unaudited financial statements, these conditions had not been satisfied, and the related amendments had not become effective.

The Company is evaluating the accounting impact of these agreements on its financial statements.

New Lease

In August 2026, the Company entered into a noncancelable operating lease agreement with HCP Life Science REIT, Inc. for approximately 48,696 rentable square feet of office, research and development, laboratory, storage and warehouse space located in La Jolla, California (the "New Lease"), which the Company intends to establish as its corporate headquarters. The Company's lease for its existing corporate headquarters expires in September 2027. The New Lease has an initial term of 93 months commencing on July 1, 2027 and expiring on March 31, 2035. The New Lease includes a beneficial occupancy period beginning on execution of the agreement and continuing through June 30, 2027, allowing the Company to complete facility improvements, install equipment and furniture, and begin certain operations prior to the July 1, 2027 lease commencement date without payment of base rent. At execution, the Company was obligated to pay $0.3 million, representing the first month's base rent and estimated direct expenses. The New Lease provides for a 23-month rent abatement period, during which no base rent is due; as a result, the Company's next base rent payment is not due until July 2029. Aggregate base rent is approximately $20.2 million, net of abatements, with refurbishment and other construction allowances of up to approximately $4.5 million and a required letter of credit of approximately $0.4 million. The Company is evaluating the accounting impact of the New Lease on its financial statements.

Reverse Stock Split

On October 22, 2026, the board of directors and stockholders of the Company approved, and on October 23, 2026, the Company effected, a reverse stock split of the shares of the Company's outstanding common stock at a ratio of 1-for-9.8821 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, options to purchase common stock, warrants, share amounts, per share amounts, and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The shares of common stock underlying outstanding stock options and warrants were proportionately reduced, and the respective exercise prices were proportionately increased. In addition, the conversion ratios for each series of the Company's convertible preferred stock, which will convert into shares of common stock upon the closing of the Company's IPO, were proportionally adjusted.

Table of Contents

9,375,000 Shares



Common Stock

Leerink Partners	**Piper Sandler**	**Stifel**
UBS Investment Bank		**Oppenheimer & Co.**

Through and including November 23, 2026 (the 25th day after the date of this prospectus), 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 dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.