UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2025.

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from |—Date—| to |—Date—|

Commission File Number: 001-41934

FibroBiologics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**86-3329066**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
455 E. Medical Center Blvd, Suite 300 **Houston, TX 77598** (Address of principal executive offices)	**77598** (Zip Code)

(281) 671-5150
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value	FBLG	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates at June 30, 2025 was $21.6 million.

At February 24, 2026, 67,594,722 shares of FibroBiologics, Inc.'s Common Stock, $0.00001 par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, and the documents incorporated by reference herein, if any, contain forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, planned research programs, preclinical studies and clinical trials, and market opportunities 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 "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our current and future product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or likelihood of regulatory submissions, filings, and approvals, including final regulatory approval of our product candidates;
- our ability to develop and advance product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates, in particular, and cell therapy, in general;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our competitive position;
- the scope of protection we and/or our licensors are able to establish and maintain for intellectual property rights covering our product candidates;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; and

- the impact of laws and regulations.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "*Risk Factors*" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, 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. You should read this Annual Report, the documents that we reference in this Annual Report and the other documents that we file with the Securities and Exchange Commission, or the SEC, with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Annual Report, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, 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 unduly rely upon these statements.

PART I

Unless otherwise indicated or the context otherwise requires, all references to the "Company," "FibroBiologics," "we," "us," "our" and the "registrant" refer to FibroBiologics, Inc. and its consolidated subsidiaries.

Item 1. Business

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing fibroblast-based therapies for patients suffering from chronic diseases with significant unmet medical needs, including wound healing, multiple sclerosis, or MS, degenerative disc disease, psoriasis, certain cancers, and potential human longevity applications including thymic involution reversal using a thymic organoid. Our most advanced product candidates are CYWC628, CYPS317, CYMS101 and CybroCell™.

We were formed in April 2021 as a Texas limited liability company under the name FibroBiologics, LLC, and converted to a Delaware corporation in December 2021 under the name Fibrobiologics, Inc. On April 12, 2023, we changed our name to FibroBiologics, Inc. In connection with our formation, we issued shares of our Series A Preferred Stock, or the Series A Preferred Stock, to our then parent, SpinalCyte LLC (d/b/a FibroGenesis), or FibroGenesis, in return for rights to certain intellectual property through a patent assignment agreement, or the Patent Assignment Agreement, and an intellectual property cross-licensing agreement, or the Intellectual Property Cross-License Agreement. Developing the intellectual property obtained from FibroGenesis was the basis for our formation. Prior to our inception, preclinical research and development related to the transferred intellectual property took place under the name FibroGenesis.

Fibroblasts Technology Platform

Fibroblasts and stem cells are the only two cell types in the human body that can regenerate tissue and organs. Studies have indicated that mesenchymal stem cells and fibroblasts share many surface markers in common, can differentiate into many cells including adipocytes, chondrocytes, osteoblasts, hepatocytes, and cardiomyocytes, and can regulate the immune system. However, transcriptomic and epigenetic studies have indicated a clear difference between the two cell types.

Fibroblasts comprise the main cell type of connective tissue, possessing a spindle-shaped morphology, whose classical function had historically been believed to be only to produce the extracellular matrix responsible for maintaining the structural integrity of the tissue. However, publications have demonstrated immune modulation, and maintenance of stem cell niches as other important roles. Fibroblasts also play an important role in every single stage of the wound healing process.

Fibroblasts are favorable to stem cells as a cell therapy treatment platform because fibroblasts:

- can be non-invasively harvested from a variety of skin donors from surgical procedures such as tummy tuck flaps;
- have a faster doubling time in culture than stem cells;
- possess superior immune modulatory activity compared with stem cells;
- are already differentiated and do not spontaneously differentiate like stem cells;
- exhibit enhanced ability to produce regenerative cytokines and growth factors compared with stem cells; and
- are more economical to isolate, culture and expand compared with stem cells because fibroblasts do not require the use of expensive tissue culture media.

Third-party studies have demonstrated that allogeneic fibroblasts, much like mesenchymal stem cells, are immune-privileged and do not provoke an immune response *in vitro* and *in vivo*. These studies include that of Valente and

colleagues (PMID 7646145) in which they looked at the aortic valve after heart transplantation and noted that even acute cases of acute myocardial rejection did not appear to compromise the long-term viability and durability of the valve, and the tissue viability was histologically confirmed and showed perfectly preserved fibroblasts. In another study by O'Brien and colleagues (PMID 3682851) the researchers illustrated, using chromosomal analysis, long-term viability of the male donor fibroblast cells from a valve leaflet removed nine years after implantation into a female recipient. This illustrated that donor fibroblast cells were able to survive and proliferate in the host without destruction by the immune system. If autologous fibroblasts were required instead, it would mean that cells would have to be harvested from each patient, processed and cultured, and then administered to the same patient, which would be more costly and inefficient.

Our Strategy

We are leveraging fibroblast cells as a technology platform to research and develop innovative treatments for chronic diseases with significant unmet treatment needs. Our vision is to become a world leader in regenerative medicine through a rigorous scientific process and commitment to serving patients' needs. To achieve our vision, we focus our efforts on the following strategy:

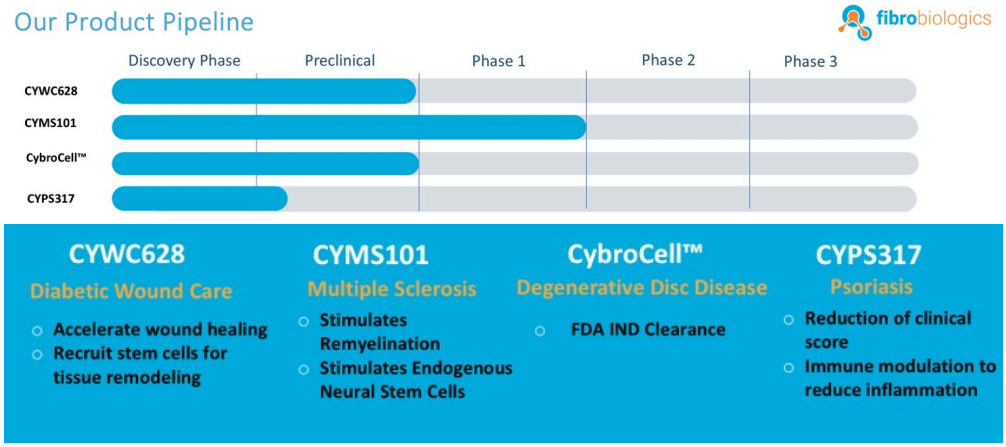
- Prioritize our clinical development efforts on product candidates with significant unmet treatment needs for their target indications.
- Partner with Clinical Research Organizations, or CROs, with the relevant expertise and experience to successfully and timely execute clinical trials to generate reliable pivotal data that can be used to seek approvals.
- Attract and retain scientists with the skill sets required to conduct preclinical studies and identify the optimal paths forward to clinical trials.
- Invest in critical capabilities required to produce and supply fibroblasts for clinical trials and initial commercialization.
- Protect, expand, and defend our intellectual property portfolio around fibroblasts.
- Expand development efforts in product candidates with longer development timelines, greater development risk and significant unmet treatment needs as funding allows.

Our People

We have assembled an executive leadership team comprised of our founder, chief executive officer and chairperson of our board of directors, our chief scientific officer, our chief financial officer, and our general counsel, each with a successful track record in startup entrepreneurial companies and in the life sciences industry. Our executive leadership team works under the oversight of our board of directors who are recognized leaders with hands-on industry experience. We also have a team of world-renowned scientists with deep expertise on our scientific advisory board to help guide our research and development efforts.

Our Current Pipeline

We have a pipeline of product candidates at various stages of development, including the following:



CYWC628 for Wound Healing

Wound Care/Healing

A chronic wound is one that is usually arrested in the inflammatory stage and cannot progress to the proliferative and remodeling phase of healing. Proinflammatory cytokines produced by necrotic tissue, foreign material and bacteria allow the inflammatory stage to continue. In addition, changes in the cellular deoxyribonucleic acid, or DNA, synthesis leads to increased formation of metalloproteases that impede the body's attempt to heal by overwhelming the building blocks—chemoattractant factors, growth factors and mitogens—needed for normal wound healing. Fibroblasts, essential cells in the wound healing process, are epigenetically altered in the setting of chronic wounds so that their ability to replicate as well as produce the necessary building blocks for the formation of granulation tissue is altered. Further, the keratinocytes at the periphery of the wounds are phenotypically different so that while being able to proliferate, they cannot fully differentiate into migrating keratinocytes. This explains the epithelial build up often seen around the edge of the wound.

Diabetic foot ulcers are the most prominent type of chronic wounds. The rising prevalence of chronic diseases globally is leading to increased incidence of chronic wounds, including diabetic foot ulcers, pressure ulcers and venous leg ulcers. These chronic wounds, especially late-stage "hard-to-heal ulcers," exert a significant economic cost burden on healthcare agencies globally. Furthermore, over 50% of diabetic foot ulcers become infected, which raises the risk of hospitalization, amputation, and death.

Available Wound Care Treatments

Several treatments are presently available for treatment of chronic wounds, including Apligraf, Grafix, DermACELL and TheraSkin. Apligraf is comprised of neonatal keratinocytes, and neonatal fibroblasts within a bovine collagen matrix, and may be used to treat venous leg ulcers and diabetic foot ulcers. Grafix is a cryopreserved human placental membrane that may be used as a wound cover, wrap and/or barrier to treat acute and chronic wounds, diabetic ulcers, pressure injuries, surgical wounds, burns and venous ulcers. DermACELL is a technologically advanced dermal matrix comprised of intact cellular matrix that has at least 97% of DNA removed and may be used in the treatment of chronic wounds such as diabetic foot ulcers. TheraSkin is a cryopreserved human skin allograft with both epidermis and dermis layers that may be used to promote wound healing. In addition, increasing application of bioactive therapies like skin grafting and growth factors in urgent treatment of wounds like diabetic foot ulcers is resulting in high investment by companies in research and development of these therapies. In January 2019, Applied Tissue Technologies LLC received FDA approval for its Platform Wound Dressing, NPWT device that eliminates the use of foam or gauze dressings. In April 2019, PolarityTE, Inc. launched clinical trials for its SkinTE regenerative tissue

product for chronic wounds. In January 2021, Smith & Nephew plc published that its PICO single-use negative pressure wound therapy system significantly reduced surgical site infections by 63.0% and the dehiscence by 30.0%, and in February 2021, Axio Biosolutions Private Limited received CE mark from Europe for its MaxioCel advanced wound care product, a bioactive microfiber gelling technology which helps wounds heal quickly.

Our Solution

We have completed our IND-enabling pre-clinical studies for the development of CYWC628 as a topically administered allogeneic fibroblast cell-based therapy for wound healing. Our pre-clinical studies focused on utilizing single cell fibroblasts, fibroblast spheroids, and fibroblast-derived materials to treat wounds in diabetic mice. We completed pre-clinical studies investigating (i) multiple administrations of CYWC628 spheroids on a chemically induced chronic wound NONcNZO10/LtJ and BKS.Cg-Dock7m +/+ LepRdb/J mouse model, (ii) dose titration to provide information on the proposed dose range of CYWC628, and (iii) acute and chronic toxicity. The results of our studies have shown statistically significant acceleration in the rate of wound closure, and statistically significant improvement in the quality of the healed wounds in comparison with both a marketed wound care product and control. Based on these results, we are initiating a twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers in the first quarter of 2026.

Market Opportunity

The wound care market size was valued at approximately $21.0 billion globally in 2024 and is projected to grow to approximately $35.9 billion by 2032 according to Fortune Business Insights. Initiatives are being undertaken by governments globally to create awareness among the general population for early diagnosis of wounds. These initiatives, along with improving reimbursement policies for wound care in the United States and Europe, are anticipated to drive the adoption of wound care products and lead to continued growth in this market.

CYMS101 for Multiple Sclerosis

Multiple Sclerosis

MS has been characterized into four distinct clinical subtypes, differing in the age of onset, aggressiveness and progression of the disease, and frequency of relapses. Most MS cases (85%) follow a relapsing-remitting pattern, or RRMS, with an average relapse every 12 to 18 months in an untreated population, and short-term episodes of neurologic deficits that resolve completely or almost completely. MS relapse is commonly defined as new or worsening symptoms that last 24 hours in duration and occur in the absence of fever or infection. Other patients may transition to a more aggressive disease form known as secondary progressive MS, or will experience steadily progressive neurologic deterioration without relapses, known as primary progressive MS.

There is no primary indicator test for MS, but common testing for suspected MS involves magnetic resonance imaging, or MRI, studies, evoked potentials testing, lumbar puncture/spinal tap, and other objective functional tests.

Once a diagnosis of MS has been determined, ongoing periodic disability measurement testing will occur as a standard clinical practice. The first Disability Status Scale was introduced by Kurtzke in 1955 and was later enhanced in 1983 into the Expanded Disability Status Scale, or EDSS. Over time, the EDSS has become the standard against which most MS clinical outcome measures are compared. Eight functional neurological systems are measured by the EDSS including vision, brainstem, pyramidal, cerebellar, sensory, bowel/bladder, mental/cerebral and ambulation (500m walk).

Other disability measurement tests include the Scripps Neurological Rating Scale, which is an overall neurological assessment; the Nine-Hole Peg Test, which measures arm function; the Paced Auditory Serial Addition Test, which measures cognitive function that assesses auditory information processing speed and calculation ability; and the Timed 25-Foot Walk Test, which measures ambulation function. The RAND 36-Question Health Survey may also be used, which is a general Quality of Life survey utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients.

Available Treatments for MS

There is no known cure for MS. Treatments available for MS include steroids for temporary flare-ups, disease-modifying drugs, and drugs that target specific symptoms such as balance, vision, spasticity, sexual dysfunction, and bladder or bowel control. The mechanism of action of current MS disease-modifying drugs is to block the host's immune-mediated attacks on the nerves to inhibit or minimize the progressive destruction of myelin. While these drugs may reduce the frequency of exacerbations and slow the disease progression from inducing further nerve damage, there is no myelin or nerve regenerative capability in any of them to restore the cumulative damage already in place. Additionally, as the disease progresses further, the ability for any of these drugs to effectively block immune-mediated myelin or nerve destruction becomes more blunted. While there are more than 20 approved treatments for MS, most of them have serious adverse effects.

Key companies currently providing MS treatments include Biogen, Inc., F. Hoffmann-La Roche Ltd (commonly known as Roche), and Novartis AG. Various companies, such as Sanofi and Novartis AG, have been investing in the treatment of MS to bring novel therapeutics with high efficacy and potency for patients. These companies have recently launched therapeutics intended for the most prevalent form of MS. In August 2020, the FDA approved Novartis AG's Kesimpta, the only self-administered, targeted B-cell therapy for patients with relapsing MS, and in March 2021, Johnson & Johnson received FDA approval for the launch of Ponvory as a daily oral drug for treatment against MS. TG Therapeutics, Inc.'s ublituximab for the indication of RMS was also recently approved by the FDA for treatment of MS.

Our Solution

We are developing CYMS101 as an intravenously administered allogeneic fibroblast single cell, and fibroblast spheroid, cell-based therapy to treat MS. After completing animal studies using CYMS101 we received approval from a U.S.-based institutional review board, or IRB, to conduct a clinical investigation in Mexico using the fibroblast cell composition for patients with MS, and completed a Phase 1 study. The study was conducted in five participants. The primary objective of the study was to assess safety, and the secondary objective was to assess efficacy. The primary objective was achieved as we saw no adverse events related to the treatment - no adverse events during intravenous injection of the tolerogenic fibroblasts, no short or long-impact in complete blood count tests during the 16-week monitoring period, and no short or long impact in electrocardiogram results during the 16-week monitoring period. In addition, the study assessed clinical activity using a standard set of neurological assessments routinely used to assess MS. The results of these assessments included:

- General improvement of Paced Auditory Serial Addition Test (PASAT) score for all patients during the 16-week monitoring period.
- General improvement of Nine-Hole Peg test completion time for all patients during the 16-week testing period.
- No general improvement or deterioration noted with the Timed 25-Foot walk test.
- No general improvement or deterioration noted with Expanded Disability Status Scale (EDSS) test.
- No patient exhibited further deterioration during the study trial.

While we believe the early data is promising and encouraging for a first in human use of fibroblast cells for a potential treatment of MS, the number of patients was not high enough to infer statistical significance to the potential efficacy findings.

We are currently conducting further research to more fully characterize the mode of action of fibroblasts in oligodendrocyte expansion. We believe that having a general sense of possible mode of action will have a tangible benefit in the development, optimization, and mitigation of possible side-effects. We plan to file an IND application for a Phase 1/2 clinical trial relating to MS in the United States in the first half of 2026. We expect to seek a strategic partner to collaborate with us on the development of CYMS101 either before initiating the Phase 1/2 study, or after its completion, if successful, and prior to commencing a potential Phase 3 clinical trial.

Market Opportunity

The MS drug market size was valued at approximately $21.3 billion globally in 2023, with North America representing approximately 48% of the market share, and is projected to grow to approximately $38.9 billion globally by 2032 according to Fortune Business Insights. Both private and public organizations are increasing their investments in search of better treatments for this complex disease, including treatments that restore lost function, and government initiatives intended to improve access to MS treatments in developing economies are another potential driver of future growth in the MS drug market.

CybroCell™ for Degenerative Disc Disease

Degenerative Disc Disease

Back pain is strongly associated with degeneration of the intervertebral disc. Disc degeneration, although in many cases asymptomatic, is also associated with sciatica and disc herniation, pain or prolapse. It alters disc height and the mechanics of the rest of the spinal column, adversely affecting the behavior of other spinal structures such as muscles and ligaments. In the long term, it can lead to spinal stenosis, a major cause of pain and disability in the elderly. The incidence of degenerative disc disease is rising with current demographic changes and an increased aged population.

The disc acts as a joint between two vertebra and absorbs shock, maintains motion, and keeps stability, all critical functions. Discs degenerate far earlier than do other musculoskeletal tissues. The first unequivocal findings of degeneration in the lumbar discs are seen in the age group 11–16 years. About 20% of people in their teens have discs with mild signs of degeneration. The percentage increases sharply with age, particularly in males, so that around 10% of 50-year-old discs and 60% of 70-year-old discs are severely degenerated ("*Current Epidemiology of Low Back Pain*" by Mattiuzzi et al, in 2020).

During growth and skeletal maturation, the boundary between annulus and nucleus becomes less obvious and, with increasing age, the nucleus generally becomes more fibrotic and less gel-like. With increasing age and degeneration, the disc changes in morphology, becoming more and more disorganized. Often, the annular lamellae becomes irregular, bifurcating and interdigitating, and the collagen and elastin networks also appear to become more disorganized.

Cleft formation with fissures frequently forms within the disc, particularly in the nucleus. Nerves and blood vessels are increasingly found with degeneration. Cell proliferation occurs, leading to cluster formation in the nucleus. Cell death also occurs, with the presence of cells with necrotic and apoptotic appearance. It has been reported that more than 50% of cells in adult discs are necrotic. With increasing age comes an increased incidence of degenerative changes, including cell death, cell proliferation, mucous degeneration, granular change, and concentric tears. It is difficult to differentiate changes that occur solely due to aging from those that might be considered 'pathological'.

According to research published in a Global Burden of Disease analysis in 2020, approximately 619 million people worldwide were living with low back pain, with a projected 843 million cases by 2050, confirming a substantial increase in global burden compared with earlier estimates. Furthermore, lower back pain is considered as one of the chief complaints that may indicate an underlying spine-related disorder. According to the research published in the Journal of Hospital Management and Health Policy, titled "*Current Epidemiology of Low Back Pain*" by Mattiuzzi et al, in 2020, incidence, prevalence and disability-adjusted life years, or DALYs, of lower back pain are 245.9 million cases per year (15th worldwide cause), 577.0 million cases (15th worldwide cause) and 64.9 million (6th worldwide cause), respectively. The paper further stated that the risk of lower back pain is marginally higher in women compared to men.

These statistics indicate the significant impact degenerative spine disorders can have on patients' lives. These indications are associated with a diverse range of clinical symptoms such as weakness, low extremity pain and back pain, and can result in a significant reduction in the quality of life.

Available Treatments for Degenerative Disc Disease

The treatments used presently are mainly conservative and palliative and are aimed at returning patients to work. They range from bed rest (no longer recommended) to analgesia, the use of muscle relaxants or injection of corticosteroids,

or local anesthetic and manipulation therapies. Various interventions (e.g., intradiscal electrotherapy) are also used, but despite anecdotal statements of success, trials thus far have found their use to be of little direct benefit. Disc degeneration-related pain may also be treated surgically either by artificial disc replacement or by immobilization of the affected vertebrae.

Most patients suffering from degenerative disc disease, at least initially, show improvement with non-surgical interventions such as physical therapy, core strengthening, and stretching. When those interventions no longer provide relief, patients typically use therapeutics, which include conventional drugs such as opioids, non-steroidal anti-inflammatory drugs, and corticosteroids for pain relief. When these non-surgical therapeutics are no longer effective, patients may undergo surgical treatment, including the use of medical devices or implants, to provide relief.

The typical surgical treatment for correcting degenerated disc is either to perform a discectomy or spinal fusion. Discectomy is an appropriate procedure and is routinely performed to remove the degenerated nucleus through a fenestration within the annulus. It allows removal of both the extruded nucleus (discectomy) and the degenerated remaining inter-vertebral nucleus fragments. Although this procedure is ideal for decompressing and relieving the nervous system (root or cauda equina), it is a poor operation for the spine, due to its resulting disabling condition which leads to a degenerative cascade and may require an additional invasive surgical procedure, like fusion or arthroplasty. Discectomy brings a good short-term effect in relieving radicular pain, but it causes disc height reduction with neuro-foramen stenosis, instability of the treated level, poor result on back pain, and/or complications, such as spinal stenosis or facet pain.

Patients who undergo these procedures are usually on painkillers for weeks and have at least three to six months of recovery time. Therefore, there is a need for a less painful, less invasive, and more effective method. The pitfalls of original treatment procedures have led to a search for the development of non-fusion technologies, such as disc or disc nucleus prosthesis. Disc arthroplasty with an artificial disc is an emerging treatment for patients with disc degeneration. Its advantages are to maintain motion, decrease incidence of adjacent segment degeneration, avoid complications related to fusion and allow early return to function. Currently, two kinds of devices are marketed: the total disc replacement and the nuclear replacement. However, both of these devices have major pitfalls.

There has been a growing demand for spinal artificial discs in the market globally. These devices are gaining popularity as they are designed with the intent to provide stabilization and eliminate pain while preserving motion of the functional spinal unit. Total disc replacement is a bulky metallic prosthesis designed to replace the entire disc: annulus, nucleus, and endplates. These prostheses use an invasive anterior (trans- or retro-peritoneal) approach that requires the presence of a vascular surgeon. Dislodgements, wear debris, degeneration of adjacent intervertebral discs, facet joint arthrosis and subsidence of this type of prosthesis have been reported. The artificial nucleus substitute preserves the remaining disc tissues and their functions. Its design allows its implantation through a posterior approach, but the major limitation of such nucleus prosthesis is that it can be used only in patients in whom disc degeneration is at an early or intermediate stage, because it requires the presence of a competent natural annulus. As a hydrogel-based device, it is fragile, and so it does not resist the outstanding biomechanical constraints of the lumbar spine (shear forces). As inert materials, they may lose their mechanical properties over time, and tears and breakages have been reported. Replacing the nucleus only and leaving in place a damaged annulus generates the conditions for implant extrusion or recidivism of discal herniation.

In addition to disc replacements, there are current treatment options for tissue engineering and regenerative medicine, which represent new options for the treatment of degenerative disc disease. A variety of approaches are used to regenerate tissues. These approaches can be categorized into the following three groups:

(i) Biomaterials, without additional cells, which are used to send signals to attract cells and promote regeneration;

(ii) Cells alone may be used, to form a tissue; and

(iii) Cells may be used with a biomaterial scaffold that acts as a frame for developing tissues.

While Autologous Chondrocyte Transplantation, or ACT, has been used for a few years to repair articular cartilage, tissue engineering for disc repair remains in its infancy. Intensive research is currently underway, and animal studies have shown the feasibility of tissue-engineered intervertebral disc. Typically, articular cartilage is a tissue that is not

naturally regenerated once damaged. Recently, efforts have been made to reconstruct damaged biological tissues by regenerating a portion of the damaged tissues in laboratories. This approach, defined as "tissue engineering," has received significant attention.

Tissue engineering involves the development of biocompatible materials capable of specifically interacting with biological tissues to produce functional tissue equivalents. Tissue engineering has a basic concept of collecting a desired tissue from a patient, isolating cells from the tissue specimen, proliferating cells, seeding the proliferated cells onto a biodegradable polymeric scaffold, culturing the cells for a predetermined period in vitro, and transplanting back the cell/polymer construct into the patient. More interestingly, recent pilot clinical trials have shown that ACT is an efficient treatment of herniated discs. The main disadvantage of ACT for disc repair is that it requires a disc biopsy. Therefore, there is a need for an improved method to restore disc anatomy and improve its functioning, and there remains a need for an improved method of cartilage repair.

Our competitors in the market for degenerative disc disease include Mesoblast Limited, Aesculap Implant Systems, LLC, Novartis AG, Pfizer Inc., Eli Lilly and Company, DiscGenics, Inc., Spine BioPharma, Inc. and Ferring B.V. In July 2021, Aesculap Implant Systems, LLC announced the long-term reporting from its pivotal trial for the activl® Artificial Disc.

Our Solution

CybroCell™ is an investigational intradiscal administered allogeneic fibroblast cell-based therapy in development for degenerative disc disease and is being designed as an alternative method for repairing the cartilage of the intervertebral disc (or any other articular cartilage). The method is based on using Human Dermal Fibroblasts, or HDFs, which are forced to differentiate into chondrocyte-like cells in vivo using the mechanical force and intermittent hydrostatic pressure found in the spine, for chondrogenic differentiation of fibroblasts. We believe our solution has potential advantages as compared to existing treatments because it is designed to be less invasive while regenerating the disc, restoring function, and reducing pain, without debilitating long-term effects.

We have completed two animal studies in rabbit models. Sixteen animals were used in the first pilot study (PMID 27853661) with the objective of determining the effects of intradiscal transplantation of neonatal human dermal fibroblasts, or nHDFs, on intravertebral disc, or IVD, degeneration by measuring disc height, MRI, signal intensity, gene expression, and collagen immunostaining. The results indicated that in the nHDF group there was a 10% increase in disk height index after eight weeks of treatment with a p value of <.05, while there was no significant difference in the saline treated group. When compared with the saline treated group, discs treated with nHDFs showed reduced expression of inflammatory markers, a higher ratio of collagen type II over collagen type I gene expression, and more intense immunohistochemical staining for both collagen types I and II. In the second study (PMID 30142460) 38 animals were used with the objective of determining the impact of donor source on the therapeutic effect of dermal fibroblast treatment on disc degeneration and inflammation when comparing rabbit dermal fibroblasts, or RDFs, to nHDFs. Eight weeks after treatment, disc height indexes of discs treated with nHDF increased significantly by 7.8% (p<.01), whereas those treated with saline or RDF increased by 1.5% and 2.0%, respectively. Gene expression analysis showed that discs transplanted with nHDFs and RDFs displayed similar inflammatory responses (p=.2 to .8). Compared to intact discs, expression of both collagen types I and II increased significantly in nHDF-treated discs (p<.05), increased in RDF-treated discs, and did not increase significantly in saline treated discs. The ratio of collagen type II/collagen type I was higher in the IVDs treated with nHDFs (1.26) than those treated with RDFs (0.81) or saline (0.59) and intact discs (1.00). Last, proteoglycan contents increased significantly in discs treated with nHDF (p<.05) and increased in the RDF- treated discs compared to those treated with saline.

The technology allowed for differentiation of the HDFs into chondrocytes, and the results showed the cells remained in the disc and did not migrate. Further, the cells created a biologic condition which appeared to increase the disc height. The results from the studies were positive and supported our IND application to run a "first in human" trial. We received IND clearance from the FDA in 2018, conditional upon approval of our master cell bank, to evaluate this candidate in a planned clinical trial. A timeline will be determined through discussions with the FDA.

Market Opportunity

The degenerative disc disease treatment market size was valued at approximately $26.1 billion globally in 2021, with North America representing approximately 36.0% of the market share, and is projected to grow to $45.9 billion globally by 2029 according to Fortune Business Insights.

CYPS317 for the Treatment of Psoriasis

Psoriasis

Psoriasis is a complex and chronic autoimmune inflammatory disease that afflicts approximately 2% of the world population and affects primarily the skin, nails and joints manifesting as raised, red, scaly patches on the skin, which can appear on various parts of the body. Psoriasis has a profound impact on the quality of life, leading to an increase in the rate of anxiety and depression among those affected by psoriasis. The disease is also associated with a significant number of comorbidities such arthritis, cardiometabolic disease, diabetes mellitus, obesity, non-alcoholic fatty liver disease, and inflammatory bowel disease.

Available Treatments for Psoriasis

The pathophysiology of psoriasis is complex, involving immune dysregulation, keratinocyte hyperproliferation, and immune cell infiltration into psoriatic lesions. As a result, targeted therapies have been developed to modulate the immune response and reduce inflammation in individuals with psoriasis. Three anti-IL-23 monoclonal antibody treatments are approved by the FDA for the treatment of psoriasis, including Tremfya®, Illumya®, and Skyrizi®. While current biological therapies focusing on the selective blockade of interleukin (IL)-17 and IL-23 signaling have shown significant efficacy in psoriasis treatment, they are accompanied by several challenges, including significant side effects, variable treatment responses, and diminished effectiveness over time. Consequently, cell therapy has emerged as a potential approach to psoriasis management. Mesenchymal stem cells (MSCs), derived from diverse sources, have demonstrated therapeutic potential in both psoriasis patients and animal models. Their immunomodulatory and anti-inflammatory properties are believed to play pivotal roles in psoriasis treatment. They have been shown to directly affect keratinocytes, T lymphocytes, macrophages, and dendritic cells, or DCs, thereby reducing disease severity, immune cell infiltration, and cytokine production associated with psoriasis.

Key companies currently providing biological treatments for psoriasis include Amgen, Johnson and Johnson, Abbvie, and Eli Lilly. These and various other companies have been investing in the treatment of psoriasis to bring novel antibody, small molecule, and peptide-based therapeutics with high efficacy and potency for patients. There are currently multiple mono-clonal antibodies approved for the treatment of psoriasis. These include monoclonal antibodies against Tumor Necrosis Factor-alpha (TNF-alpha), IL-17 and IL-23. The most recent FDA approvals for the treatment of psoriasis were Bimzelx® from UCB Pharma in 2023, and Sotyktu® from BMS in 2022.

Our Solution

Fibroblasts share phenotypic and functional properties with MSCs and are increasingly recognized as key players in immune modulation. In clinical settings, fibroblasts have been applied in wound care, effectively treating conditions such as diabetic foot ulcers and recessive dystrophic epidermolysis bullosa. The therapeutic potential of fibroblasts has also been observed in preclinical models of autoimmune diseases, including type I diabetes, alopecia areata, arthritis, and multiple sclerosis. These findings shed light on the prospect of using fibroblasts in psoriatic patients who do not respond to currently available therapies. As an immune modulator, fibroblasts have demonstrated a potential ability to alleviate autoimmunity by stimulating regulatory T cells, or Tregs, while suppressing pro-inflammatory Th17 cells, autoreactive T cells, and DC maturation. Consequently, fibroblasts may positively impact the onset and progression of autoimmune disease. Notably, fibroblasts offer a potential solution to scalability challenges often associated with MSC therapy, as a cost-effective alternative to MSCs, particularly for patients requiring long-term treatment and at risk of relapse.

CYPS317 is our allogeneic intravenously administered fibroblast spheroid cell-based investigational therapeutic for the treatment of psoriasis. We have completed preliminary IND-enabling pre-clinical studies utilizing chronic and acute psoriasis mouse models to assess the potential use of intravenous administration of fibroblast spheroids for the treatment of psoriasis. Results included that a single administration of fibroblast spheroids resulted in significant

improvement in mice with moderate psoriasis, and that multiple administrations of fibroblast spheroids resulted in significant improvement in mice with severe psoriasis. We also completed IND-enabling animal model studies, which included carrying out a dosage study to determine optimal efficacious dose range, in addition to determining the durability of treatment for mild to moderate, and moderate to severe psoriasis. On December 30, 2025, we filed a Phase 1/2 Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) seeking regulatory clearance to initiate clinical trials of CYPS317.

Market Opportunity

The psoriasis treatment market size was valued at approximately $20.3 billion in North America in 2024 and is projected to grow to $42.6 billion by 2032, according to Fortune Business Insights.

Our Early-Stage Research

CYTER915 for Human Longevity

Human Longevity

Fibroblasts are no longer considered as mere structural components of organs but as dynamic participants in immune processes. Fibroblasts produce an environment that influences regulatory T cell migration, proliferation, and activity, to provide immunotolerance.

One of the key organs of the immune system is the thymus. It serves a vital role in T cell maturation and selection, elimination of self-reactive cells, establishment of central tolerance and T cell migration to recognize a wide range of pathogens. A variety of cells have been identified inside the thymus. These include epithelial cells, thymocytes, dendritic cells, or DC, macrophages, B lymphocytes, myoid cells, endothelial cells, and fibroblasts. With age, the thymus declines in functionality through a process referred to as thymus or thymic involution. Publications have indicated that the process of involution enhances regulatory T cell generation which leads to increased susceptibility to pathogen infections, tumors, and autoimmune diseases.

The thymus is critically important to the immune system, which serves as the body's defense mechanism providing surveillance and protection against diverse pathogens, tumors, antigens, and mediators of tissue damage. The immune system comprises a complex network of cellular and molecular components subdivided into thymus-independent (innate) and thymus-dependent (adaptive) arms which function synergistically in all immune responses. Innate immunity constitutes the first line of defense and is mediated by innate immune cells such as tissue macrophages, DC and granulocytes which elicit their effector function within minutes to hours following antigen exposure. Innate cells become activated via germ-line encoded pattern recognition receptors, including toll like receptors and nucleotide oligomerization domain-like receptors, which recognize invariant features of pathogens (pathogen-associate molecular patterns) and tissue damage.

Once activated, innate cells such as macrophages and neutrophils can effectively clear antigens via phagocytosis. Other types of innate cells, such as DC, take up and process antigens, resulting in expression of antigenic epitopes in conjunction with their major histocompatibility complex, or MHC, or human leukocyte antigen molecules. These DC can then serve as antigen-presenting cells for the priming of the adaptive immune system. In this way, the early innate response is coupled to, and facilitates, adaptive immunity.

The adaptive immune system consists of T and B lymphocytes which express specific antigen recognition receptors and develop highly specialized effector functions with the ability to form long-term immunological memory. Both B cells and T cells develop from bone marrow-derived progenitors; while mature B cells are exported to the periphery directly from the bone marrow, T cell development, maturation and export require critical differentiation steps to occur in the thymus. Thymus-dependent T cell differentiation processes include expression of an antigen-specific cell surface T cell receptor through recombination of germline-encoded gene segments, and thymic "education" involving negative selection of potentially self-reactive T cells and positive selection of T cells with the capacity to recognize antigens encountered in the periphery. These important thymic processes ensure that T cells can recognize antigens in the context of self-MHC, but do not elicit self-reactivity.

The spleen is one of the key secondary lymphoid organs responsible for the rapid response of the immune system to pathogens in the blood, and to maintain a long-term adaptive response to such pathogens. The spleen also serves as the key organ for iron metabolism and erythrocyte homeostasis. The organ also functions as a key storage site for platelets and leukocytes. A variety of cells have been identified in the spleen, including endothelia cells, mesothelial cells, reticular cells, erythrocytes, granulocytes, mononuclear cells, hemopoietic cells, macrophages, dendritic cells, plasma cells, CD4+ and CD8+ T cells, and migrating B cells. With age, the structure and function of the spleen changes, leading to decreased ability to respond positively to vaccination, increased susceptibility to viral and bacterial pathogen infections, and increased incidence of autoimmune disease. Accordingly, there may be a need for therapies designed to improve and extend the productive life of the thymus and spleen through cell therapy, with the hope of extending the quality of human life by better positioning these organs to fight diseases that may otherwise be allowed to proliferate during the declining process of these vital organs.

Our Solution

Our research program is in the very early stages and is being designed to study the ability to regenerate or reinvigorate production of the thymus and/or spleen. The regeneration comprises organogenesis and/or T cell development, wherein the tissue is differentiated and/or expansion of epithelial cells uses activated or inactivated fibroblasts. In addition to fibroblasts, we anticipate using other agents such as nucleic acids, cytokines, chemokines, transcription factors, epigenetic factors, growth factors, hormones, or a combination thereof. The population of cells may be activated *in vitro* or *ex vivo*. The next step in developing fibroblasts to study potential thymic or splenic involution reversal will be to design and conduct preclinical studies to demonstrate whether thymic or splenic involution reversal can be achieved in animal models.

TCB190 for the Treatment of Certain Cancers

Our research on certain cancers is just beginning and further information about the opportunity will be released as it becomes available.

Artificial Pancreatic Organoid Program

Our research on artificial pancreatic organoids is just beginning and further information about the opportunity will be released as it becomes available.

Manufacturing and Supply

CYWC628

We contracted with a CDMO for the production of our master cell bank and working cell bank for CYWC628. The manufacturing of our master cell bank and working cell bank for CYWC628 is now complete and both are certified as released by our CDMO. This CDMO will also manufacture CYWC628 for use in our twelve-week Phase 1/2 clinical trial for treatment of diabetic foot ulcers that we plan to conduct in Australia. Please see “Risk Factors – Risks Related to Manufacturing” in this Annual Report.

CybroCell™

We successfully carried out experiments that demonstrated the ability to use the CYWC628 spheroid master cell bank for the manufacturing of a modified CybroCell™ drug product. We also supported animal trials confirming that the therapeutic effects of the fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank are significantly better than those of single-cell fibroblasts, which supported our IND clearance with the FDA for the planned Phase I clinical trial. Based on these results, we will work to amend the IND clearance with the FDA to replace single-cell fibroblasts with fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank. A timeline for the trial will be determined in connection with discussions with the FDA.

If any of our product candidates receive marketing approval, we expect to evaluate the feasibility of building our own current Good Manufacturing Practice, or cGMP, manufacturing facility or continuing to outsource manufacturing to

a CDMO for clinical testing and commercial supply. We expect to rely on third parties for our cell therapy manufacturing process for the foreseeable future.

Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and compositions, when available, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to compositions, methods of treatment and patient selection created or identified from our ongoing development of our product candidates. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions.

As of December 31, 2025, we own 124 issued patents and 175 pending patent applications in various countries.

Given present patent ineligibility laws concerning products of nature, there are presently no composition of matter patents covering CybroCell™, although there are patents related to the method of use or making of CybroCell™. We currently have patent applications pending for the methods of use for both CYWC628 and CYMS101.

Our patent protections for our issued patents generally expire in years ranging from 2027 to 2043.

In connection with our formation, we entered into, among other agreements, the Patent Assignment Agreement and the Intellectual Property Cross-License Agreement. The Patent Assignment Agreement transferred all right, title and interest to certain patents/applications related to the spine, cancer, orthopedics, and multiple sclerosis from SpinalCyte to us. The Intellectual Property Cross-License Agreement allocates between SpinalCyte and us, exclusive fields of use for both assigned and retained patents issued/pending.

Through the Patent Assignment Agreement and the Intellectual Property Cross-License Agreement, SpinalCyte effectively granted to us exclusive rights to develop fibroblasts in the following fields of use for the diagnosis, treatment, prevention, and palliation of:

- spinal diseases, disorders, or conditions;
- cancers;
- orthopedic diseases, disorders, or conditions; and
- multiple sclerosis.

SpinalCyte has retained exclusive rights for all other fields of use for both issued patents and patent applications transferred to us or retained by SpinalCyte. When we refer to "our patents," we refer to the patents that we own and the exclusive rights we have to the SpinalCyte retained patents in our field of use.

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These

agreements also generally provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our property.

We rely primarily on the protection of intellectual property that we own as opposed to intellectual property rights that we license from others outside of SpinalCyte. We use tools, procedures, and material from others that either expressly or implicitly include licenses to third party intellectual property rights, but we do not have any exclusive rights to such third-party intellectual property that provides us a competitive advantage in the marketplace.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, 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 candidates 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 conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Many of our current and potential competitors may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may succeed in obtaining approval from the FDA, the EMA, or other comparable foreign regulatory authorities or in discovering, developing, and commercializing products in our field before we do. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any products we may develop, if approved, could be adversely affected.

Regulatory Environment

Government Regulation and Product Approval

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries and jurisdictions impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, and distribution of products such as those we are developing. These entities regulate, among other things, the research, development, testing, manufacture, quality control, packaging, safety, effectiveness, labeling, storage, record keeping, approval, advertising, promotion, distribution, post-approval monitoring and reporting, sampling, export and import of our product candidates. Any product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to

regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

U.S. Product Development Process

In the United States, the FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, and biologics under the FDCA and the Public Health Service Act and their implementing regulations. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the U.S. Department of Justice or other governmental entities. In addition, an applicant may need to recall a product. Additionally, certain of our product candidates will be subject to regulation in the United States as combination products. If marketed individually, each component would be subject to different regulatory pathways and would require approval of independent marketing applications by the FDA. A combination product, however, is assigned to a center within the FDA that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our CybroCell™ product candidate, we believe that the primary mode of action is attributable to the biologic component of the product. We expect to seek approval of this combination product candidate through a Biologics License Application, or BLA, and we do not expect that the FDA will require a separate marketing authorization for each of the drug and biologic constituents of the product. We also anticipate that other of our cell therapeutic candidates will be regulated as biologics. With this classification, commercial production of our cellular therapeutics will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. We currently anticipate that our cellular therapeutic candidates will be considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

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

- completion of nonclinical or preclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's good laboratory practice, or GLP, requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an IRB or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug for its intended use, or with respect to biologics, the safety, purity, and potency of the product candidate for each proposed indication;
- submission to the FDA of a BLA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements to assure that the

facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with good clinical practices, or GCPs;

- a potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the BLA; and

- the FDA's review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical studies include laboratory evaluation of product chemistry, toxicity, and formulation, as well as in vitro and animal studies to assess potential safety and efficacy. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies submitted in support of the IND.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. Some preclinical studies may continue even after the IND is submitted. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects, or their legal representative, provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some clinical trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may recommend that the clinical trial be halted if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

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, in certain cases such as certain cancers, patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as certain cancers, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- ***Phase 2***: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, dose tolerance and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- ***Phase 3***: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for physician labelling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-marketing studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, such as with accelerated approval drugs, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval.

Concurrent with clinical trials, companies may complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, 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.

While the IND is active and before product approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report 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. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other nonclinical studies, and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of the use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug 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. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews a BLA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard BLA to review and act on the submission. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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 the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug 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. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the BLA, addressing all of 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 regulatory approval of a product is granted, such approval will be granted for particular indications and may contain limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more post-marketing studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug 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 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. Orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

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 drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of products that meet certain criteria. For example, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development, and 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 fee upon submission of the first section of the BLA.

A product, including a product with a Fast Track 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 product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort 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 standard BLAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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 can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

In addition, the FDA may designate a product as a regenerative medicine advanced therapy, or RMAT. The RMAT designation is intended to facilitate an efficient development program for, and expedited review of, any product

candidate that meets the following criteria: (i) the product candidate qualifies as a RMAT, which is defined 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; (ii) the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review of BLAs. Cell therapy 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 reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate. RMAT-designated cell therapy candidates that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the completion of clinical trials, patient registries, or through submission of other sources of real world evidence, such as electronic health records, 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.

Fast track designation, breakthrough therapy designation, priority review, RMAT designation 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 candidate 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 or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials 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 clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license 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.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are consistent with the provisions of the FDA-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, in their independent professional medical judgment, 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. 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 communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription biopharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription biopharmaceutical product samples and impose requirements to ensure accountability in distribution.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the product. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Data Privacy and Security

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, collectively referred to as HIPAA, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statements or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties, such as research institutions, which are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, private litigation and/or adverse publicity that could negatively affect our business. In addition, regulators and legislators around the world are increasingly scrutinizing certain data transfers and may impose data localization requirements, which could impact our ability to conduct our business across international borders.

Failure to achieve and sustain compliance with applicable federal and state privacy, security and fraud laws could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, private litigation and/or adverse publicity that could negatively affect our results of operations and business.

Other U.S. Regulatory Requirements

Biopharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. 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 and biologics. Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan, (ii) safe, effective, and medically necessary, (iii) appropriate for the specific patient, (iv) cost-effective and (v) neither experimental nor investigational. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs, and services and may impose additional utilization management requirements, such as prior authorization, step therapy, quantity limits or restrictive formularies. 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 and because reimbursement may be bundled with procedural or site-of-care payments rather than paid separately for the product itself.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Recent legislative and regulatory initiatives have also increased scrutiny of drug pricing practices and expanded manufacturer financial responsibility under certain government healthcare programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the biopharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Additionally, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019, and later eliminated altogether under the Inflation Reduction Act of 2022 (the "IRA")) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. In addition, the IRA introduced significant reforms affecting prescription drug pricing and reimbursement under Medicare, including inflation-based rebate obligations, a redesign of the Medicare Part D benefit and a drug price negotiation program for certain high-cost drugs and biologics without generic or biosimilar competition. Although certain drugs with a single orphan designation may be exempt from the negotiation program, that exemption is limited, and the overall impact of the IRA on our business and the biopharmaceutical industry remains uncertain.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

International Regulation

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions.

The regulation of our product candidates outside of the United States varies by country. Certain countries regulate human tissue products as a pharmaceutical product, which would require us to make extensive filings and obtain regulatory approvals before selling our product candidates. Certain other countries classify our product candidates as human tissue for transplantation but may restrict its import or sale. Other countries may have no application regulations regarding the import or sale of products similar to our product candidates, creating uncertainty as to what standards we may be required to meet.

Employees

As of December 31, 2025, we had 15 full-time employees, including seven employees with medical or doctoral degrees and nine employees directly engaged in research and development, with the rest providing administrative, business and operations support. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be good.

Our Facilities

Our principal executive offices are located at 455 E. Medical Center Blvd., Suite 300, Houston, Texas, where we lease approximately 23,000 square feet of office space. The space serves as the location of our corporate headquarters. The lease expires in April 2027. In addition, we have leased research labs and offices in Houston, Texas, for our research and cell manufacturing operations. This lease expires in May 2031.

We believe that our facilities are adequate for our current and anticipated near-term needs and that suitable additional or substitute space would be available if needed.

Legal Proceedings

From time to time, we may be party to litigation arising in the ordinary course of business. We are currently not a party to any material legal proceedings and, to the best of our knowledge, no material legal proceedings are currently pending or threatened. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Exchange Act are available through the “Investor Relations” page of our website at

https://ir.fibrobiologics.com/ free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report or any of our other securities filings unless specifically incorporated herein or therein by reference. In addition, our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Our code of ethics and business conduct, corporate governance guidelines and the charters of our Audit Committee, Compensation Committee and Governance and Nominating Committee are available on our corporate website.

Item 1A. Risk Factors

Our business involves significant risks. You should carefully consider the risks described below, as well as all other information included in this Annual Report and in the other documents that we file with the SEC. If any of the following risks actually occurs, our business, financial condition, results of operations, prospects, and ability to accomplish our strategic objectives could be materially harmed. As a result, the market price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business operations and the market price of our common stock. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" elsewhere in this Annual Report for more information. Our actual results could differ materially and adversely from those anticipated in our forward-looking statements as a result of certain factors, including those described below.

Summary of Risk Factors

- There is substantial doubt about our ability to continue as a going concern.
- We have a limited operating history and none of our current product candidates have been approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses since inception, expect to continue to incur significant net losses for the foreseeable future, and may never achieve or maintain profitability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations, require us to relinquish rights to our product candidates on unfavorable terms to us and could cause our stock price to fall.
- The regulatory approval processes of the FDA, the EMA, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The outcome of preclinical studies or early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, the EMA, or other comparable foreign regulatory authorities.
- The successful development of biopharmaceutical products is highly uncertain.

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

- Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

- Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

- Our refrigerated product candidates require specific distribution, storage, handling, and administration at the clinical sites.

- Because cell therapy is novel and the regulatory landscape that governs any cell therapy product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

- We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.

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

- Our company has limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

- We have never commercialized a fibroblast cell-based therapy product candidate before and may lack the necessary expertise, personnel, and resources to successfully commercialize any product candidates on our own or together with suitable collaborators.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

- We have identified a material weakness in our internal controls over financial reporting due to lack of segregation of duties. Failure to maintain effective internal control over financial reporting could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls over financial reporting are not effective, we may not be able to accurately report our financial results or prevent fraud.

- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be adversely harmed.

- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- Manufacturing cell therapy products is complex and subject to both human and systemic risks. Our third-party manufacturers or we may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of critical components. If we or any of our third-party manufacturers encounter such

difficulties, our ability to supply our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

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- Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

- Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

- The FDA, the EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

- Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

- If we cannot maintain compliance with the applicable Nasdaq continued listing requirements, our common stock may be delisted from Nasdaq, which could limit stockholders' ability to trade our common stock.

- An active trading market may not be sustained and the market price of shares of our common stock may be volatile.

- We have 2,500 shares of Series C Preferred Stock with super voting rights which may adversely affect holders of our common stock.

- Our management and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

- Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent a take-over that may be in the best interests of our stockholders.

- Our internal computer systems, or those of any of our CROs, CDMOs, other contractors, consultants, collaborators and third-party service providers, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data

or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

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

Risks Related to Our Financial Condition and Capital Requirements

There is substantial doubt about our ability to continue as a going concern.

We have incurred recurring operating losses and negative cash flows from operating activities since inception and expect to continue incurring operating losses and negative cash flows in the future. In connection with the preparation of our Annual Report, our management concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of the Annual Report, and our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2025, that raised substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon raising capital to maintain current operations and continue research and development efforts. We plan to raise additional capital to fund our operations through public or private equity offerings, debt financings, and/or potential collaborations and license arrangements or other sources. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that we will be able to obtain financing or enter into a collaboration on terms acceptable to us.

These factors raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If existing or potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. If we are unable to continue as a going concern, we will be forced to delay, reduce or discontinue our research and development programs or consider other various strategic alternatives and you could lose all or part of your investment in us.

We have a limited operating history and none of our current product candidates have been approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We were formed in April 2021 and to date we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying, and developing potential product candidates, securing related intellectual property rights and conducting and planning preclinical studies and clinical trials of our product candidates. None of our current product candidates are approved for commercial sale and we have not generated any revenue from such product candidates. In relation to our current product candidates, we have not yet demonstrated our ability to successfully complete any clinical trials beyond Phase 1, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biotechnology companies in rapidly evolving fields. We also may need to transition from a company with a research 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 significant net losses since inception, expect to continue to incur significant net losses for the foreseeable future, and may never achieve or maintain profitability.

We have incurred significant net losses since our inception, have not generated any revenue from product sales to date and have financed our operations principally through public and private financings. For the years ended December 31, 2025 and 2024, we incurred net losses of $18.6 million and $11.2 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $54.2 million and $35.5 million, respectively. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from management and administrative costs and related expenses that we have incurred while building our business infrastructure. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for, and commercializing, one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our product candidates through clinical development, and, if approved by the FDA, commercialization;
- advance our preclinical development programs into clinical development;
- incur manufacturing costs for cell production to supply our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- meet the requirements and demands of being a public company;
- invest in further development to maintain, protect and expand our intellectual property portfolio;
- establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- expand our manufacturing and develop our commercialization efforts;
- make milestone, royalty, or other payments due under any potential future in-license or collaboration agreements; and
- make milestone, royalty, interest, or other payments due under any potential future financing or other arrangements with third parties.

The net losses we incur may fluctuate significantly from period to period, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and

expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, one or more product candidates we are developing or may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability.

We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough for us 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 could impair our ability to raise capital, expand our business, diversify our product offerings, or continue our operations. If we continue to incur losses as we have since our inception, investors may not receive any return on their investment and may lose their entire investment.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, our current product candidates and any future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other comparable regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Because the design and outcome of our anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we may develop. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2025, we had approximately $4.9 million in cash and cash equivalents. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently expect, and we may need to seek additional funds sooner than planned. We may also raise additional financing on an opportunistic basis in the future. For example, 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 funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost, and results of our clinical trials for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;

- the cost and timing of manufacturing activities, including our planned manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development through commercialization;
- the costs associated with acquiring or licensing additional product candidates, technologies, or assets, including the timing and amount of any milestones, royalties or other payments that may be due in connection with such acquisitions and licenses;
- the potential expansion of our current development programs to seek new indications;
- the outcome, timing and cost of any regulatory review and meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the cost of general operating expenses, including the cost of attracting, hiring, and retaining skilled personnel;
- the cost of future commercialization activities, including establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays; and
- the costs of operating as a public company.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangement with collaborators on terms unfavorable to us or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, require us to relinquish rights to our product candidates on unfavorable terms to us and could cause our stock price to fall.

We need additional capital to continue our planned operations, including conducting clinical trials, regulatory approval efforts, pre-commercialization and commercialization activities, expanded research and development activities and costs associated with operating as a public company. We may seek additional capital through a variety of means, including through equity offerings, debt financings, collaborations and licensing arrangements or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. For example, the future issuance of shares of preferred stock with voting rights, dividend or conversion rights, liquidation preferences or other economic terms favorable to the holders of the preferred stock may adversely affect the voting power of the holders of shares of our common stock, either by diluting the voting power of our common stock if the preferred stock votes together with the common stock as a single class, or by giving the holders of any such preferred stock the right to block an action on which they have a separate class vote, even if the action were approved by the holders of our shares of our common stock, and could adversely affect the market price for our common stock by making an investment in the common stock less attractive. Investors in our common stock may not wish to purchase common stock at a price above the conversion price of a series of convertible preferred stock because the holders of the preferred stock would effectively be entitled to purchase common stock at the lower conversion price, causing economic dilution to the holders of common stock.

Future financings may also result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may adversely affect our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that are not favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable.

We are party to a standby equity purchase agreement, or the SEPA, dated December 20, 2024, with YA II PN, LTD., or Yorkville. Pursuant to the SEPA, Yorkville advanced us the principal amount of $15 million evidenced by convertible promissory notes in three tranches and, subject to the satisfaction of certain conditions, we may elect to issue and sell to Yorkville up to $10 million worth of shares of our common stock for a period ending December 20, 2026. On January 7, 2025, we satisfied the commitment fee owing to Yorkville under the SEPA by issuing 118,991 shares of our common stock. The conversion of the convertible promissory notes by Yorkville and our election to issue and sell to Yorkville shares of our common stock pursuant to the SEPA has resulted, and will result, in dilution to our existing stockholders.

Any of these occurrences, or the possibility of such occurrences, may cause the market price of our common stock to decline and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Development, Regulatory Approval and Commercialization

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

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA, the EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the

approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, the EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our current and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA, the EMA or other comparable regulatory authorities that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events, or AEs, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design, implementation, or results of our clinical trials;
- the FDA, the EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, the EMA, or other comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- the FDA, the EMA or other comparable foreign regulatory authorities may fail to approve our manufacturing processes, test procedures and specifications or facilities or those of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy, uncertain approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA, the EMA, or comparable foreign regulatory authorities may change their policies, adopt additional regulations, or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Moreover, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes.

We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA, the EMA, or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, the EMA or other comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- challenges or delays in recruiting principal investigators or study sites to lead 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;
- obtaining approval from one or more independent IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to pandemics or other events outside our control;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;

- manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected product-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA, the EMA, or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, the EMA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- approval policies or regulations of the FDA, EMA or other comparable regulatory authorities significantly changing in a manner rendering our clinical data insufficient for approval.

Conducting clinical trials in foreign countries, as we contemplate doing for CYWC628 and may do for our other product candidates, 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 protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;

- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA and comparable foreign regulatory authorities have substantial discretion in the review and approval process and may disagree that our data support the claims we propose. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business.

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

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, 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 our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, and prospects significantly.

The outcome of preclinical studies or early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, the EMA, or other comparable foreign regulatory authorities.

Positive results from preclinical studies and early clinical trials do not mean that future clinical trials will be successful. Failure can occur at any time during the clinical trial process. To date, we have only completed one Phase 1 feasibility study. We do not know whether any of our product candidates will perform in current or future clinical trials as they have performed in preclinical studies and early clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, the EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

Additionally, our only clinical trial conducted to date utilized, and our contemplated twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers will utilize, an "open-label" trial design, and some of our planned clinical trials may be designed similarly. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving either the investigational product candidate or an existing approved pharmaceutical or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving 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. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies or clinical trials nonetheless failed to obtain FDA, EMA, or comparable foreign regulatory authority approval. We cannot guarantee that the FDA, the EMA, or comparable foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA, the EMA, or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, the EMA, or comparable foreign regulatory authorities delaying, limiting, or denying approval of our product candidates.

The successful development of biopharmaceutical products is highly uncertain.

Successful development of biopharmaceutical products involves a lengthy and expensive process, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results showing the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;

- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or BLA preparation, discussions with the FDA or other comparable regulatory

authority, an FDA or other comparable regulatory authority request for additional preclinical or clinical data or unexpected safety or manufacturing issues;

- preclinical study results showing the product candidate to be less effective than desired or to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Even if we are successful in obtaining marketing approval, commercial success of approved products may also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of an approved product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were to not provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success may be reduced. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, which prevent our products from achieving market acceptance by the healthcare or patient communities. For additional information, see the section of this report titled, "*Business—Regulatory Environment—Coverage and Reimbursement*."

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information, reports and registration, and will need to continue to comply (or ensure that any third-party providers comply) with cGMPs and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition, and results of operations.

While we may in the future seek designations for our product candidates with the FDA, EMA and other comparable regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA, EMA, and other comparable regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The

FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot provide any assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

Similarly, we may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Where appropriate, we may pursue approval from the FDA, EMA, or other comparable regulatory authorities through the use of expedited approval pathways, such as accelerated approval. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA, or other comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA, or such other regulatory authorities may seek to withdraw the accelerated approval.

Where possible, we may pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our therapeutic candidates from the FDA, EMA, or other comparable regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic 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. Under the Food and Drug Omnibus Reform Act, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, we would seek feedback from the FDA, EMA, or other comparable regulatory authorities and would otherwise evaluate our ability to seek and receive such 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 any other form of expedited development, review, or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA, or other comparable regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace.

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

From time to time, we may publicly disclose interim, preliminary, or topline data from our preclinical studies or clinical trials, 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 different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Interim, preliminary, and topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline, and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, topline, or interim data and final data could significantly harm our business prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. 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, our product candidates may be harmed, which could harm our business, results of operations, prospects, or financial condition.

Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, 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, and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition, and prospects significantly.

Patients in our ongoing and planned clinical trials in the future may suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other comparable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. We may be unable to overcome any such suspensions or holds that are placed on our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition, and prospects significantly.

Additionally, if any of our product candidates 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. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled and restrictive. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace;
- regulatory authorities may withdraw or change their approvals of that product;

- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

We have never commercialized a product, and even if any of our product candidates receive regulatory approval and become a product, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients, and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- the prevalence and severity of any side effects;
- restrictions on the use of our product, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of products over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;

- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications or changes in the standard of care for the targeted indications for the product.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from those product candidates and our financial results could be negatively impacted.

Our refrigerated product candidates require specific distribution, storage, handling, and administration at the clinical sites.

Our refrigerated product candidates must be distributed and stored at low temperatures in specialized refrigerated containers until immediately prior to use. For administration, the product container must be carefully removed from storage, warmed to room temperature, and inverted to place cells into suspension prior to drawing the product into syringes. The handling, warming and administration of the cell therapy product must be performed according to specific instructions. Failure to correctly handle the product, follow the instructions for warming and administration and/or failure to administer the product within the specified period post-warming could negatively impact the efficacy and or safety of the product, or cause a loss of product. Even if we are able to manufacture and distribute our product candidates, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

Because cell therapy is novel and the regulatory landscape that governs any cell therapy product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop. At the moment, only a small number of cell therapy products have been approved in the United States and the European Union.

Our strategy is to identify, develop and commercialize cell therapy product candidates using our proprietary fibroblast technology, which involves collecting skin biopsies from donor patients, isolating cells and expanding them in culture. Our future success depends on the successful development of these novel therapeutic approaches. To date, no fibroblast therapy products have been approved. In addition, there have only been a small number of clinical trials involving fibroblasts as compared to other, more conventional forms of therapy.

The regulatory requirements that will govern any novel cell therapy product candidates we develop are not entirely clear and are subject to change. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing cell therapy products have changed frequently and will likely continue to change in the future. Although the FDA has approved other cell-based therapies, there is no assurance that these previous approvals will affect the FDA's review of our product candidates.

The same applies in the European Union. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. Advanced-therapy medicinal products include cell therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a cell therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a cell therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for cell therapy products and require that we comply with these new guidelines. As a result, the procedures and standards applied to cell therapy products may be applied to any cell therapy product candidate we may develop, but that remains uncertain at this point.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy and cell regulation products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing cell therapy technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for diseases in which, in some cases, there is little clinical experience with potential new endpoints and methodologies, there is heightened risk that the FDA, the EMA, or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. In addition, we may not be able to identify or develop appropriate animal disease models to enable or support planned clinical development. Any natural history studies that we may conduct or rely upon in our clinical development may not be accepted by the FDA, the EMA, or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing cell therapy technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop our product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, and distribution of drugs. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain, and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed, or completed any clinical trials in the U.S. nor managed the regulatory approval process with the FDA, the EMA or any other regulatory authority with respect to our current product candidates, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity, and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often do change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials, and FDA regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing, and marketing authorization, pricing, and third-party reimbursement. The foreign regulatory approval process varies among countries and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

We may develop our current and future product candidates in combination with other therapies, which exposes us to additional risks, and certain of our product candidates are regulated as combination products.

We may develop our current and future product candidates in combination with one or more other approved or unapproved therapies to treat skin and connective tissue diseases or other diseases. We may also develop certain product candidates such as biologic/drug combination products. Additional time may be required to obtain regulatory approval for our product candidates because they are combination products. Our product candidates that are biologic/drug combination products require coordination within the FDA and similar foreign regulatory agencies for review of their biologic and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

In addition, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA, or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA, or comparable foreign regulatory authorities may require us to conduct additional clinical trials. Further, the FDA, the EMA, or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement or increase our cost of development. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. The occurrence of any of these risks could result in our own product candidates, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA, or comparable foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product candidate. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, the EMA, or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidates we develop, we may be unable to obtain approval of or market such combination therapy.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a

biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or 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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences on our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must decide which research programs, therapeutic platforms, and product candidates to pursue and advance and the amount of resources to allocate to each. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, our business, financial condition, and results of operations could be materially and adversely affected. Further, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Our present and potential future international operations may expose us to business, political, operational, and financial risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. For example, our CRO and clinical trial sites for our contemplated twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers are located outside of the United States and we formed an Australian subsidiary to act as a sponsor for the clinical trial. If we succeed in obtaining approval of any product candidates, we anticipate marketing them in the European Union and other jurisdictions in addition to the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, data transfer restrictions, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;

- additional potentially relevant third-party patent and other intellectual property rights that may be necessary to develop and commercialize our products and product candidates;
- complexities and difficulties in obtaining, maintaining, enforcing, and defending our patent and other intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions, and implementation of tariffs;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our contemplated clinical trial in Australia, as well as our current and any future international operations and, consequently, our business, financial condition, prospects, and results of operations.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, including executive and congressional priorities, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, the current U.S. administration has proposed substantial reductions in force at various government agencies that, if applied in a material way, could significantly reduce the FDA's and other agencies' capacities to perform their functions in a manner consistent with past practices. If a prolonged government shutdown occurs or if the FDA or SEC experiences significant decreases in funding or personnel, it could significantly impact the ability of the FDA to issues licenses needed for conduct of our clinical trials and the abilities of both agencies to timely review and process our regulatory submissions, which could have a material adverse effect

on our business and our timelines. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the change in the U.S. presidential administration in 2025, there continues to be substantial uncertainty as to the extent and manner in which the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations

We are subject to export and import controls, economic sanctions, and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can 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 Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation 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.

Risks Related to Our Business

Our company has limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our planned clinical trials or any future clinical trials will be successful. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned BLAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any BLA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

The sizes of the markets for our product candidates are estimates, and these markets may be smaller than estimated.

Since our current product candidates and any future product candidates will likely represent novel approaches to treating various conditions, the potential annual addressable markets for our product candidates are difficult to precisely estimate. Our estimates of the annual addressable markets for our product candidates are based on third-party estimates and include several key assumptions. While we believe the assumptions and the data underlying the estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting the assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, the estimates of the annual addressable market for our product candidates may prove to be incorrect. If the actual market for our product candidates is smaller than we expect, our product revenues may be limited, it may be harder than expected to raise funds, and it may be more difficult for us to achieve or maintain profitability.

Our long-term prospects may depend in part upon discovering, developing, and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results may be dependent on our ability to successfully discover, develop, obtain regulatory approval for, and commercialize product candidates beyond those we currently have in clinical development. A product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials and successfully completing such trials pursuant to the applicable regulatory frameworks;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- positive results from our future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations of any product candidates we may develop;
- the timely manufacture of sufficient quantities of the product candidate and other key materials needed for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory, and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our product candidates. If we are unable to advance our additional product candidates to clinical development, obtain regulatory approval and ultimately commercialize our additional product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have never commercialized a fibroblast cell-based therapy product candidate before and may lack the necessary expertise, personnel, and resources to successfully commercialize any product candidates, if approved, on our own or together with suitable collaborators.

We have never commercialized a fibroblast cell-based therapy product candidate, and we currently have no sales force, marketing, or distribution capabilities. To achieve commercial success for our current product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any approved product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to, or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates, if approved. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability. Even if we and/or our third-party contractors are able to effectively establish a sales force and develop a marketing and sales infrastructure, such sales force and marketing teams may not be successful in commercializing our current or future product candidates.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, 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 candidates 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 conditions for which we may attempt to develop product candidates. See "Business—Our Current Pipeline" and "Business—Competition" for additional details regarding our competition. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Many current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may succeed in obtaining approval from the FDA, the EMA, or other comparable foreign regulatory authorities or in discovering, developing, and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any product candidates that we may develop. Our competitors may also obtain marketing approval from the FDA, the EMA, or other comparable foreign regulatory authorities 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. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or uneconomical before we recover the expense of developing and commercializing such product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any products we may develop, if approved, could be adversely affected.

We have incurred increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. We are subject to financial reporting and other

requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, we have incurred, and will continue to incur significant legal, accounting and other expenses. In addition, the federal securities laws, including the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and rules and regulations subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual, quarterly, and event driven reports with respect to their business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. These rules and regulations have increased, and will continue to increase, our legal and financial compliance costs, made certain activities more time-consuming and costly, and required our management and other personnel to devote a substantial amount of time to compliance initiatives. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years after completion of a company's initial public offering. 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.

Despite our best efforts, we may not be able to produce reliable consolidated financial statements or file such consolidated financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate consolidated financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. 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.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires an annual management assessment of the effectiveness of our internal control over financial reporting. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following the completion of our Direct Listing. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our consolidated financial statements and require us to incur the expense of remediation.

As a public company, we are required to maintain disclosure controls and procedures. Disclosure controls and procedures means our controls and other procedures that are designed to reasonably ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the SEC. We do not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. We believe a control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Due to the inherent limitations in all control systems, no

evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. 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. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We have identified a material weakness in our internal controls over financial reporting due to lack of segregation of duties. Failure to maintain effective internal control over financial reporting could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls over financial reporting are not effective, we may not be able to accurately report our financial results or prevent fraud.

During the preparation of our consolidated financial statements for the fiscal years ended December 31, 2025, 2024, 2023 and 2022, our management identified a material weakness in our internal control over financial reporting due to a lack of segregation of duties. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Specifically, our management identified a deficiency in our internal controls within the financial reporting function that resulted from an ineffective design and implementation of controls over proper segregation of duties for the period of time covered by our consolidated financial statements prior to our then Chief Financial Officer joining us in June 2025 when all financial functions were handled by a single individual, and afterward, through December 31, 2025, due to a limited number of individuals. Based upon management's evaluation, and due to the material weakness identified, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were not effective.

We will continue to add staff, evaluate segregation of duties, and implement initiatives to improve our internal controls over financial reporting as we grow. However, the implementation of these initiatives may not fully address the material weakness in our internal control over financial reporting and we cannot assure you that we will not identify other material weaknesses or deficiencies, which could negatively impact our results of operations in future periods. Further, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

We expect to incur additional costs to remediate these control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

Risks Relating to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be adversely harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies

and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products manufactured under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. Moreover, many CROs are experiencing enrollment challenges. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or halted entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. Patient enrollment is affected by many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;

- the number and location of study sites and proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for our product candidates or any other potential future product candidates if we are unable to sufficiently demonstrate the potential of any such product candidate. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or any other potential future product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

If we are unable to enroll a sufficient number of patients for our clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates or any other potential future product candidates, cause the value of the company to decline and limit our ability to obtain additional financing if needed.

If we decide to establish additional collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product candidate development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development

for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, mergers among large biopharmaceutical companies may result in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In the future we may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates, which could adversely affect our ability to advance our product candidates.

We may in the future seek third-party collaborators for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size biopharmaceutical companies, regional and national biopharmaceutical companies, and biotechnology companies. We have and will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product candidates relative to other products;
- collaborators may not properly obtain, maintain, defend, or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property-related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and

- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product candidate development or commercialization program could be delayed, diminished, or terminated.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these 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 a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Risks Related to Manufacturing

Manufacturing cell therapy products is complex and subject to both human and systemic risks. Our third-party manufacturers or we may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of critical components. If we or any of our third-party manufacturers encounter such difficulties, our ability to supply our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

The manufacture of biologic cell therapy product candidates, and products, if approved, is complex and requires significant expertise and capital investment, including developing advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production and sourcing, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing processes (including the absence of contamination), in light of variations and supply constraints of critical components. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including consistency, stability, purity, and efficacy of the product, product testing, operator error, and availability of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. For example, initial timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia were extended as we worked with our CDMO to resolve process issues with the manufacturing training run and increased the number of test manufacturing runs needed to confirm no sterility issues. Furthermore, if

contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability, purity, and efficacy failures, deficiencies, or other issues relating to manufacturing our product candidates will not occur in the future.

Additionally, our product candidates are derived from cells collected from humans. Such cells may vary in type and quality as the donors may vary in age, medical history, and many other factors. We have strict specifications for donor cell material and our product candidates. The donor cell material variability may exceed our manufacturing process capability or deviate from the specified ranges and result in failure in the production of the cell therapy product, lower quality batches, or even require adjustments to the specifications approved by authorities. The donor cell material may also be variable in factors that we currently may not be able to detect with the analytical methods used or may not know how to measure. We may also discover failures with the material after production. As a result, we may not be able to deliver the quality and consistency of our cell therapy products that we need or may need to re-collect cell material which can increase costs and/or cause delay, result in recalls, adversely impact patient outcomes and otherwise harm our clinical trials, reputation, business, and prospects.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site, shipping the product candidate back to the relevant parties, and experiencing delays or shortages of certain clinical or commercial-grade supplies and components. Logistical and shipment delays and problems caused by us, our vendors, or other factors not in our control, including business interruptions, global supply chain issues, and weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to donor material as it moves to the manufacturing facility, through the manufacturing processes, and ultimately to a patient. Failure to maintain a chain of identity and chain of custody could result in patient death, loss of product, or regulatory action.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA, or other comparable regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The production of our cell banks and product candidates by a contract development manufacturing organization may fail and result in delays, additional costs, or technical failure.

We have contracted with a CDMO for the production of our master cell bank and working cell bank to enable our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia. If the CDMO is unable to maintain our master cell bank and working cell bank for CYWC628 or produce CYWC628 or any other fibroblast cell-based product candidates to enable clinical trials, we may encounter delays, additional costs, or technical failure of one or more of our product candidates. For example, timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia were extended as we worked with our CDMO to resolve process issues encountered with the manufacturing training run and increased the number of test manufacturing runs needed to confirm no sterility issues.

Our reliance on third parties reduces our control over our product candidate development activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and industry standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP requirements. Any failure by our third-party manufacturers to comply with cGMP or maintain a compliance status acceptable to the FDA or other regulatory authorities or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

If we were to need an alternate CDMO, we would incur added costs and delays in identifying and qualifying any such replacement. In addition, we expect to order drug product and services on a statement of work or purchase order basis and do not plan to enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Changes in the methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation, materials, and processes, are altered along the way in an effort to optimize processes and product characteristics. Such alterations can also occur due to changes in manufacturers. Such changes carry the risk that they will not achieve their intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay the completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials beyond those we currently anticipate, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates if approved. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of future product candidates. For example, we encountered process issues with the manufacturing training run of CYWC628 and increased the number of test manufacturing runs needed to confirm no sterility issues, which we had to resolve and complete before we could begin the manufacture of CYWC628 for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia. These issues required us to extend the initial timelines for the initiation and completion of the clinical trial.

If we or our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and our third-party manufacturers. We currently outsource all manufacturing to third parties. Still, we and our manufacturers are subject to federal, state, and local laws and regulations in the United States governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not currently have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations.

We rely on third parties for our manufacturing process and may, in the future, depend on third-party manufacturers for our product candidates, and this increases the risk related to the timely and sufficient production of our product candidates.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing our cell therapy product candidates. Third-party manufacturers may be unable to comply with cGMP regulations or similar regulatory requirements outside the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA, or other regulatory authorities, we will not be able to produce our product candidates. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. For example, we encountered process issues with the manufacturing training run of CYWC628 and increased the number of test manufacturing runs needed to confirm no sterility issues, which we had to resolve and complete before we could begin the manufacture of CYWC628 for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia. If these issues were not resolved and completed, we would have been unable to manufacture CYWC628 for our clinical trial in a timely manner. If the FDA, the EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply, or storage issues or otherwise, we could experience delays, disruptions, suspensions, or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We currently rely on third-party manufacturers to produce our product candidates. In the event that we or any of our third-party manufacturers fail to comply with such requirements or to perform with certain requirements in relation to quality, timing, or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our third-party manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to us or the third-party manufacturer. We may have difficulty transferring such skills or technology to another third party, and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company. Therefore, we may experience delays in our development programs if we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturers or require us to obtain a license from such manufacturers in order to have another third party manufacture our product candidates. If we are required to or voluntarily stop manufacturing our product candidates for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in our facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute our manufacturing requirements, do so on commercially reasonable terms and timelines, and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;

- delays in submitting regulatory applications or receiving marketing approvals for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- 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 product candidates or any future product candidates.

Any contamination or interruption in our manufacturing processes, shortages of raw materials, or failure of our suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of cell therapy manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Additionally, although our cell therapies are tested for contamination prior to release if a contaminated product candidate were administered to a patient, it could result in harm to the patient. Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for the purchase, lease, order, arrangement, or recommendation 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 the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil fines and criminal penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 federal False Claims Act or federal civil money penalties;

- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. 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;

- HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose certain requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the use, creation, maintenance, receipt or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there are additional federal, state, and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances to which we may be subject and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- The ACA, including the provision commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians, nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals and to disclose ownership and investment interests held by physicians and their immediate family members; and

- many state laws that govern the privacy of personal information in specified circumstances. For example, in California, the California Consumer Privacy Act, or the CCPA, is a comprehensive privacy law that applies to covered businesses and creates data privacy rights for consumers in the State of California, imposes restrictions on the sale of personal information, and allows for potentially significant statutory fines and damages for

violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the CCPA, other personal information collection practices may be subject to the CCPA and possible changes to the CCPA may broaden its scope. Moreover, some states, such as Washington, Nevada, and Connecticut, have adopted legislation protecting consumer health information specifically. Washington's My Health My Data Act, which is now in effect, features a private right of action, which could result in a heightening risk of litigation in addition to regulatory risks.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require biopharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require biopharmaceutical companies to make marketing or price disclosures to the state and require the registration of biopharmaceutical sales representatives.

Privacy and data protection laws outside of the United States, including, for example, the European Union and United Kingdom General Data Protection Regulation, collectively, the GDPR, also govern the privacy and security of personal information, including health information in some circumstances, and many of these laws differ from each other in significant ways, thus complicating compliance efforts. In addition, in the United States, there are a number of states that have enacted laws that govern the privacy and security of personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare and privacy laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, 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 ourselves against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we do, or expect to do, business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

We, our collaborators, and our service providers are, or may become, subject to evolving global data protection laws and regulations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we, our collaborators and our service providers may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability, or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

At the federal level, in addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission (the FTC) Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by U.S. Department of Justice, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

In addition, certain state laws govern privacy and security of personal information. For example, in addition to the CCPA, which establishes a comprehensive framework for the protection of California consumer personal information, numerous states have passed and are proposing consumer privacy laws that impose similar protections for personal information. In addition, some states have passed or are proposing privacy laws that regulate specific sectors or data categories. For example, as noted above, several states have passed laws regulating health privacy, and many states are continuing to propose new laws, or modifications to existing laws, to enhance protections for health data and other forms of sensitive data. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, our contemplated twelve-week Phase 1/2 clinical trial for treatment of diabetic foot ulcers will be conducted in Australia and subject us to additional Australian data privacy laws, regulations and guidelines, including the Privacy Act 1988 and the thirteen (13) Australian Privacy Principles, which regulate the collection, use, disclosure, and storage of personal and health information. Key Australian requirements include obtaining informed, voluntary consent, ensuring data security, and managing cross-border transfers. We may also seek to conduct clinical trials in the United Kingdom or the European Economic Area, or the EEA, and may become subject to additional European data privacy laws, regulations and guidelines, including the GDPR. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the EEA or UK, such as in connection with clinical trials in those jurisdictions. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

The GDPR imposes a broad range of requirements relating to personal data, including requirements relating to having lawful bases for processing personal data and transferring such information outside the EEA/UK, including to the United States, providing detailed disclosures to individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving

personal data to the competent national data protection authority and affected individuals, and internal accountability processes, such as record-keeping and conducting data protections impact assessments.

Other countries around the world have adopted privacy legislation similar to the GDPR, and the EEA, United Kingdom, and other countries are continuing to modify and adopt privacy and data protection laws, including laws and regulations that affect the health and life sciences sector. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition, and results of operations.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing, and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. If we succeed in marketing product candidates, such claims could result in an FDA, EMA, or other regulatory authority investigation of the safety and effectiveness of our product candidates, our manufacturing processes and facilities or our marketing programs. FDA, EMA, or other regulatory authority investigations could potentially lead to a recall of our product candidates or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, if approved, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. While our Australian subsidiary maintains clinical trial insurance for our contemplated twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers, we currently do not maintain clinical trial or product liability insurance in the Unites States and may need to obtain such coverage prior to commencing clinical trials in the United States or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations, which could make it difficult for us to sell them profitably.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. 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. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. 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 and biologics. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product candidates to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective, and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our product candidates. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

For additional information, see the section of this report entitled, "*Business—Regulatory Environment—Coverage and Reimbursement.*"

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of

individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party contract manufacturing organizations, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected product candidates that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our product candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

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

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

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

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

The FDA, the EMA, and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

To date, we have completed one clinical trial in Mexico, we will conduct our contemplated twelve-week Phase 1/2 clinical trial for the treatment of diabetic foot ulcers in Australia, and we may conduct international clinical trials in the future. The acceptance of study data by the FDA, the EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA

will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means, to the extent necessary. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA, or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. If the FDA, the EMA, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or the EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the products, 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 in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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, the EMA, or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for our product candidates 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 on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug 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. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In

addition, failure to comply with FDA, the EMA or other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers, or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties, including fines;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

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 enacted that could prevent, limit, or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the issuance of a number of Executive Orders could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The 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 U.S. federal 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.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. biopharmaceutical industry. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments and may result in additional reductions in Medicare and other healthcare funding, as well as the potential for the government to select certain single-source drugs and biologics for drug price negotiations under Medicare, all of which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations. For additional information, see the section of this report entitled, "*Business—Regulatory Environment—Healthcare Reform."*

There have also been several changes and challenges to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how these developments could affect covered hospitals who might purchase our future product candidate and affect the rates we may charge such facilities for our approved product candidates in the future, if any.

Moreover, there has been heightened governmental scrutiny in recent years over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several U.S. 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 programs, and reform government program reimbursement methodologies for pharmaceutical products. The U.S. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

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

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses to operate without infringing the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around, invalidated or rendered unenforceable by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our or our licensors' rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although we own issued patents in the United States and foreign countries, we cannot be certain that the claims in our other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- our competitors, many of whom have substantially greater resources than we or our licensors do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If we fail to do so, this could cause us to lose rights in any applicable intellectual property that we own, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Composition of matter patents for biological and pharmaceutical products such as cell therapy product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Moreover, we may become subject to claims that we directly or indirectly (through our consultants, advisors, or independent contractors that we may engage to assist us in developing our product candidates or any other potential future product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third parties.

We do not currently have rights to any composition of matter patents or patent applications covering our CybroCell product candidate and we cannot be certain that any of our pending patent applications or our future patent applications will result in issued patent claims covering such aspects of our product candidate.

Composition-of-matter patents are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the drug product used. We do not have any composition of matter patents or pending applications for our CybroCell product candidate. Although we have filed patent applications on other aspects of our CybroCell product candidate and intend to file patent applications in the future, we cannot be certain that these or our future owned patent applications will cover our current or future product candidates.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the drug product. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use

patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute. In addition, there are numerous publications and other prior art that may be relevant to our method-of-use patents and patent applications and may be used to challenge the validity of these patents and patent applications in litigation or other intellectual property-related proceedings. If these types of challenges are successful, our patents and patent applications may be narrowed or found to be invalid, and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions, prospects and results of operations.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other countries. Even if patents do successfully issue, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and third parties may challenge the validity, enforceability or scope of our owned patents in courts or patent offices in the United States and abroad, which may result in those patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our owned patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own with respect to our product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If the scope of any patent protection we have is not sufficiently broad, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

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 existence, issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates or that effectively prevent others from commercializing competitive product candidates.

Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent is issued, and claim scope can be reinterpreted after issuance. Even if our 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 that we own or have rights to may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may not cover our product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without

payment to us. Such loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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 product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in PGR procedures, oppositions, derivations, reexaminations or IPR proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

In the future, some of our intellectual property may be discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference

for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we may acquire or license in the future may be generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. These U.S. government rights may include retained rights in the intellectual property, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government may have the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government may also have the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether our patent applications will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;

- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application and obtain an issued patent covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;

- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;

- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;

- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although, to our knowledge, no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources or more mature and developed intellectual property portfolios, or both. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, our ability to compete in the marketplace, results of operations, financial condition and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our patents or other intellectual property rights. To cease such infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. In addition, in a patent infringement proceeding, a court may decide that a patent we own or otherwise have rights to is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or written description, obviousness, written description, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention,

or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Such announcements could also harm our reputation or the market for our future product candidates, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to, or correct the inventorship of, our patents or patent applications. An unfavorable outcome could result in a loss of our current patent rights and require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act could increase uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which,

assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. 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 were 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 or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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 that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights, and, more generally, could affect the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us or narrows the scope of our owned patents.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. We cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

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

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

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.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its first effective filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval, if any, of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or 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 revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than

might otherwise be the case. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

Although we have pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries, particularly certain developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information, and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

In addition, certain countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we 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.

Because of the expense and uncertainty of litigation in certain foreign jurisdictions, we may conclude that even if a third-party is infringing our issued patents, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action, which typically last for years before they are concluded, may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings and that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

In addition to the protection afforded by other types of intellectual property, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties (including, but not limited to, contractors, collaborators, and outside scientific advisors), and proprietary information and inventions assignment agreements with employees, consultants, licensors and advisors, we cannot provide any assurances that all such agreements have been duly executed, and 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. We require our employees to enter into written proprietary information and inventions assignment agreements that assign to us any inventions, developments, creative works and useful ideas of any description that are conceived of, reduced to practice or developed in the course of their employment. In addition, we require our third-party contractors to enter into a written non-disclosure agreement that requires the third party to not disclose certain of our confidential information in any manner or for any purpose other than as necessary and/or appropriate in connection with their obligations for a defined period of time, subject to certain exclusions. 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. We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Currently, many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees, independent contractors, or consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our

business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

Moreover, any name we have proposed to use with product candidates in the United States may need FDA approval, 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 an equivalent administrative body in a foreign jurisdiction) 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 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. 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 claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Employee Matters and Managing our Growth

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage, and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain

high-quality personnel, the rate and success at which we can discover, develop, and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 15 full-time employees. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process of our product candidates and any other product candidate we develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

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

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and any future product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, 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 will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Risks Related to Ownership of Our Common Stock

Failure to maintain compliance with the applicable Nasdaq continued listing requirements could result in our common stock being delisted, which could limit stockholders' ability to trade our common stock.

As a listed company on Nasdaq, we are required to meet certain financial, public float, bid price and liquidity standards on an ongoing basis to continue the listing of our common stock. If we fail to meet these continued listing requirements, our common stock may be subject to delisting, which could materially impact the liquidity of our common stock making it more challenging to buy and sell shares of our common stock. We are currently listed on the Nasdaq Capital Market and trade under the symbol "FBLG." On March 27, 2025, we submitted to Nasdaq an application to transfer the listing of our common stock from The Nasdaq Global Market to the Nasdaq Capital Market. This transfer allowed us to satisfy less stringent financial, liquidity, and market capitalization requirements to continue the listing of our common stock. For example, the market value requirement of the Nasdaq Capital Market is $35 million versus $50 million for the Nasdaq Global Market and the stockholders' equity requirement for the Nasdaq Capital Market is $2.5 million versus $10 million for the Nasdaq Global Market. If we fail to meet any of the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted from Nasdaq.

On July 1, 2025, we received a notification letter from the Nasdaq Listing Qualifications Staff, or the Staff, notifying us that the closing bid price of our shares of common stock was below the minimum closing bid price of $1.00 per share during the previous 30 consecutive trading days, as required for continued listing on the Nasdaq Capital Market, or the Bid Price Rule. We were provided an initial period of 180 calendar days, or until December 29, 2025, to regain compliance with the Bid-Price Rule. To regain compliance, the closing bid price of our common stock had to be $1.00 per share or more for a minimum of 10 consecutive business days at any time before December 29, 2025. If we did not regain compliance with the Bid Price Rule by December 29, 2025, we would be eligible for an additional 180 calendar day compliance period if we met the continued listing requirement for market value of publicly held shares, or MVLS, and all other initial listing standards for the Nasdaq Capital Market, except the bid price requirement, and provided written notice to Nasdaq of our intention to cure the deficiency during the second compliance period. If it appeared to the Staff that we would not be able to cure the deficiency, or if we were otherwise not eligible for the additional compliance period, Nasdaq would notify us that our securities would be subject to delisting. In the event of such notification, we could appeal the Staff's determination to delist our securities, but there could be no assurance the Staff would grant our request for continued listing.

On August 4, 2025, we received a notification letter from the Staff notifying us that our MVLS had closed below the minimum $35 million threshold required for continued listing on the Nasdaq Capital Market, or the MVLS Rule, for the previous thirty (30) consecutive trading day period. We were provided a 180-calendar day period to regain compliance with the MVLS Rule, through February 2, 2026. To regain compliance, our MVLS needed to be $35 million or more for a minimum of 10 consecutive business days at any time before February 2, 2026. If we did not regain compliance with the MVLS Rule by February 2, 2026, Nasdaq would notify us that our securities would be subject to delisting. In the event of such notification, we could appeal the Staff's determination to delist our securities, but there could be no assurance the Staff would grant our request for continued listing.

On December 30, 2025, we received a notification indicating that the Staff planned to delist our securities due to our continued non-compliance with the Bid-Price Rule as of December 29, 2025, unless we timely requested a hearing before the Nasdaq Hearings Panel, or the Panel. We timely requested a hearing before the Panel.

On February 3, 2026, we received formal notice from the Staff that, based on our continued non-compliance with the MVLS Rule, the deficiency serves as an additional basis for the delisting of our common stock. The notice indicated

that, in addition to the deficiency under the Bid Price Rule, the Panel will consider our plan to regain compliance with the MVLS Rule in their decision regarding our request for continued listing on the Nasdaq Capital Market.

At our hearing before the Panel, we presented our plan to regain compliance with both the Bid Price Rule and the MVLS Rule. On February 12, 2026, we received a determination from the Panel granting our request for the continued listing of our common stock on the Nasdaq Capital Market, subject to our satisfying (i) the equity standard of $2.5 million required under Rule 5550(b)(1) as an alternative to the MVLS Rule on or before February 27, 2026, (ii) the Bid Price Rule on or before April 13, 2026, and (iii) all other applicable criteria for continued listing on Nasdaq on or before April 13, 2026. We will remain listed and trading on the Nasdaq Capital Market at least pending the expiration of the extension granted to us by the Panel.

We intend to actively monitor the closing bid price of our common stock, our MVLS, and our stockholders' equity and evaluate all available options to regain compliance with the applicable rules. Although we are taking definitive steps to regain compliance with the applicable rules, there can be no assurance that we will be granted a further extension to do so or that any actions we take will be successful in our effort to regain compliance with the listing rules. Furthermore, there can be no assurance that we will be able to maintain compliance with the applicable rules, or if we implement an option that regains our compliance, maintain compliance thereafter. If we fail to regain or maintain compliance with the Nasdaq continued listing standards, our common stock will be subject to delisting from Nasdaq.

Without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. Further, if we are delisted, we would lose federal pre-emption of state securities laws as it relates to our securities and thus also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. If our common stock is delisted, it may come within the definition of "penny stock" as defined in the Exchange Act and would be covered by Rule 15g-9 of the Exchange Act. Rule 15g-9 imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

An active trading market may not be sustained and the market price of shares of our common stock may be volatile.

Our common stock is listed and traded on Nasdaq. An active market for our common stock may not be sustained, which could depress the market price of shares of our common stock and could affect the ability of our stockholders to sell our common stock. While our common stock may be sold on Nasdaq, there can be no assurance that any of our stockholders will sell any of their shares of common stock and there may be a lack of supply of, or demand for, common stock on Nasdaq. In the absence of an active public trading market, investors may not be able to liquidate their investments in our common stock. An inactive market may also impair our ability to raise capital by selling shares of our common stock, our ability to motivate our employees through equity incentive awards and our ability to acquire other companies, products, or technologies by using shares of our common stock as consideration. Further, institutional investors may be discouraged from purchasing our common stock if they are unable to purchase a block of our common stock in the open market due to a potential unwillingness of our stockholders to sell a sufficient amount of common stock at the price offered by such institutional investors. The market for our common stock may be more volatile without the influence of long-term institutional investors that are unable to purchase and hold significant amounts of our common stock.

In addition, we cannot predict the prices at which our common stock may trade on Nasdaq, and the market price of our common stock may fluctuate significantly in response to various factors, some of which are beyond our control. For example, between March 1, 2024 and February 1, 2026, the closing price of our common stock on Nasdaq ranged from $13.00 per share to $0.225 per share.

The public price of our common stock could be subject to wide fluctuations in response to the risk factors described in this Annual Report and other periodic reports we file with the SEC and other risks beyond our control, including:

- changes in the industries in which we operate;
- the commencement, enrollment, completion, or results of our current or future preclinical and clinical trials for any current or potential future product candidates;
- our failure to commercialize any current or potential future product candidates, if approved;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- variations in our operating performance and the performance of our competitors in general;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements, and our filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political, and economic risks and acts of war or terrorism.

In addition, securities exchanges have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. Stock prices of many companies have fluctuated in a manner often unrelated to the operating performance of those companies.

We have 2,500 shares of Series C Preferred Stock with super voting rights which may adversely affect holders of our common stock.

Our board of directors and stockholders approved the creation and issuance of an aggregate of 2,500 shares of Series C Preferred Stock, all of which were issued to Pete O'Heeron, our founder and Chief Executive Officer, in conjunction with our direct listing.

The Series C Preferred Stock (i) have no dividend rights, (ii) convert into common stock upon any transfer from the initial holder, (iii) have a liquidation preference of $18.00 per share (subject to appropriate adjustment in the event of any stock split, combination, or other similar recapitalization) upon our liquidation, dissolution or winding up and (iv) are entitled to 13,000 votes for each share of Series C Preferred Stock.

The Series C Preferred Stock are subject to an irrevocable proxy issued by Mr. O'Heeron in favor and for the benefit of, our board of directors, granting our board of directors the irrevocable proxy, for as long as the Series C Preferred Stock remain outstanding, to vote all of the Series C Preferred Stock on all matters on which the Series C Preferred Stock are entitled to vote, in any manner that our board of directors may determine in its sole and absolute discretion; provided, however, that such irrevocable proxy shall not, without the written consent of Mr. O'Heeron, permit our board of directors to vote the Series C Preferred Stock with respect to any proposal to amend, delete or waive any rights of Mr. O'Heeron with respect to the Series C Preferred Stock as set forth in our amended and restated certificate of incorporation. In light of the superior voting rights associated with the Series C Preferred Stock, the irrevocable proxy is intended to ensure that such superior voting rights are utilized in our best interest and to avoid or mitigate conflicts that may arise in the future for Mr. O'Heeron as an individual stockholder employee.

In addition to the dilutive effect on the voting power and value of our common stock, the foregoing structure of our capital stock may render our common stock ineligible for inclusion in certain securities market indices, and thus adversely affect the price and liquidity of, and public sentiment regarding, our common stock or other securities. The existence of, and voting rights associated with, our Series C Preferred Stock, either alone or in conjunction with certain of the other provisions of our amended and restated certificate of incorporation, such as the requirement to have a staggered board, could also have the effect of delaying, deterring or preventing a change in our control or make the removal of our management more difficult.

Our management and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of February 1, 2026, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 45% of the voting power of our outstanding voting securities. To the extent that the same group continue to own a significant percentage of our voting securities, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors, amendments to our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions. This concentration of voting power may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders.

Future issuances of our common stock pursuant to our 2022 Stock Plan could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Pursuant to our 2022 Stock Plan, we are authorized to grant stock options and other equity-based awards to our employees, directors, and consultants. At December 31, 2025, there were 6,783,761 shares available for future grants under the 2022 Plan and 5,716,239 stock options outstanding. If we issue common stock or other equity securities under the 2022 Stock Plan, existing investors may be materially diluted. The issuance of additional shares of common stock or securities convertible into common stock or perceptions that such issuance may occur, or the exercise of outstanding equity securities, could have a material dilutive impact on existing stockholders and could have a material negative effect on the market price of our common stock.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have never declared or paid any cash dividends on our common stock and we currently intend to retain all available funds and any future earnings to fund the development, commercialization, and growth of our business, and therefore we do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Our future ability to pay cash dividends on our common stock may also be limited by the terms of any future debt securities or credit facility. As a result, capital appreciation, if any, of the common stock you purchase or own will be your sole source of gain for the foreseeable future.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure 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. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) having the option of delaying the adoption of certain new or revised financial accounting standards, (iii) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements, and registration statements and (iv) 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 may take advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. Further, pursuant to Section 107 of the JOBS Act, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our results of operations and consolidated financial statements may not be comparable to the results of operations and consolidated financial statements of other companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earliest of (i) December 31, 2028, (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 was $700.0 million or more 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 non-convertible 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 until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is $250 million or more measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter.

It is possible that some investors will find our common stock less attractive as a result of the foregoing, which may result in a less active trading market for our common stock and higher volatility in our stock price.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent a take-over that may be in the best interests of our stockholders.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may be deemed to have anti-takeover effects, which include, among others, (i) the existence of our Series C Preferred Stock entitled to 13,000 votes per share of Series C Preferred Stock, (ii) a classified board of directors serving staggered three-year terms, (iii) who can fill vacancies of our board of directors, (iv) supermajority voting thresholds for the removal of members of our board, and (v) when and by whom special meetings of our stockholders may be called, and may delay, defer or prevent a takeover attempt.

In addition, our amended and restated certificate of incorporation authorizes the issuance of shares of preferred stock which will have such rights and preferences determined from time to time by our board of directors. Accordingly, our board of directors may, without stockholder approval (except as may be required under Nasdaq rules), issue additional preferred shares with dividends, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. Further, our amended and restated certificate of incorporation authorizes the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan (also known as a "poison pill").

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

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, (i) the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (c) any action arising pursuant to any provision of the General Corporation Law of the State of Delaware, or the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws or (d) any action asserting a claim governed by the internal affairs doctrine and (ii) to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Pursuant to our amended and restated certificate of incorporation, any person or entity purchasing or otherwise acquiring or holding any interest in shares of our common stock will be deemed to have had notice of and consented to the forum selection clause in our amended and restated certificate of incorporation described in this paragraph.

The foregoing provision would not preclude stockholders that assert claims under the Exchange Act from bringing such claims in federal court, to the extent that the Exchange Act confers exclusive federal jurisdiction over such claims, subject to applicable law.

We believe our choice of forum provision may benefit us by providing increased consistency in the application of Delaware law by chancellors and judges particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, our choice of forum provision may impose additional litigation costs on stockholders in pursuing claims and may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. In addition, while the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the choice of forum provision, and there can be no assurance that such provision will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision in our 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.

General Risk Factors

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock.

Securities research analysts have established and published their own periodic projections for our Company. These projections may vary widely and may not accurately predict the results we actually achieve. The price of our common stock may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our stock price or trading volume could decline.

Our internal computer systems, or those of any of our CROs, CDMOs, other contractors, consultants, collaborators and third-party service providers, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures, we, like other organizations in our industry, have experienced and expect to continue to experience threats to our internal computer systems. Our systems and those of our current and

any future CROs, CDMOs, and other contractors, consultants, collaborators, and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. For example, the third-party service provider of our equity management system experienced a cybersecurity event in the third quarter of 2025 that prevented us from accessing the system for several days before the matter was resolved. Information security risks for us and our third-party vendors have increased significantly in recent years, in part because of the proliferation of new technologies, including artificial intelligence, the ubiquity of internet connections, and the increased sophistication and activities of threat actors. 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 breaches that may remain undetected for an extended period. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information, it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state, and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties for certain portions of our manufacturing process, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our office and lab facilities are located in Houston, Texas, a region which experiences severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major hurricane, tornado, flood, fire, earthquake, power loss, terrorist activity or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unfavorable global economic and geopolitical conditions could adversely affect our business, financial condition, stock price, and results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. Changes to policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation, and other areas. For example, in April 2025, the United States imposed broad tariffs on imports from virtually all countries, with particularly high tariffs on imports from China. Since this announcement, most tariffs for countries other than China have been suspended or reduced temporarily. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, some countries have implemented retaliatory tariffs

on U.S. goods, while others seek to negotiate agreements regarding U.S.-imposed tariffs. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

The global credit and financial markets have also generally experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation, and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by military conflict, including the ongoing conflicts 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 continue to 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. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and any other potential future product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

There are also current geopolitical tensions with China that may affect our operations. For example, the recently enacted BIOSECURE Act, which, among other things, prohibits U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese "biotechnology companies of concern" and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services from one of these entities. Any additional executive action, legislative action similar to the BIOSECURE Act or potential sanctions with China could materially impact manufacturing partners and our agreements with them. We continue to assess any legislation as it develops to determine the effect, if any, on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials.

In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Fluctuations in foreign currency exchange rates could negatively impact our results of operations and result in changes in our foreign currency translation adjustments.

We contract with our CRO and other vendors in foreign countries and expect to contract with clinical trial sites in foreign countries in the normal course of business. We are, therefore, subject to fluctuations in foreign currency rates in connection with these agreements. Our principal exchange rate exposure is with the Australian dollar against the U.S. dollar. Fluctuations in foreign currency exchange rates could negatively impact our results of operations. Any

changes in foreign currency exchange rates would be reflected as a foreign currency exchange gain or loss. We do not hedge against our foreign currency exchange rate risk.

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

Natural disasters or public health crises could severely disrupt our operations, and have a material adverse impact on our business, financial condition, results of operations and growth prospects. If a natural disaster, power outage, public health crisis or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results or delaying our ability to obtain regulatory approval for our product candidates and any other potential future product candidates, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, or results of operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed periods of market volatility, certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have processes for assessing, identifying, and managing cybersecurity risks that include physical, procedural, and technical safeguards to identify, assess and mitigate risks from cybersecurity threats.

We have engaged an external Information Technology Managed Service Provider, or IT MSP, to support our management team's maintenance of our information technology systems and infrastructure. A member of our executive leadership team provides oversight of the activities of the IT MSP to monitor cybersecurity controls. Further, through diligence and/or contract, we assess the cybersecurity posture of certain third parties.

Governance

Our management team is responsible for assessing and managing cybersecurity risks, and is informed by our IT MSP regarding cybersecurity matters.

The Audit Committee of our Board of Directors is responsible for oversight of enterprise risk management, including cybersecurity risk management. The Audit Committee, with assistance from the Governance and Nominating Committee of our Board, reviews our processes for assessing and managing such risks. The Audit Committee and Governance and Nominating Committee receive periodic updates from management regarding cybersecurity matters.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party service providers experience threats and security incidents that could affect our information or systems. For more information, please see Section 1A. Risk Factors.

Item 2. Properties

We lease approximately 23,000 square feet of office space for our headquarters in Houston, Texas. This lease ends in November 2027.

We lease approximately 10,700 square feet of office and lab space in Houston, Texas. This lease ends in May 2031.

We believe that our leased facilities are adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position, or cash flows. There are no legal proceedings at this time.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol "FBLG."

Holders

As of February 24, 2026, we have 67,594,722 shares of common stock outstanding held by 543 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities we sold during the three months ended December 31, 2025. Unless stated otherwise, the sales of the securities listed below were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering.

Below is a summary of conversions during the three months ended December 31, 2025 by YA II PN, LTD., or the Investor, of short-term convertible notes issued to the Investor under the SEPA:

Date	Tranche	Principal Amount	Shares Issued	Price Per Share
October 14, 2025	Third Note	$ 200,000	482,741	$ 0.4143
October 15, 2025	Third Note	$ 100,000	246,305	$ 0.4060
October 16, 2025	First Note	$ 200,000	492,610	$ 0.4060
October 20, 2025	First Note	$ 200,000	492,610	$ 0.4060
October 21, 2025	First Note	$ 300,000	738,916	$ 0.4060
October 27, 2025	First Note	$ 300,000	738,916	$ 0.4060
November 5, 2025	First Note	$ 300,000	855,675	$ 0.3506
November 17, 2025	First Note	$ 300,000	963,081	$ 0.3115

Item 6. Reserved

Item 7. 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 consolidated financial statements and related notes and other financial information appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, 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

We are a clinical-stage biotechnology company focused on developing and commercializing fibroblast-based therapies for patients suffering from chronic diseases with significant unmet medical needs, including wound healing, multiple sclerosis, degenerative disc disease, psoriasis, certain cancers, and potential human longevity applications including thymic involution reversal using a thymic organoid. Our most advanced product candidates are CYWC628, CYPS317, CYMS101 and CybroCell™.

We have completed our IND-enabling pre-clinical studies for the development of CYWC628 as a topically administered allogeneic fibroblast cell-based therapy for wound healing. Our pre-clinical studies focused on utilizing single cell fibroblasts, fibroblast spheroids, and fibroblast-derived materials to treat wounds in diabetic mice. We completed pre-clinical studies investigating (i) multiple administrations of CYWC628 spheroids on a chemically induced chronic wound NONcNZO10/LtJ and BKS.Cg-Dock7m +/+ LepRdb/J mouse model, (ii) dose titration to provide information on the proposed dose range of CYWC628, and (iii) acute and chronic toxicity. The results of our studies have shown statistically significant acceleration in the rate of wound closure, and statistically significant improvement in the quality of the healed wounds in comparison with both a marketed wound care product and control. Based upon our results, we are planning to initiate a twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers in the first quarter of 2026.

We are developing CYMS101 as an intravenously administered allogeneic fibroblast single cell, and fibroblast spheroid, cell-based therapy to treat MS. After completing animal studies using CYMS101, we received approval from a U.S.-based IRB to conduct clinical investigations in Mexico using the fibroblast cell composition for patients with MS, and completed a Phase 1 study. The study was conducted in five participants. The primary objective of the study was to assess safety, and the secondary objective was to assess efficacy. The primary objective was achieved as

we saw no adverse events related to the treatment - no adverse events during intravenous injection of the tolerogenic fibroblasts, no short or long-impact in complete blood count tests during the 16-week monitoring period, and no short or long impact in electrocardiogram results during the 16-week monitoring period. In addition, the study assessed clinical activity using a standard set of neurological assessments routinely used to assess MS. We are currently conducting further research to more fully characterize the mode of action of fibroblasts in oligodendrocyte expansion. We plan to file an IND application for a Phase 1/2 clinical trial relating to MS in the United States in the first half of 2026. We expect to seek a strategic partner to collaborate with us on the development of CYMS101 either before initiating the Phase 1/2 study, or after its completion, if successful, and prior to commencing a potential Phase 3 clinical trial.

CybroCell™ is an investigational intradiscal administered allogeneic fibroblast cell-based therapy in development for degenerative disc disease and is being designed as an alternative method for repairing the cartilage of the intervertebral disc (or any other articular cartilage). We have completed two animal studies in rabbit models. The results from the studies were positive and supported our IND application to run a "first in human" trial. We received IND clearance from the FDA in 2018, conditional upon approval of our master cell bank, to evaluate this candidate in a planned clinical trial. A timeline for the trial will be determined in connection with discussions with the FDA.

CYPS317 is our allogeneic intravenously administered fibroblast spheroid cell-based investigational therapeutic for the treatment of psoriasis. We have completed preliminary IND-enabling pre-clinical studies utilizing chronic and acute psoriasis mouse models to assess the potential use of intravenous administration of fibroblast spheroids for the treatment of psoriasis. We also completed IND-enabling animal model studies to determine the optimal efficacious dose range and the durability of treatment for mild to moderate, and moderate to severe psoriasis. On December 30, 2025, we filed a Phase 1/2 Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) seeking regulatory clearance to initiate clinical trials of CYPS317.

We also have human longevity, certain cancer, and artificial pancreatic organoid research programs in the very early stages of research and development. We plan to accelerate such programs as funding allows.

The manufacturing of our master cell bank and working cell bank for CYWC628 is now complete and both are certified as released by our CDMO. This CDMO will also manufacture CYWC628 for use in our twelve-week Phase 1/2 clinical trial for treatment of diabetic foot ulcers that we will conduct in Australia. We successfully carried out experiments that demonstrated the ability to use the CYWC628 spheroid master cell bank for the manufacturing of a modified CybroCell™ drug product. We also supported animal trials confirming that the therapeutic effects of the fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank are significantly better to those of single-cell fibroblasts, which supported our IND clearance with the FDA for the planned Phase I clinical trial. Based on these results, we will work to amend the IND clearance with the FDA to replace single-cell fibroblasts with fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank. A timeline for the trial will be determined in connection with discussions with the FDA. If any of our product candidates receive marketing approval, we expect to evaluate the feasibility of building our own cGMP manufacturing facility or continuing to outsource manufacturing to a CDMO for clinical testing and commercial supply. We expect to rely on third parties for our cell therapy manufacturing process for the foreseeable future.

Since our April 2021 separation from FibroGenesis, our activities have consisted primarily of (i) corporate and strategic planning, (ii) recruiting and retaining personnel, (iii) financing our operations, (iv) prosecuting, maintaining and expanding our intellectual property portfolio, and (v) conducting preclinical and other research and development related to our product candidates. These activities allow us to continue building our fibroblast cell-based therapy platform..

We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through investment from FibroGenesis, the sale of $15.0 million of our convertible promissory notes, which were all subsequently converted to equity, the sale of $18.6 million of preferred stock, $10.4 million in proceeds from the sale of common stock, $0.00001 par value per shares, or the Common Stock, through the share purchase agreement, dated November 12, 2021, or the GEM SPA, with GEM Global Yield LLC SCS, or GEM Global, and GEM Yield Bahamas Limited, or GYBL, and together with GEM Global, GEM, $13.1 million in proceeds from the issuance of additional convertible promissory notes, and $6.7 million in net proceeds from the sale of Common Stock in direct placements.

As of December 31, 2025, we had cash and cash equivalents of approximately $4.9 million. Since our inception, we have incurred significant operating losses. We incurred net losses of approximately $18.6 million and $11.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately $54.2 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our product candidates through clinical development, and, if approved by the FDA, commercialization;
- advance our preclinical development programs into clinical development;
- incur manufacturing costs for cell production to supply our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- meet the requirements and demands of being a public company;
- invest in further development to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize; and
- expand our manufacturing and develop our commercialization efforts.

Due to the numerous risks and uncertainties associated with biopharmaceutical product development and the economic and developmental uncertainty, we may be unable to accurately predict the timing or magnitude of all expenses. Our ability to ultimately generate revenue to achieve profitability will depend heavily on the development, approval, and subsequent commercialization of our product candidates. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. As a result, we will need substantial additional funding to support our short-term and long-term continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we will have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for any of our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

We may never succeed in obtaining regulatory approval for any of our product candidates and, even if we do, we may never generate revenue that is significant enough for us to achieve profitability.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates and include:

- employee-related expenses, which include salaries, benefits, travel and stock-based compensation for our research and development personnel;
- laboratory equipment and supplies;
- direct third-party costs such as expenses incurred under agreements with CROs and CMOs;
- consultants that conduct research and development activities on our behalf;
- costs associated with conducting preclinical studies and clinical trials;
- costs associated with technology; and
- facilities and other allocated expenses, which include expenses for rent and other facility related costs and other supplies.

We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates as they advance into later stages of clinical development and our other product candidates in preclinical development as they advance into clinical development. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. This is due to the numerous risks and uncertainties associated with developing product candidates, including uncertainty related to:

- the duration, costs, and timing of clinical trials of our current development programs and any further clinical trials related to new product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- the acceptance of IND applications for future clinical trials;
- the successful and timely enrollment and completion of clinical trials;
- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;

- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- the entry into collaborations to further the development of our product candidates;
- the cost of hiring additional personnel;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- successfully launching our product candidates and achieving commercial sales, if and when approved.

A change in the outcome of any of these variables with respect to the development of any of our programs or any product candidate we develop would significantly change the costs, timing and viability associated with the development and/or regulatory approval of such programs or product candidates.

General, Administrative and Other Expenses

Our general, administrative, and other expenses consist primarily of personnel costs, allocated facilities costs, and other expenses for outside professional services, including legal, marketing, investor relations, human resources services, and accounting services. Personnel costs consist of salaries, benefits, and stock-based compensation for our general and administrative personnel. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Interest Expense

Our interest expense consists primarily of accrued interest expense, interest on short-term borrowing to finance D&O insurance premiums, and amortization of discount on our convertible notes.

Statements of Operations

Results of Operations

Comparison of Fiscal Years December 31, 2025 and 2024

The following table sets forth our results of operations for the years ended December 31, 2025 and 2024.

	For the Year Ended December 31,		Change Amount
	2025	2024	
	(in thousands)		
Operating expenses:			
Research and development	$ 7,407	$ 4,504	$ 2,903
General, administrative and other	9,242	9,233	9
Total operating expenses	16,649	13,737	2,912
Loss from operations	(16,649)	(13,737)	(2,912)
Other income/(expense)			
Change in fair value of warrant liability	—	5,385	(5,385)
Change in fair value of forward contract liability	—	(417)	417
Change in fair value of SEPA put option liability	352	(460)	812
Change in fair value of convertible debt	(1,773)	232	(2,005)
Commitment fee expenses	—	(2,191)	2,191
Placement agent and tail fee expenses	—	(1,450)	1,450
Gain on termination of warrant and commitment fee liabilities	—	1,214	(1,214)
Other income/(expense)	(619)	32	(651)
Interest income	247	251	(4)
Interest expense	(204)	(20)	(184)
Total other income/(expense)	(1,997)	2,576	(4,573)
Net loss	$ (18,646)	$ (11,161)	$ (7,485)

Research and Development Expenses

Research and development expenses were $7.4 million and $4.5 million for the years ended December 31, 2025 and 2024, respectively. The increase of $2.9 million was primarily due to:

- increased drug product and CRO expenses of $2.2 million to prepare for the clinical trial in 2026;
- increased personnel related expenses of $0.3 million due to hiring additional research scientists during 2025;
- increased research facility costs of $0.3 million; and
- increased depreciation expense of $0.1 million

Research and development expenses are not tracked by product candidate.

General, Administrative and Other Expenses

General, administrative and other expenses were $9.2 million and $9.2 million for the years ended December 31, 2025 and 2024, respectively. The increase of $0.0 million was primarily due to:

- increased professional expenses of $0.3 million for legal, accounting fees and marketing costs;
- increased office expense, personnel, board of directors costs, and associated travel of $0.2 million;
- decreased offering and listing expenses of $0.4 million.
- decreased insurance expense of $0.1 million.

Change in fair value of warrant liability

Change in fair value of warrant liability was $0 and a gain of $5.4 million for the years ended December 31, 2025 and 2024, respectively. The liability instrument to investors under the Share Purchase Agreement among us, GEM Global Yield LLC SCS, or GEM, and GEM Yield Bahamas Limited, or GYBL, dated November 12, 2021, or the GEM SPA, was comprised of the contingent warrant liability and contingent put option. The $5.4 million gain during the year ended December 31, 2024 resulted from the mark to market of the warrant liability, which occurred at the end of each reporting period until the warrant liability was derecognized in December 2024, and resulted primarily from the decrease in our stock price.

Change in fair value of forward contract liability

Change in fair value of forward contract liability was $0 and $0.4 million for the years ended December 31, 2025 and 2024, respectively. A forward contract liability to sell shares to the investor at 90% of the average daily closing price per share over the Draw Down Pricing Period is recorded each time we issue a Draw Down Notice to GEM under the Share Purchase Agreement. The forward contract liability is remeasured at the end of each quarter, if open, and again upon receipt of the Closing Notice from the investor. The forward contract liability was derecognized upon receipt of the Closing Notice and funds from the investor.

Change in fair value of SEPA put option liability

On December 20, 2024, we entered into a Standby Equity Purchase Agreement (the "SEPA") with a certain investor. Pursuant to the SEPA, and subject to certain conditions, we have the right, from time to time, until December 20, 2026, to require the investor to purchase up to $10.0 million of shares of Common Stock by delivering written notice to the investor. The SEPA was accounted for as a liability under ASC 815 because it includes an embedded put option and an embedded forward option. The SEPA put option liability was recognized at inception, and its fair value was estimated at $0.1 million and $0.5 million at December 31, 2025 and 2024, respectively. The change in fair value of the SEPA put option liability was a gain of $0.4 million during the year ended December 31, 2025 and a loss of $0.5 million during the year ended December 31, 2024 and resulted primarily from changes in stock price and other assumptions used in the valuation model.

Change in fair value of convertible debt

We received advances in the form of convertible notes pursuant to our Standby Equity Purchase Agreement in December 2024 and June 2025 and elected to account for the short-term convertible notes under the fair value option. Under the fair value option, all costs associated with raising the funds were expensed immediately and the difference between the net proceeds and the fair value of the convertible notes at issuance was recorded as a $0.1 million gain during the year ended December 31, 2024. The convertible notes were paid off in November 2025 and during the year ended December 31, 2025, the Company recorded a $1.8 million loss of change in fair value resulting from the decrease in fair value.

Commitment Fee Expenses

Commitment fee expense was $0 and $2.2 million for the years ended December 31, 2025 and 2024, respectively. A $2 million commitment fee pursuant to the GEM SPA became payable to GEM upon completion of the Direct Listing in January 2024. The commitment fee is payable to GEM as drawdown notices are issued, with any remaining balance payable one year after public listing. We sold $3.0 million of common stock to GEM under the GEM SPA during the three months ended March 31, 2024, which made approximately $0.1 million of the commitment fee payable immediately. This $0.1 million portion of the commitment fee was netted against the proceeds received in additional paid-in capital. The remaining $1.9 million was expensed immediately because we were planning to raise funds through other sources and had no plans to issue further Draw Down Notices to GEM prior to the one-year anniversary of our public listing when this remaining amount would have been due.

A $0.3 million commitment fee was recorded during the year ended December 31, 2024 following the closing of the first pre-advance under our Standby Equity Purchase Agreement entered into in December 2024.

Placement agent and tail fee expenses

There were no placement agent and tail fee expenses in the year ended December 31, 2025. In the year ended December 31, 2024, we recorded a $0.7 million tail fee expense for amounts due to Maxim under our agreements dated April 24, 2023 and February 5, 2024 as a result of issuing $10.0 million of convertible debt in December 2024. We also recorded a $0.7 million placement agent expense for amounts due to the placement agent upon the execution of our Standby Equity Purchase Agreement and receipt of advances in the form of convertible notes in December 2024.

Gain on termination of warrant and commitment fee liabilities

There was no gain on termination of warrant and commitment fee liabilities in the year ended December 31, 2025. In the year ended December 31, 2024, we entered into a side letter agreement with GEM to issue 1,152,074 shares to GEM at a valuation of $2.17 per share to satisfy the remaining commitment fee and warrant liabilities due to GEM. We recorded a $1.2 million gain for the amount by which the combined value of the commitment fee and warrant liabilities exceeded the $2.5 million value of the shares issued.

Other income/(expense)

Other loss was $0.6 million for the year ended December 31, 2025, compared with Other income of $32,000 for the year ended December 31, 2024, which is comprised of the payments to FibroGenesis in excess of the derivative liability established at inception of the Agreement Regarding Right of First Negotiation entered into by us and FibroGenesis in January 2023, or the ROFN Agreement.

Interest income

Interest income for the years ended December 31, 2025 and 2024 was $0.2 million and $0.3 million, respectively and is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest expense

Interest expense was $0.2 million and approximately $20,000 for the years ended December 31, 2025 and 2024, respectively. The increase of $0.2 million was due to the payoff of the convertible notes during the year ended December 31, 2025. Interest expense was recorded in 2024 for the nominal interest rate of 6.0% plus the amortization of the discount on the 2022 convertible notes.

Income taxes

The effective income tax rate was 0.0% for all periods. Currently, we have recorded a full valuation allowance against our net deferred tax assets.

Liquidity and Capital Resources

Overview

Through December 31, 2025, we have financed our operations primarily with investment from FibroGenesis, proceeds from borrowings under our convertible loan agreements, proceeds from the issuance of preferred stock, proceeds from the sale of common stock through the GEM SPA, and proceeds from registered direct offerings. We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through investment from FibroGenesis, the sale of $15.0 million of our convertible promissory notes, which were all subsequently converted to equity, the sale of $18.6 million of preferred stock, $10.4 million in proceeds from the sale of common stock, $0.00001 par value per shares, or the Common Stock, through the share purchase agreement, dated November 12, 2021, or the GEM SPA, with GEM Global Yield LLC SCS, or GEM Global, and GEM Yield Bahamas Limited, or GYBL, and together with GEM Global, GEM, $13.1 million in proceeds from the issuance of additional convertible promissory notes, and $6.7 million in net proceeds from the sale of Common Stock in direct placements. As of December 31, 2025, we had cash and cash equivalents of approximately $4.9 million and an accumulated deficit of approximately $54.2 million.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2025 and 2024.

	For the Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (16,394)	$ (11,901)
Net cash used in investing activities	(262)	(184)
Net cash provided by financing activities	7,565	16,907
Net decrease in cash and cash equivalents	$ (9,091)	$ 4,822

Operating Activities

Net cash used in operating activities was $16.4 million and $11.9 million for the years ended December 31, 2025 and 2024, respectively, and consisted primarily of net losses of $18.6 million and $11.2 million, respectively. Net losses for the year ended December 31, 2025 were partially offset by $2.7 million in noncash stock-based compensation expense, $0.4 million in noncash change in fair value of SEPA put option liability, a change in fair value of convertible debt of $1.9 million, an increase of $1.2 million in prepaid expenses, noncash depreciation expense of $0.2 million, and a decrease in accounts payable and accrued expenses of $1.5 million, and a decrease in operating lease liability of $0.6 million. Net losses for the year ended December 31, 2024 were partially offset by $2.2 million in noncash stock-based compensation expense, $1.9 million in noncash change in commitment fee payable to GEM, $0.4 million in noncash change in fair value of forward contract liability, an increase of $1.3 million in accounts payable and accrued expenses, noncash depreciation expense of $0.2 million, and were combined with a $5.4 million decrease in warrant liability, $1.2 million gain on termination of warrant and commitment fee liabilities, $0.1 million gain on issuance of convertible note, $0.1 million change in fair value of convertible debt, $0.2 million decrease in prepaid expenses, and $0.1 million decrease in payable to Parent.

Investing Activities

Net cash used in investing activities was approximately $0.3 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively. In 2025, we purchased approximately $0.3 million of equipment for cash. In 2024, we purchased approximately $0.1 million of equipment for cash and $0.1 million of equipment in accounts payable and accrued expenses.

Financing Activities

Net cash provided by financing activities was approximately $7.6 million and $16.9 million for the years ended December 31, 2025 and 2024, respectively. In 2025, we received approximately $4.4 million in net proceeds from the issuance of convertible notes and we had repayments of these notes in their entirety of $3.6 million. In addition, we received approximately $6.7 million in net proceeds from three registered direct offerings as discussed further in Note 6 of these Consolidated Financial Statements. In 2024, we received $7.5 million in net proceeds from the sale of common stock and received $9.4 million in net proceeds from the issuance of convertible notes.

Funding Requirements

We have incurred operating losses since our formation and expect such losses to continue in the future as we build infrastructure, develop intellectual property and conduct research and development activities. Moreover, we have incurred, and expect to continue to incur, additional costs associated with operating as a public company. We do not have any products approved for sale, and we have never generated any revenue from product sales. We have primarily relied on a combination of angel investors, private debt placements, convertible debt issuances, and sales of equity to fund our operations. As of December 31, 2025, we had an accumulated deficit of $54.2 million and cash and cash equivalents of $4.9 million. We do not expect to generate any meaningful revenue unless and until we obtain

regulatory approval of and commercialize any of our current or future product candidates and we do not know when, or if, that will occur. Unless and until such time that revenue and net income are generated, we will need to continue to raise additional capital. These factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the consolidated financial statements included in this Annual Report. The consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our ability to continue as a going concern is dependent on our ability to raise additional capital. We believe we will be able to obtain additional capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on acceptable terms. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing arrangements. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

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

- the initiation, progress, timeline, cost, and results of our clinical trials for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities, including our planned manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development through commercialization;
- the potential expansion of our current development programs to seek new indications;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the costs of operating as a public company.

We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Contractual Obligations and Commitments

Please see “Part II., Item 1A. Risk Factors—Risks Related to Our Financial Condition and Capital Requirements.”

We have material cash requirements and other contractual obligations related to our office and lab rent (as described in Note 10, “Leases” to the consolidated financial statements in this Annual Report).

Critical Accounting Estimates

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

We define our critical accounting estimates as those under GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, we believe the following are the critical accounting estimates used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Warrant Liability

Upon completion of the Direct Listing on January 31, 2024, the warrant liability and the forward contract liability were no longer contingent and were bifurcated out of the liability instrument and treated as separate units of account. As of January 31, 2024, the warrant liability value for the warrant issued to GEM Yield Bahamas Limited, or GYBL, was determined using a Monte Carlo simulation and Black-Scholes valuation model. Inputs used in the Black-Scholes valuation model included the 1,299,783 warrants issued to GYBL, the closing bid price of $29.10 per share on January 31, 2024, the five-year time to maturity, a 0% dividend yield, an annual risk-free interest rate of 3.67% for the five-year time to maturity, and an assumed annualized volatility of 100% based on comparable companies with a five-year history of stock prices. As of December 19, 2024, just prior to cancellation, the warrant liability value for the warrant issued to GYBL was determined using a Monte Carlo simulation and Black-Scholes valuation model. Inputs used in the Black-Scholes valuation model included the 1,299,783 warrants issued to GYBL, the closing bid price of $2.03 per share on December 19, 2024, the four-year time to maturity, a 0% dividend yield, an annual risk-free interest rate of 4.36% for the five-year time to maturity, and an assumed annualized volatility of 100% based on comparable companies with a five-year history of stock prices.

Fair Value Option for Short-term Convertible Notes Payable

On December 20, 2024, we entered into a Standby Equity Purchase Agreement (the “SEPA”) with a certain investor. Pursuant to the SEPA, the investor will advance to the Company, subject to the satisfaction of certain conditions, a total principal amount of $15.0 million, which will be evidenced by short-term convertible notes, in three tranches. We received net proceeds of $4.3 million on December 20, 2024 from the first tranche of short-term convertible notes with $5.0 million principal (the “First Note”), and we received net proceeds of $4.4 million on December 30, 2024 from the second tranche of short-term convertible notes with $5.0 million principal (the “Second Note”). We received net proceeds of $4.4 million on June 15, 2025 from the third tranche of short-term convertible notes with $5.0 million principal (the “Third Note”). We elected to account for the short-term convertible notes under the fair value option in accordance with ASC 825-10-15-4 (“ASC 825”), and Note 5 includes further discussion of their fair values. In November 2025, these convertible notes were paid off.

Under ASC 825, the fair value option may be elected on an instrument-by-instrument basis and is irrevocable unless a new election date occurs. When the fair value option is elected for an instrument, unrealized gains and losses for

such instrument are reported in the Statements of Operations at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. These amounts are included in Other income/(expense) in the Statements of Operations.

See Notes 5 and 9 to our consolidated financial statements included elsewhere in this Annual Report for further information concerning the SEPA and the assumptions we used in in determining fair values.

SEPA Put Option Liability

The SEPA was accounted for as a liability under ASC 815 because it includes an embedded put option and an embedded forward option. The put option was recognized at inception and the forward option will be recognized upon the issuance of a notice for the sale of the Company's Common Stock. The fair value of the derivative liability related to the embedded put option was estimated at $0.5 million at inception of the agreement on December 20, 2024, and at December 31, 2024. The $0.1 million SEPA put option liability as of December 31, 2025 is recognized as a current liability on the balance sheet. The estimated issuance date fair value is presented as a single line item within other income (expense) in the accompanying statements of operations under the caption Change in fair value of SEPA put option liability.

See Notes 5 and 8 to our audited consolidated financial statements included elsewhere in this Annual Report for further information concerning the SEPA and the assumptions we used in in determining fair values.

The JOBS Act

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

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

We will remain an emerging growth company until the earliest of (i) December 31, 2028, (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 was $700.0 million or more 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 non-convertible debt securities during the prior three-year period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements required by this item are attached to this Form 10-K beginning with page F-1, and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision, and with the participation, of management including our chief executive officer and chief financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e)) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Annual Report on Form 10–K. During the preparation of our consolidated financial statements for the fiscal year ended December 31, 2025, our management identified a material weakness in our internal control over financial reporting due to a lack of segregation of duties. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Specifically, our management identified a material weakness in our internal controls within the financial reporting function that resulted from an ineffective design and implementation of controls over proper segregation of duties for the period of time covered by our consolidated financial statements prior to our Chief Financial Officer joining us in June 2025 when all financial functions were handled by a single individual, and afterward, through December 31, 2025, due to a limited number of individuals. Based upon such evaluation, and due to the material weakness identified, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were not effective.

Remediation Plan for Material Weakness

With the addition of our Chief Financial Officer in June 2025, we continue to make valuable changes to our accounting and financial reporting processes and internal controls. The Company's plan is to add additional accounting staff, strengthen segregation of duties, and implement initiatives to improve our internal controls over financial reporting as we grow.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management used the Committee of Sponsoring Organizations of the Treadway Commission Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, and has concluded that as of such date, our internal control over financial reporting was not effective due to the material weakness identified.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission applicable to emerging growth companies that permit us to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

There has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the year ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures and our internal control over financial reporting are designed to provide reasonable, not absolute, assurance that the objectives of the control system are met. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Item 9B. Other Information

(a) Not applicable

(b) Director and Officer Trading Plans and Arrangements

None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this Item is incorporated herein by reference to information in the proxy statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates, or the 2026 Proxy Statement, including under the headings "Proposal 1. Election of Directors - Information Regarding Director Nominees and Continuing Directors," "Executive Officers," "Corporate Governance" and "Delinquent Section 16(a) Reports." We have adopted a Code of Ethics and Business Conduct that applies to all of our directors, officers, and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Ethics and Business Conduct is posted on our website located at https://ir.fibrobiologics.com under "Governance." We intend to disclose future amendments to certain provisions of the Code of Ethics and Business Conduct, and waivers of the Code of Ethics and Business Conduct granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers, and employees that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards. Our insider trading policy states, among other things, that our directors, officers, and employees are prohibited from trading in such securities while in possession of material, nonpublic information. The foregoing summary of our insider trading policies and

procedures does not purport to be complete and is qualified by reference to our insider trading policy filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to information in the 2026 Proxy Statement, including under the headings "Executive and Director Compensation" and "Corporate Governance."

Item 12. Security Ownership of Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference to information in the 2026 Proxy Statement, including under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information."

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated herein by reference to information in the 2026 Proxy Statement, including under the headings "Related Person Transactions" and "Corporate Governance."

Item 14. Principal Accountant Fees and Services

Our independent public accounting firm is WithumSmith+Brown, PC, East Brunswick, New Jersey, PCAOB Auditor ID 100.

The information required by this Item is incorporated herein by reference to information in the 2025 Proxy Statement, including under the heading "Proposal 2 - Ratification of Appointment of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statements and Financial Statement Schedules

The consolidated financial statements filed as part of this Annual Report on Form 10-K are listed in the Index to Financial Statements (see page F-1). Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the consolidated financial statements or notes thereto. The Exhibits are listed in the Exhibit Index below.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-41934	3.1	August 28, 2024
3.2	Amendment to Amended and Restated Certificate of Incorporation of FibroBiologics, Inc.	8-K	001-41934	3.1	June 13, 2025
3.3	Amended and Restated Bylaws of the Registrant	8-K	001-41934	3.1	June 27, 2024
4.1	Reference is made to exhibits 3.1 through 3.3.				

4.2	Description of our Securities				
4.3	Form of Warrant issued to Series B-1 Holders.	S-1	333-278938	4.3	April 26, 2024
4.4	Form of Common Stock Purchase Warrant issued November 19, 2025.	8-K	001-41934	10.2	November 19, 2025
4.5	Form of Pre-Funded Common Stock Purchase Warrant issued November 19, 2025.	8-K	001-41934	10.3	November 19, 2025
4.6	Form of Common Stock Purchase Warrant issued November 25, 2025.	8-K	001-41934	4.1	November 25, 2025
4.7	Form of Placement Agent Warrant issued November 25, 2025.	8-K	001-41934	4.2	November 25, 2025
4.8	Form of Common Stock Purchase Warrant issued December 16, 2025.	8-K	001-41934	4.1	December 16, 2025
4.9	Form of Placement Agent Warrant issued December 16, 2025.	8-K	001-41934	4.2	December 16, 2025
10.1	Intellectual Property Cross-License Agreement dated as of May 17, 2021, between SpinalCyte LLC and FibroBiologics, LLC.	S-1/A	333-275361	10.1	December 4, 2023
10.2	Amendment 1 to the Intellectual Property Cross-License Agreement between SpinalCyte LLC and FibroBiologics, Inc., effective as of May 17, 2021.	10-Q	001-41934	10.1	August 7, 2024
10.3	Patent Assignment Agreement dated May 17, 2021, between SpinalCyte LLC and FibroBiologics, LLC.	S-1/A	333-275361	10.2	November 30, 2023
10.4	Amendment 1 to the Patent Assignment Agreement, effective August 2, 2022.	S-1/A	333-275361	10.18	November 30, 2023
10.5	Amendment 2 to the Patent Assignment Agreement between SpinalCyte LLC and FibroBiologics, Inc., effective as of May 17, 2021.	10-Q	001-41934	10.2	August 7, 2024
10.6	IP Transfer Agreement between SpinalCyte, LLC and FibroBiologics, LLC, dated as of May 17, 2021.	S-1/A	333-275361	10.17	November 30, 2023
10.7	Agreement Regarding Right of First Negotiation dated January 20, 2023.	S-1/A	333-275361	10.19	November 30, 2023
10.8	Sublease Agreement between United Fire & Casualty Company and FibroBiologics, Inc., effective October 5, 2022.	S-1/A	333-275361	10.6	December 4, 2023
10.9#	2022 Stock Plan.	S-1/A	333-275361	10.12	November 30, 2023
10.10#	Form of Stock Option Notice and Grant Agreement.	S-1/A	333-275361	10.20	December 4, 2023

10.11#	Employment Agreement effective from December 1, 2023, between FibroBiologics, Inc. and Pete O'Heeron.	S-1/A	333-275361	10.22	December 4, 2023
10.12#	Employment Agreement effective from July 20, 2021, between FibroBiologics, LLC and Hamid Khoja.	S-1/A	333-275361	10.13	December 4, 2023
10.13#	Employment Agreement effective from May 31, 2022, between FibroBiologics, Inc. and Jason D. Davis.	8-K	001-41934	10.1	June 9, 2025
10.14#	Employment Agreement effective from March 1, 2024, between FibroBiologics, Inc. and Ruben Garcia.	S-1/A	333-277019	10.24	March 15, 2024
10.15#+	Offer Letter, dated October 29, 2024, between FibroBiologics, Inc. and Robert E. Hoffman	S-1	333-284077	10.15	December 30, 2024
10.16#	Consulting Agreement, dated May 15, 2025, between FibroBiologics, Inc. and Robert E. Hoffman.	10-Q	001-41934	10.3	July 31, 2025
10.17#	Employment Agreement effective from May 31, 2022, between FibroBiologics, Inc. and Mark Andersen.	S-1/A	333-275361	10.14	December 4, 2023
10.18#+	Separation Letter Agreement, dated October 28, 2024, between FibroBiologics, Inc. and Mark Andersen.	S-1	333-284077	10.14	December 30, 2024
10.19#	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers	S-1/A	333-275361	10.15	December 4, 2023
10.20+	Master Services Agreement, effective September 19, 2024, between FibroBiologics, Inc. and Charles River Laboratories, Inc.	8-K	001-41934	10.1	September 4, 2024
10.21	Standby Equity Purchase Agreement, dated December 20, 2024, between the Registrant and YA II PN, LTD.	8-K	001-41934	10.1	December 23, 2024
10.22	Form of Securities Purchase Agreement, dated November 18, 2025, between FibroBiologics, Inc. and the purchasers named therein.	8-K	001-41934	10.1	November 25, 2025
10.23	Form of Securities Purchase Agreement, dated November 24, 2025, between FibroBiologics, Inc. and the purchasers named therein.	8-K	001-41934	10.1	November 25, 2025
10.24	Form of Securities Purchase Agreement, dated December 14, 2025, between FibroBiologics, Inc. and the purchasers named therein.	8-K	001-41934	10.1	December 16, 2025
10.25	Form of Voting Agreement, dated December 14, 2025, entered into by each of FibroBiologics, Inc.'s Chief Executive Officer and the purchaser party to the securities purchase agreement, dated November 18, 2025, between FibroBiologics, Inc. and such purchaser.	8-K	001-41934	10.2	December 16, 2025
19.1	FibroBiologics, Inc. Insider Trading Policy	10-K	001-41934	19.1	March 31, 2025
21.1	List of subsidiaries of the registrant				

23.1	Consent of WithumSmith+Brown, PC.				
24.1	Power of Attorney (included on signature page of this report)				
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
97.1	FibroBiologics, Inc. Clawback Policy	10-K	001-41934	97.1	March 31, 2025
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document.				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).
# Indicates management contract or compensatory plan.
* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FibroBiologics, Inc.

Date: February 24, 2026

By: */s/ Pete O'Heeron*
Pete O'Heeron
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Pete O'Heeron and Jason D. Davis, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Pete O'Heeron Pete O'Heeron	Chairperson and Chief Executive Officer (Principal Executive Officer)	February 24, 2026
/s/ Jason D. Davis Jason D. Davis	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 24, 2026
/s/ Richard Cilento Richard Cilento	Director	February 24, 2026
/s/ Stacy Coen Stacy Coen	Director	February 24, 2026
/s/ Robert E. Hoffman Robert E. Hoffman	Director	February 24, 2026
/s/ Matthew Link Matthew Link	Director	February 24, 2026
/s/ Victoria Niklas Victoria Niklas, M.D.	Director	February 24, 2026

FIBROBIOLOGICS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
FibroBiologics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of FibroBiologics, Inc. (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring operating losses and negative cash flows from operating activities since inception and expects to continue incurring operating losses and negative cash flows in the future. These matters raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC.

We have served as the Company's auditor since 2022.

East Brunswick, New Jersey
February 24, 2026

PCAOB ID Number 100

FibroBiologics, Inc.
Consolidated Balance Sheets
(in thousands, except shares and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 4,894	$ 13,985
Prepaid expenses	1,455	225
Other current assets	—	18
Total current assets	6,349	14,228
Property and equipment, net	842	824
Operating lease right-of-use asset, net	2,380	1,393
Other assets	48	—
Total assets	$ 9,619	$ 16,445
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 945	$ 2,697
Operating lease liability, short-term	706	401
SEPA put option liability	108	460
Short-term convertible debt	—	9,168
Total current liabilities	1,759	12,726
Operating lease liability, long-term	1,704	984
Total liabilities	3,463	13,710
Stockholders' equity		
Preferred Stock, $0.00001 par value; 10,000,000 shares authorized as of December 31, 2025 and 2024	—	—
Preferred Stock, $0.00001 par value; 2,500 Series C Preferred shares authorized; 2,500 shares issued and outstanding as of December 31, 2025 and 2024	—	—
Voting Common Stock, $0.00001 par value; 300,000,000 shares and 100,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 66,519,722 shares and 35,085,718 shares issued and outstanding as of December 31, 2025 and 2024, respectively	1	—
Additional paid-in capital	60,319	38,253
Accumulated deficit	(54,164)	(35,518)
Total stockholders' equity	6,156	2,735
Total liabilities and stockholders' equity	$ 9,619	$ 16,445

The accompanying notes are an integral part of these Consolidated Financial Statements.

FibroBiologics, Inc.
Consolidated Statements of Operations
(in thousands, except shares and per share data)

	For the Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 7,407	$ 4,504
General, administrative and other	9,242	9,233
Total operating expenses	16,649	13,737
Loss from operations	(16,649)	(13,737)
Other income/(expense):		
Change in fair value of warrant liability	—	5,385
Change in fair value of forward contract liability	—	(417)
Change in fair value of SEPA put option liability	352	(460)
Change in fair value of convertible debt	(1,773)	232
Commitment fee expenses	—	(2,191)
Placement agent and tail fee expenses	—	(1,450)
Other income/(expense)	(619)	32
Gain on termination of warrant and commitment fee liabilities	—	1,214
Interest income	247	251
Interest expense	(204)	(20)
Total other income/(expense)	(1,997)	2,576
Net loss	$ (18,646)	$ (11,161)
Net loss per share, basic and diluted	$ (0.42)	$ (0.34)
Weighted-average shares outstanding, basic and diluted	44,660,518	32,875,075

The accompanying notes are an integral part of these Consolidated Financial Statements.

FibroBiologics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2025 and 2024
(in thousands, except shares)

	Series A Preferred Stock		Series B Preferred Stock		Series B-1 Preferred Stock		Series C Preferred Stock		Non-voting Common Stock		Voting Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance – December 31, 2023	**8,750,000**	**$ —**	4,171,445	**$ —**	**89,781**	**$ —**	**—**	**$ —**	**28,230,842**	**$ 1**	**—**	**$ —**	**$ 25,609**	**$ (24,357)**	**$ 1,253**
Issuance of Series C Preferred Stock	—	—	—	—	—	—	2,500	—	—	—	—	—	45	—	45
Conversion of Series B Preferred Stock, Series B-1 Preferred Stock and Non-voting common stock to Voting Common Stock	—	—	(4,171,445)	—	(89,781)	—	—	—	(28,230,842)	(1)	32,492,068	—	1	—	—
Cancellation of Series A Preferred Stock upon Direct Listing	(8,750,000)	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Sale of Voting Common Stock	—	—	—	—	—	—	—	—	—	—	1,441,576	—	7,924	—	7,924
Issuance of Voting Common Stock to terminate Share Subscription Agreement	—	—	—	—	—	—	—	—	—	—	1,152,074	—	2,500	—	2,500
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	2,174	—	2,174
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(11,161)	(11,161)
Balance – December 31, 2024	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**35,085,718**	**$ —**	**$ 38,253**	**$ (35,518)**	**$ 2,735**
Issuance of Voting Common Stock for commitment fee payable	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	118,991	$ —	$ 250	$ —	$ 250
Conversion of Short-term convertible debt into Voting Common Stock	—	—	—	—	—	—	—	—	—	—	18,070,124	—	12,541	—	12,541
Issuance of Voting Common Stock for Registered Direct Offerings											13,244,889	1	6,589	—	6,590
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	2,686	—	2,686
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,646)	(18,646)
Balance – December 31, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**66,519,722**	**$ 1**	**$ 60,319**	**$ (54,164)**	**$ 6,156**

The accompanying notes are an integral part of these Consolidated Financial Statements.

FibroBiologics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	For the Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (18,646)	$ (11,161)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	(5,385)
Change in fair value of forward contract liability	—	417
Change in fair value of SEPA put option liability	(352)	460
Change in fair value of convertible debt	1,773	(232)
Commitment fee expense	—	1,863
Gain on termination of warrant and commitment fee liabilities	—	(1,214)
Non-cash discount on convertible debt	625	—
Stock-based compensation expense	2,686	2,219
Amortization of operating lease right-of-use asset	588	416
Depreciation expense	244	157
Changes in operating assets and liabilities:		
Prepaid expenses	(1,230)	(189)
Accounts payable and accrued expenses	(1,502)	1,253
Other current assets	18	(2)
Other assets	(48)	—
Payable to Parent	—	(141)
Operating lease liability	(550)	(362)
Net cash used in operating activities	(16,394)	(11,901)
Cash flows from investing activities		
Purchases of property and equipment	(262)	(184)
Net cash used in investing activities	(262)	(184)
Cash flows from financing activities		
Proceeds from short-term convertible debt	4,375	9,400
Proceeds from short-term borrowings	—	574
Repayments of short-term borrowing	—	(574)
Repayments of short-term convertible debt	(3,400)	—
Proceeds from issuance of common stock, net of direct costs	6,590	7,507
Net cash provided by financing activities	7,565	16,907
Net decrease in cash and cash equivalents	(9,091)	4,822
Cash and cash equivalents, beginning of year	13,985	9,163
Cash and cash equivalents, end of year	$ 4,894	$ 13,985
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 204	$ 20
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of forward contract liability for sale of shares to GEM pursuant to Draw Down and Closing Notices	$ —	$ 417
Issuance of Voting Common Stock to terminate Share Subscription Agreement	$ —	$ 2,500
Additions to accounts payable and accrued expenses for purchases of property and equipment	$ —	$ 17
Right-of-use asset obtained in exchange for operating lease liability	$ 1,575	$ —
Issuance of Voting Common Stock for commitment fee payable	$ 250	$ —
Conversion of Short-term convertible debt into shares of common stock	$ 12,541	$ —

The accompanying notes are an integral part of these Consolidated Financial Statements.

FibroBiologics, Inc.
Notes to the Consolidated Financial Statements
December 31, 2025

1. Organization, Description of Business, and Liquidity

Organization and Business

FibroBiologics, Inc. (the "Company" or "FibroBiologics") was originally formed as a limited liability company under the laws of the State of Texas on April 8, 2021 ("Inception") and then converted to a Delaware corporation on December 14, 2021. FibroBiologics is an early stage, cell therapy company headquartered in Houston, Texas, developing innovative treatments for chronic diseases using fibroblast cells. The Company's primary focus is the initiation and progression of preclinical studies and clinical-stage U.S. Food and Drug Administration trials related to fibroblast treatments for wound healing, multiple sclerosis, degenerative disc disease, psoriasis and certain cancers, and potential human longevity applications including thymic involution reversal. Prior to Inception, preclinical research and development related to these disease pathways took place under the parent company, SpinalCyte, LLC (the "Parent").

Direct Listing

On January 31, 2024, the Company completed a direct listing of its common stock on Nasdaq (the "Direct Listing"). Upon completion of the Direct Listing, all outstanding shares of the Company's Non-voting Common Stock, Series B Preferred Stock, and Series B-1 Preferred Stock automatically converted into shares of Voting Common Stock on a one-for-one basis, and all outstanding shares of the Company's Series A Preferred Stock were canceled for no consideration.

Formation of Wholly-Owned Subsidiary

On June 12, 2025, the Company formed a wholly-owned subsidiary, FibroBiologics Australia Pty Ltd. This entity will act as the local sponsor for the Company's twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia.

Going Concern and Management's Plan

The Company has incurred operating losses since Inception and expects such losses to continue in the future as it builds infrastructure, develops intellectual property, and conducts research and development activities. The Company has primarily relied on a combination of angel investors, private debt placements, convertible debt issuances, and sales of equity to funds its operations. As of December 31, 2025, the Company had an accumulated deficit of $54.2 million and cash and cash equivalents of $4.9 million. A transition to profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support the Company's cost structure. The Company currently does not generate revenues and may never achieve profitability. Unless and until such time that revenue and net income are generated, the Company will need to continue to raise additional capital. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the consolidated financial statements. While management has implemented plans to obtain additional funding, these plans are not sufficient to alleviate the substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company's ability to raise additional capital. The consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Segments

The Company adopted Accounting Standard Update ("ASU") 2023-07, *Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures*, as of January 1, 2024.

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the chief operating decision maker ("CODM") in making decisions

regarding resource allocation and assessing performance. The Company is a clinical-stage cell therapy company with a limited number of employees working on fibroblast-based targets. The Company's operations are organized and reported as a single reportable segment, which includes all activities related to the discovery, development, and commercialization of its products. The Company's CODM, its chief executive officer, reviews operating results on an aggregate basis and manages the operations as a single operating segment.

The accounting policies of the Company's single operating and reportable segment are the same as those described in the summary of significant accounting policies. The measure of segment assets is reported on the balance sheets as total assets. The CODM evaluates performance and allocates resources based on net income (loss) that also is reported on the statements of operations as net loss, and cash used in operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's statement of operations, and expenses are not regularly provided to or reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources. Other segment items included in net loss primarily include changes in the fair value of the Company's financial instruments and other income and expenses.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding annual financial reporting.

Principles of Consolidation

The accompanying consolidated financial statements, which include the accounts of the Company and its wholly-owned subsidiary, FibroBiologics Australia Pty Ltd., have been prepared in accordance with GAAP. All intercompany balances and transactions are eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. These estimates are based on information available as of the date of the consolidated financial statements; therefore, actual results could differ from those estimates and assumptions. The most significant estimates include the SEPA put option liability, fair value of the short-term convertible note payable, and stock-based compensation.

Fair Value Option of Accounting

The Company has elected the option under ASC 825-10, F*inancial Instruments* ("ASC 825"), to measure its Short-term convertible notes payable issued pursuant to a Standby Equity Purchase Agreement (see Note 8) at fair value. The fair value option may be elected on an instrument-by-instrument basis and is irrevocable unless a new election date occurs. When the fair value option is elected for an instrument, unrealized gains and losses for such instrument are reported in the Statements of Operations at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. These amounts are included in Other income/(expense) in the Statements of Operations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company has significant cash balances at financial institutions, which, throughout the year, regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations and cash flows.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the timing of, and the Company's ability to advance its current and future product candidates into and through clinical development; costs and timelines associated with the manufacture of clinical supplies of the Company's product candidates; regulatory approval and market acceptance of its product candidates; performance of third-party contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"); competition from pharmaceutical companies with greater financial resources or expertise; protection of the intellectual property, litigation or claims against the Company based on intellectual property, or other factors; the need to obtain additional funding; and its ability to attract and retain employees necessary to support its growth. Disruption from the operations of CROs, CMOs or suppliers would likely have a negative impact on the Company's business, financial position, and results of operations.

Cash and Cash Equivalents

Cash and cash equivalents consist of unrestricted cash balances and short-term, liquid investments with an original maturity date of three months or less at the time of purchase. The Company had $4.9 million and $14.0 million of cash equivalents as of December 31, 2025 and 2024, respectively.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years, and includes laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives of five years. Depreciation expense is classified in either research and development expense or in general and administrative expense, depending upon the nature of the asset, in the accompanying Statements of Operations. When property and equipment assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the balance sheets and the resulting gain or loss is recorded in other income (loss) in the period realized. Maintenance and repairs are expensed as incurred.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. There were no such losses for the years ended December 31, 2025 and 2024.

Leases

The Company determines if an arrangement is a lease at inception. An arrangement is or contains a lease if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If a lease is identified, classification is determined at lease commencement. Operating lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The Company's leases do not provide an implicit interest rate and therefore the Company estimates its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the interest rate that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment over a similar term. Operating lease right-of-use ("ROU") assets are based on the corresponding lease liability adjusted for any lease payments made at or before commencement, initial direct costs, and lease incentives. Renewals or early terminations are not accounted for unless the Company is reasonably certain to exercise these options. Operating lease expense is recognized and the ROU asset is amortized on a straight-line basis over the lease term.

Operating leases are included in operating lease right-of-use asset, operating lease liability, short-term, and operating lease liability, long-term on the Company's Balance Sheets.

The Company has elected in accordance with Accounting Standards Codification ("ASC") 842-20-25-2 an accounting policy to not record short-term leases, defined as those with terms of 12 months or less, on the Balance Sheets. Rent expense recorded under leases, for financial statement purposes, is recognized on a straight-line basis over the lease term based on the most recent contractual terms available.

Fair Value Measurements

ASC 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

Level 1 - Quoted market prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates, and yield curves.

Level 3 - Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

Categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Derivatives

Derivative financial instruments are recorded at fair value on the Balance Sheets. Liability classified derivatives are remeasured at their fair value at each reporting date, with decreases or increases in the fair value recognized as other gain or loss, respectively, within the Statement of Operations. Equity classified derivatives are not remeasured at each reporting date. If a liability classified derivative becomes eligible for reclassification to an equity classified derivative, any gains or losses recognized up to the point of reclassification are not reversed. If an equity classified instrument is subsequently required to be reclassified as a liability, an amount reflective of that instruments fair value would be reclassified to a liability at that time.

Research and Development

Research and development costs are charged to expense as incurred. Research and development costs consist of costs incurred in performing research and development activities, including salaries and bonuses, scientist recruiting costs, employee benefits, facilities costs, laboratory supplies, manufacturing expenses, preclinical expenses, research materials, and consulting and other contracted services. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development.

Marketing and Advertising Costs

Marketing and advertising costs to promote the company and its product candidates are expensed as incurred. Marketing and advertising costs were $0.7 million and $0.6 million for the years ended December 31, 2025 and 2024, respectively.

Patent Costs

As the Company continues to incur costs to obtain market approval of patented technology, patent costs are expensed as incurred in general, administrative and other expense in the Statements of Operations. Costs include fees to renew or extend the term of recognized intangible assets, patent defense costs, and patent application costs. Management will continue to expense such costs until market approval is obtained through regulatory approval by the appropriate governing body.

Income Taxes

The Company is a C corporation, and accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized.

Under the provisions of ASC 740-10, *Income Taxes*, the Company evaluates uncertain tax positions by reviewing against applicable tax law all positions taken by the Company with respect to tax years for which the statute of limitations is still open. ASC 740-10 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. The Company recognizes interest and penalties related to the liability for unrecognized tax benefits, if any, as a component of the income tax expense line in the accompanying Statements of Operations.

Stock-Based Compensation

The Company recognizes compensation costs related to stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant and recognizes expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Forfeitures are recognized as they occur. The fair value of stock options is estimated on the date of grant using a Black-Scholes option pricing model which requires management to apply judgment and make estimates, including:

- *Fair Value of Common Stock*—The estimated fair value of our common stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management. Prior to completion of the Direct Listing in January 2024, the fair value of our common stock was based upon our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the Practice Aid). After completion of the Direct Listing, a public trading market for our common stock has been established so the fair value of our common stock is based on the closing price as reported on The Nasdaq Global Market on the date of grant.

- *Expected Term*—The expected term represents the period that a stock-based award is expected to be outstanding. The Company uses the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the option.

- *Expected Volatility*— Due to the Company's limited operating history and lack of company-specific historical and implied volatility data, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period of time commensurate with the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle, or area of specialty. The Company will continue to apply this process until sufficient historical information regarding the volatility of its own stock price becomes available.

- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

- *Expected Dividend*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Emerging Growth Company

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, an EGC can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. 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; however, the Company may adopt new or revised accounting standards early if the standard allows for early adoption.

In addition, the Company will utilize other exemptions and reduced reporting requirements provided to EGCs by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, an EGC is not required to, among other things, (i) provide an auditor's attestation report on the company's system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-EGC public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) 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 consolidated financial statements (auditor discussion and analysis), or (iv) disclose certain executive compensation-related items, such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which enhances the transparency and decision usefulness of income tax disclosures. Adjustments to the annual disclosure of income taxes include: a tabular rate reconciliation comprised of eight specific categories. Income taxes paid, disaggregated between significant federal, state, and foreign jurisdictions. Eliminating requirements to disclose the nature and estimate of reasonably possible changes to unrecognized tax benefits in the next 12 months or that an estimated range cannot be made. Adds a requirement to disclose income (or loss) from continuing operations before income tax expense (or benefit) and income tax expense (or benefit) from continuing operations disaggregated between domestic and foreign. The ASU is effective for public business entities for fiscal years beginning on or after December 15, 2024, with early adoption permitted. The amendments in ASU 2023-09 should be applied on a prospective basis. The Company adopted ASU 2023-09 on January 1, 2025 and there was no material impact to the Company's consolidated financial statements as a result of adopting ASU 2023-09.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures* (Subtopic 220-40) – *Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively to consolidated financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the consolidated financial statements. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

3. Net Loss per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

(in thousands, except share and per share amounts)	For the Year Ended December 31, 2025	2024
Numerator:		
Net loss	$ (18,646)	$ (11,161)
Denominator:		
Weighted-average number of common shares outstanding, basic and diluted	44,660,518	32,875,075
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.42)	$ (0.34)

As further described in Note 8, during the year ended December 31, 2025, the Company issued 118,991 shares of Common Stock to satisfy the $250,000 commitment fee payable, and $11,600,000 of short-term convertible notes were converted into 18,070,124 shares of Common Stock. As further described in Note 6, the Company issued 13,244,889 shares of common stock in three registered direct offerings in November 2025 and December 2025. For the years ended December 31, 2025 and 2024, the Company reported net losses and, accordingly, other than 8,570,203 pre-funded warrants which were issued during the year ended December 31, 2025, potential common shares were not included since such inclusion would have been anti-dilutive. As a result, the Company's basic and diluted net loss per share is the same in all periods presented.

The weighted average number of shares outstanding for the year ended December 31, 2024 is based upon the non-voting common stock shares issued on August 18, 2022, the conversion of all outstanding shares of non-voting common stock, Series B Preferred Stock and Series B-1 Preferred Stock into voting common stock upon completion of the Direct Listing on January 31, 2024, and the issuance of 2,593,650 shares of common stock to GEM Global Yield LLC SCS, or GEM, during the year ended December 31, 2024.

4. Property and Equipment

Property and equipment, net consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Laboratory equipment	$ 1,198	$ 981
Computer equipment, software, and other	92	47
Total property and equipment at cost	1,290	1,028
Less: Accumulated depreciation	(448)	(204)
Property and equipment, net	$ 842	$ 824

The useful life of Laboratory equipment is five years, and the useful life of Computer equipment, software, and other is three years, for deprecation. Depreciation expense was $0.2 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

5. Fair Value of Financial Instruments

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy:

(in thousands)	Fair Value Measurement as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 2,860	$ —	$ —	$ 2,860
Total assets fair value	$ 2,860	$ —	$ —	$ 2,860
Liabilities:				
SEPA put option liability	$ —	$ —	$ 108	$ 108
Total liabilities fair value	$ —	$ —	$ 108	$ 108

(in thousands)	Fair Value Measurement as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 13,501	$ —	$ —	$ 13,501
Total assets fair value	$ 13,501	$ —	$ —	$ 13,501
Liabilities:				
SEPA put option liability	$ —	$ —	$ 460	$ 460
Short-term convertible debt	—	—	9,168	9,168
Total liabilities fair value	$ —	$ —	$ 9,628	$ 9,628

The following table summarizes the activity related to Level 3 financial liabilities for the year ended December 31, 2025:

(in thousands)	Short-term Convertible Debt	SEPA Put Option Liability
Fair value at December 31, 2024	$ 9,168	$ 460
Addition of short-term convertible debt	5,000	—
Repayment of short-term convertible debt	(3,604)	—
Conversions of convertible debt into shares of stock	(12,337)	—
Change in fair value of SEPA put option liability	—	(352)
Change in fair value of convertible debt	1,773	—
Fair value at December 31, 2025	$ —	$ 108

The following table summarizes the activity related to Level 3 financial liabilities for the year ended December 31, 2024:

(in thousands)	Liability Instrument	Forward Contract Liability	Warrant Liability	Short-term Convertible Debt	SEPA Put Option Liability
Fair value at December 31, 2023	$ 7,236	$ —	$ —	$ —	$ —
Bifurcation of the liability instrument upon Direct Listing	(7,236)	—	7,236	—	—
Increase in Warrant liability at issuance January 31, 2024	—	—	23,578	—	—
Change in fair value of Warrant liability	—	—	(28,963)	—	—
Termination of Warrant liability on December 19, 2024	—	—	(1,851)	—	—
Fair value of SEPA put option liability at issuance on December 20, 2024	—	—	—	—	460
Fair value of convertible debt at issuance in December 2024	—	—	—	9,288	—
Change in fair value of convertible debt	—	—	—	(120)	—
Fair value at December 31, 2024	$ —	$ —	$ —	$ 9,168	$ 460

As further described in Note 8, the Company issued short-term convertible debt on December 20, 2024 and December 30, 2024 with a total principal balance of $10.0 million and recorded those notes at their initial fair values totaling $9.3 million. On June 16, 2025, the Company issued short-term convertible debt with a principal balance of $5.0 million and recorded those notes at their initial fair value of $4.5 million. In November 2025, the Company repaid the outstanding balance of the convertible notes which was $3.4 million. In connection with this payoff, the Company also paid a premium of $0.2 million which is recorded in interest expense and a $0.7 million loss on the fair value valuation. The total of the fair values of these notes at December 31, 2025 and 2024 was $0 and $9.2 million, respectively. The fair values of these notes were determined using a Monte Carlo simulation valuation model. Assumptions used in the valuation models at issuance on December 20, 2024 and December 30, 2024 included the closing bid price of $2.25 and $2.24, respectively, a term of one year, an annual risk-free rate of 4.2% and 4.1%, respectively, and a volatility of 60%. Assumptions used in the valuation models at issuance on June 16, 2025 included the closing bid price of $0.80, a term of one year, an annual risk-free rate of 4.3%, and a volatility of 60%.

As further described in Note 8, the Company entered into the SEPA on December 20, 2024 and recorded a put option liability for the Company's right, subject to the satisfaction of the conditions to the investor's purchase obligations set forth therein, to require the investor to purchase up to an additional $10.0 million of shares of Common Stock by delivering written notice to the investor. As of December 20, 2024 and December 31, 2024, the fair value of the SEPA put option liability was $0.5 million and $0.5 million, respectively. The fair value of this SEPA put option liability was determined using a Monte Carlo simulation valuation model. For the valuations on December 20, 2024 and December 31, 2024, inputs used in the model included a stock price of $2.25 per share, a 96% purchase price, Company advance notice date of January 1, 2026, expected settlement date of January 4, 2026, expected advance amount of $5,000 thousand, a simulation term of 1.04 years, volatility of 120%, and a 4.23% risk-free rate. As of June 16, 2025, the fair value of the SEPA put option liability was $0.5 million. The fair value of this SEPA put option liability was determined using a Monte Carlo simulation valuation model. For the valuation on December 31, 2025, inputs used in the model included a stock price of $0.22 per share, a 96% purchase price, Company advance notice date of February 14, 2026, expected settlement date of February 17, 2026, expected advance amount of $1.2 million, a simulation term of 0.13 years, volatility of 107%, and a 3.69% risk-free rate.

The carrying amounts of cash, prepaid expenses, other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

There were no transfers in or out of Level 1, Level 2 or Level 3 assets and liabilities for the years ended December 31, 2025 and 2024.

6. Stockholders' Equity/(Deficit)

Authorized Capital

As of December 31, 2025, the Company authorized 300,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, of which 2,500 were shares of Series C preferred stock. As of December 31, 2024, the Company had authorized 100,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, of which 2,500 were shares of Series C preferred stock.

In January 2024, the Company issued 2,500 shares of Series C Preferred Stock to its chief executive officer, who in turn granted a proxy to the Board of Directors to vote these shares as outlined in the amended and restated certification of incorporation.

On January 31, 2024, the Company completed its Direct Listing, which qualified as an IPO transaction pursuant to the Company's Amended and Restated Certificate of Incorporation. As a result of the Direct Listing, the outstanding shares of Series A Preferred Stock were canceled for no consideration and the outstanding shares of Series B Preferred Stock, Series B-1 Preferred Stock, and non-voting Common Stock were all converted 1:1 into shares of voting Common Stock. In addition, the Series C Preferred Stock voting rights increased from none to 13,000 votes per share and, if transferred, these shares will automatically convert 1:1 into Common Stock.

In August 2024, the Company amended and restated its certificate of incorporation with the State of Delaware to eliminate its non-voting Common Stock, Series A Preferred Stock, Series B Preferred Stock, and Series B-1 Preferred Stock, and to reduce to 10,000,000 shares its authorized preferred stock, par value $0.00001 per share, of which 2,500 shares are designated as Series C Preferred Stock.

In June 2025, the Company amended and restated its certificate of incorporation with the State of Delaware to increase its authorized Common Stock, par value $0.00001 per share, from 100,000,000 shares to 300,000,000 shares.

November 18, 2025 Registered Direct Offering

On November 18, 2025, the Company entered into a securities purchase agreement with a single investor, pursuant to which (i) the Company agreed to issue and sell to the investor, in a registered direct offering, 3,540,000 shares of the Company's common stock, $0.00001 par value per share and pre-funded warrants to purchase up to an aggregate of 8,570,203 shares of Common Stock. The price of each share of common stock in the registered direct offering was $0.3303 per share and the price of each pre-funded warrant was $0.33029.

Additionally, pursuant to the purchase agreement, the Company issued and sold to the investor, in a concurrent private placement, warrants to purchase one share of its common stock for each share of common stock or pre-funded warrant purchased in the registered direct offering, for an aggregate of 12,110,203 shares of Common Stock. The warrants are subject to stockholder approval. The exercise price of the warrants is $0.3303 per share.

The purchase price for the shares of common stock or pre-funded warrants were not in cash but with sovereign-issued 983 gold coins, with .9999 purity, valued at $4,069.18 per oz. based on the spot price of gold at the time of signing of the securities purchase agreement, delivered to the Company's depository. The Company liquidated the gold into cash on November 20, 2025.

The gross proceeds to the Company from the registered direct offering were approximately $4.0 million, before deducting offering expenses payable by the Company.

On January 14, 2026, the investor exercised 1,075,000 pre-funded warrants for $17.50.

November 25, 2025 Registered Direct Offering

On November 24, 2025, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which (i) the Company agreed to issue and sell to the institutional investors, in a registered direct offering, 4,477,614 shares of the Company's common stock, $0.00001 par value per share. The price of each share of the Company's common stock in the Registered Direct Offering was $0.335.

Additionally, pursuant to the securities purchase agreement, the Company issued and sold to the institutional investors,

in a concurrent private placement, warrants to purchase one share of its Common Stock for each share of Common Stock purchased in the registered direct offering for an aggregate of 4,477,614 shares of Common Stock. The exercisability of the warrants is subject to stockholder approval as described below. The exercise price of the warrants is $0.335 per share.

Additionally, the Company issued to the placement agent (or its designees) warrants to purchase 7.0% of the number of shares of Common Stock sold in this the registered direct offering, warrants to purchase up to 313,433 shares of Common Stock, at an exercise price of $0.4188 per share. The exercisability of the warrants is subject to stockholder approval.

The gross proceeds to the Company from the offerings were approximately $1.5 million, before deducting placement agent fees and offering expenses payable by the Company.

December 14, 2025 Registered Direct Offering

On November 24, 2025, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which (i) the Company agreed to issue and sell to the institutional investors, in a registered direct offering, 5,227,275 shares of the Company's common stock, $0.00001 par value per share. The price of each share of the Company's common stock in the Registered Direct Offering was $0.33.

Additionally, pursuant to the securities purchase agreement, the Company issued and sold to the institutional investors, in a concurrent private placement, warrants to purchase one share of its Common Stock for each share of Common Stock purchased in the registered direct offering for an aggregate of 5,227,275 shares of Common Stock. The exercisability of the warrants is subject to stockholder approval. The exercise price of the warrants is $0.33 per share.

Additionally, the Company issued to the placement agent (or its designees) warrants to purchase 7.0% of the number of shares of Common Stock sold in this registered direct offering, warrants to purchase up to 365,909 shares of Common Stock, at an exercise price of $0.4125 per share. The exercisability of the warrants is subject to stockholder approval.

The gross proceeds to the Company from the offerings were approximately $1.7 million, before deducting placement agent fees and offering expenses payable by the Company.

7. Share Subscription Agreement

On November 12, 2021, the Company entered into a Share Purchase Agreement with certain investors for the sale of up to $100 million of common stock (the "Aggregate Limit"). This agreement is contingent upon the Company achieving a public listing of its common stock. Major terms of the agreement include a commitment fee of 2% of the Aggregate Limit, which is due no later than one year after public listing even if no drawdowns are taken, and five-year warrants issued to the investors at the time of public listing to purchase common stock shares equal to 4% of the total equity interests of the Company at the lesser of a) the price per share at the time of the public listing or b) the quotient of $700 million divided by the total number of equity interests (fully diluted common shares). The Company may request a drawdown, or sale of common stock shares to the investors, over the five-year term of this agreement following the public listing unless terminated earlier. The amount of the drawdowns requested is limited by the trading volumes of the Company's common stock shares over the 30-day period preceding the drawdown, and the price per share is equal to 90% of the average price per share over that same period. A 1% fee must be paid to the investors if the Company is sold in a private sale transaction rather than completing a public listing of its shares.

After completion of its public listing on January 31, 2024, and during the three months ended March 31, 2024, the Company sold a total of 227,057 shares of common stock for $2.8 million of net proceeds through the Share Purchase Agreement.

Upon completion of its public listing the Company recorded a payable of $2.0 million for the commitment fee obligation due under the Share Purchase Agreement within one year, and expensed the $1.9 million remaining amount of the commitment fee at March 31, 2024.

On June 27, 2024, the Company issued 3,000,000 shares of Common Stock to facilitate a Draw Down Notice under the Share Purchase Agreement. The Company recorded upon issuance a $1.4 million fair value of the forward contract liability for its requirement to sell up to 3,000,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, the closing price per share of $4.66 on June 27, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. The fair value of the forward contract liability was remeasured to $0.6 million at July 11, 2024, upon receipt of the Closing Notice from GEM, based upon the 840,000 shares accepted, the $4.85 closing price per share, and a net purchase price per share of $4.09 after the 10% discount provided to the investor, and the forward contract liability was eliminated. GEM returned 560,000 shares to the Company, which canceled those shares, and the remaining 1,600,000 shares were retained by GEM to facilitate a subsequent Draw Down Notice.

On July 12, 2024, the Company issued a Draw Down Notice for 1,600,000 shares. The Company recorded upon issuance a $0.8 million fair value of the forward contract liability for its requirement to sell up to 1,600,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, the closing price per share of $4.74 on July 12, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. The fair value of the forward contract liability was remeasured to a $0.3 million asset at August 26, 2024, upon receipt of the Closing Notice from GEM, based upon the 100,000 shares accepted, the $1.65 closing price per share, and a net price per share of $4.51 after the 10% discount provided to the investor, and the forward contract liability was eliminated. GEM returned 500,000 shares to the Company, which canceled those shares, and the remaining 1,000,000 shares were retained by GEM to facilitate a subsequent Draw Down Notice.

On September 12, 2024, the Company issued a Draw Down Notice for 1,000,000 shares. The Company recorded upon issuance a $0.3 million fair value of the forward contract liability for its requirement to sell up to 1,000,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, a price per share of $3.25, based on the floor price of $3.25 per share because the closing price was lower than the floor price on September 12, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. Upon receipt of an initial Closing Notice from GEM on September 26, 2024, the fair value of the portion of the forward contract liability covered by the Closing Notice was remeasured to $0.1 million based upon the 258,836 shares accepted, the $3.14 price per share, and a net price per share of $2.93 after the 10% discount provided to the investor, and that portion of the forward contract liability was eliminated. The September 12, 2024, Draw Down Notice remained open for 741,164 shares. The fair value of the of the remaining portion of the forward contract liability was remeasured at September 30, 2024, based on the remaining 741,164 shares, a price per share of $3.25, based on the floor price of $3.25 per share because the closing price was lower than the floor price on September 30, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company.

On October 18, 2024, the Company received a Closing Notice from GEM for 15,683 shares and remeasured the fair value of the forward contract liability based upon the 15,683 shares accepted, the $3.23 price per share, and a net price per share of $2.91 after the 10% discount provided to the investor, and the forward contract liability was eliminated. GEM returned 700,000 shares to the Company, which canceled those shares, and the remaining 25,481 shares were retained by GEM to facilitate a subsequent Draw Down Notice.

On December 19, 2024, the Company entered into a side letter agreement to terminate this share subscription agreement, including termination of the remaining commitment fee liability and the warrant liability. The Company issued 1,152,074 shares of Common Stock, which included the remaining 25,481 shares held by GEM pursuant to the September 12, 2024 Draw Down Notice, at a fixed purchase price of $2.17 per share, for total consideration of $2.5 million for this termination and recorded a gain of $1.2 million, which is the amount by which the combined fair values of the commitment fee liability and warranty liability exceeded the fair value of the shares issued.

8. Standby Equity Purchase Agreement

On December 20, 2024, the Company entered into the Standby Equity Purchase Agreement (the "SEPA"). Pursuant to the SEPA, the investor will advance to the Company, subject to the satisfaction of certain conditions, a total principal amount of $15 million, which will be evidenced by short-term convertible notes, in three tranches. The short-term convertible notes will accrue interest on the outstanding principal balance at an annual rate equal to 0%, which will increase to an annual rate of 18% upon the occurrence of an event of default for so long as such event remains

uncured. The short-term convertible notes will mature on December 20, 2025, which may be extended at the option of the Company to January 19, 2026 by paying an extension fee of $100,000, and to February 18, 2026 by paying an additional extension fee of $100,000. The maturity date may also be extended at the option of the investor.

The Company received net proceeds of $4.3 million on December 20, 2024 from the first tranche of short-term convertible notes with $5.0 million principal (the "First Note"). The Company received net proceeds of $4.4 million on December 30, 2024 from the second tranche of short-term convertible notes with $5.0 million principal (the "Second Note"). The Company received net proceeds of $4.4 million on June 16, 2025 from the third tranche of short-term convertible notes with $5.0 million principal (the "Third Note"). The Company has elected to account for the short-term convertible notes under the fair value option in accordance with ASC 825-10-15-4, and Note 5 includes further discussion of their fair values.

The First Note is convertible at a conversion price equal to the lower of (i) $2.41 per share or (ii) 94% of the lowest daily volume-weighted average price ("VWAP") during the five consecutive trading days immediately preceding the conversion date (but no lower than the "floor price" then in effect, subject to adjustment from time to time).

The Second Note is convertible at a conversion price equal to the lower of (i) $2.84 per share or (ii) 94% of the lowest daily VWAP during the five consecutive trading days immediately preceding the conversion date (but no lower than the "floor price" then in effect, subject to adjustment from time to time).

The Third Note is convertible at a conversion price equal to the lower of (i) $0.98 per share or (ii) 94% of the lowest daily VWAP during the five consecutive trading days immediately preceding the conversion date (but no lower than the "floor price" then in effect, subject to adjustment from time to time).

Below is a summary of conversions during the year ended December 31, 2025.

Date	Tranche	Principal Amount	Shares Issued	Price Per Share
January 23, 2025	Second Note	$ 900,000	552,113	$ 1.6301
January 27, 2025	Second Note	$ 500,000	317,238	$ 1.5761
January 29, 2025	Second Note	$ 500,000	334,336	$ 1.4955
February 7, 2025	Second Note	$ 1,100,000	732,941	$ 1.5008
February 21, 2025	Second Note	$ 250,000	232,169	$ 1.0768
March 4, 2025	Second Note	$ 350,000	361,794	$ 0.9674
April 11, 2025	Second Note	$ 200,000	263,643	$ 0.7586
April 15, 2025	Second Note	$ 200,000	263,643	$ 0.7586
May 15, 2025	Second Note	$ 300,000	388,450	$ 0.7723
June 2, 2025	Second Note	$ 100,000	147,579	$ 0.6776
June 3, 2025	Second Note	$ 300,000	442,739	$ 0.6776
June 20, 2025	Second Note	$ 100,000	144,216	$ 0.6934
June 24, 2025	Second Note	$ 200,000	295,377	$ 0.6771
June 26, 2026	Third Note	$ 300,000	443,066	$ 0.6771
June 27, 2025	Third Note	$ 500,000	738,443	$ 0.6771
July 15, 2025	Third Note	$ 300,000	533,428	$ 0.5624
July 28, 2025	Third Note	$ 300,000	493,258	$ 0.6082
August 1, 2025	Third Note	$ 600,000	1,035,911	$ 0.5792
August 18, 2025	Third Note	$ 300,000	571,537	$ 0.5249
August 25, 2025	Third Note	$ 300,000	544,959	$ 0.5505
September 9, 2025	Third Note	$ 300,000	566,572	$ 0.5295
September 16, 2025	Third Note	$ 300,000	597,133	$ 0.5024
September 25, 2025	Third Note	$ 400,000	815,660	$ 0.4904
September 30, 2025	Third Note	$ 1,100,000	2,243,065	$ 0.4904
October 14, 2025	Third Note	$ 200,000	482,741	$ 0.4430
October 1, 2025	Third Note	$ 100,000	246,305	$ 0.4060
October 16, 2025	First Note	$ 200,000	492,610	$ 0.4060
October 20, 2025	First Note	$ 200,000	492,610	$ 0.4060
October 21, 2025	First Note	$ 300,000	738,916	$ 0.4060
October 27, 2025	First Note	$ 300,000	738,916	$ 0.4060
November 5, 2025	First Note	$ 300,000	855,675	$ 0.3506
November 17, 2026	First Note	$ 300,000	963,081	$ 0.3115

The Company recognized a net loss of $0.9 million during the year ended December 31, 2025 on these conversions into shares of Common Stock.

In November 2025, the Company repaid the outstanding balance of the convertible notes which was $3.4 million. In connection with this payoff, the Company also paid a premium of $0.2 million which is recorded in interest expense and a $0.7 million loss on the fair value valuation.

Pursuant to the SEPA, and subject to certain conditions, the Company will have the right, from time to time, until December 20, 2026, to require the investor to purchase up to an additional $10.0 million of shares of Common Stock by delivering written notice to the investor.

The Company paid the investor a structuring fee of $25,000, which was expensed immediately, and agreed to pay the investor a commitment fee totaling $0.3 million (the "Commitment Fee"), which was expensed immediately and included in accrued liabilities at December 31, 2024. On January 7, 2025, the Company satisfied the Commitment Fee by issuing 118,991 shares of its Common Stock to the investor at a $2.1010 price per share.

The SEPA was accounted for as a liability under ASC 815 because it includes an embedded put option and an embedded forward option. The put option was recognized at inception and the forward option will be recognized upon the issuance of a notice for the sale of the Company's Common Stock. The fair value of the derivative liability related to the embedded put option was estimated at $0.5 million at inception of the agreement on December 20, 2024, and at December 31, 2024, and at $0.1 million at December 31, 2025. The SEPA put option liability is recognized as a current

liability on the consolidated balance sheets as of December 31, 2025 and 2024, respectively. The change in estimated issuance date fair value is presented as a single line item within other income (expense) in the accompanying consolidated statements of operations under the caption, *Change in fair value of SEPA put option liability*. The embedded forward option was deemed to have no value at December 31, 2025 and 2024 because there were no notices for the sale of the Company's Common Stock as of December 31, 2025 and 2024.

9. Income Taxes

For the 2025 year, ASU 2023-09 presentation of the reconciliation of income tax expense is as follows:

	As of December 31, 2025	
	Amount	**Percent**
U.S. Federal Statutory Tax Rate	$ (4,086)	-21.0%
State and local income taxes, net of federal income tax effect	—	0.0%
Changes in valuation allowance	3,896	20.0%
Nontaxable or nondeductible items		
Share based compensation	295	1.5%
Change in fair value of nontaxable instruments	298	1.5%
Other	147	1.0%
Other adjustments		
Prior year deferred adjustments	(667)	0.0%
Other	118	0.0%
Effective tax rate	$ —	0.0%

	As of December 31, 2024	
Federal statutory rate	$ (2,247)	-21%
State income taxes, net of federal benefit	(322)	-3.0%
Change in fair value of nontaxable instruments	(1,347)	-12.6%
Return to provision adjustment	296	2.8%
Non-deductible transaction costs	877	8.2%
Non-deductible stock compensation	291	2.7%
Permanent differences	129	1.2%
Change in valuation allowance.	2,323	21.7%
Total	$ —	0.0%

The following table details the components of our deferred tax assets and liabilities:

(in thousands of dollars)	As of December 31, Percent	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 7,483	$ 3,613
Capitalized research and development	1,108	1,273
Lease liability	506	291
Accrued liabilities	174	221
Stock compensation	473	279
Gross Deferred tax assets	9,744	5,677
Valuation allowance	(9,232)	(5,258)
Deferred tax assets, net of valuation allowance	512	419
Deferred tax liabilities:		
Lease right-of-use asset	(500)	(292)
Fixed assets	(12)	(127)
Gross Deferred tax liabilities	(512)	(419)
Net deferred tax assets	$ —	$ —

As a result of generating net operating losses during the years ended December 31, 2025 and 2024, the Company had no income tax expense for years ended December 31, 2025 and 2024. As of December 31, 2025, the Company had U.S. federal net operating loss ("NOL") carryforwards of $33.7 million and state NOL carryforwards of $4.5 million. The federal NOL carries forward indefinitely and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest. Section 382 of the Internal Revenue Code ("IRC") imposes limits on the ability to use NOL carryforwards that existed prior to a change in control to offset future taxable income. Such limitations would reduce, potentially significantly, the gross deferred tax assets disclosed in the table above related to the NOL carryforwards. The Company continues to disclose the NOL carryforwards at their original amount in the table above as no potential limitation has been quantified. The Company has also established a full valuation allowance for all deferred tax assets,including the NOL carryforwards, since the Company could not conclude that it was more likely than not able to generate future taxable income to realize these assets.

Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance at December 31, 2025 and 2024. The Company will continue to assess the realizability of its deferred tax assets going forward and will adjust the valuation allowance as needed.

As of December 31, 2025 and 2024, the Company had no uncertain tax positions. The Company recognizes both interest and penalties associated with unrecognized tax benefits as a component of income tax expense. The Company has not recorded any interest or penalties for unrecognized tax benefits since its inception, and no taxes are due.

The One Big Beautiful Bill Act ("OBBBA"), which was signed into law on July 4, 2025, extends and modifies certain key provisions of the U.S. Tax Cuts and Jobs Act of 2017. The OBBBA change most relevant to the Company is full expensing of domestic research and experimental expenditures and bonus depreciation of qualified property. Although OBBBA allows taxpayers to immediately expense qualified personal depreciable property, the Company has not elected to deduct 100% bonus depreciation for qualified property. The Company will continue to evaluate the impacts of OBBBA when future guidance is issued.

10. Leases, Commitments and Contingencies

In October 2022, the Company entered into a lease agreement for office space with a term of 62 months, which expires on November 30, 2027. This lease will be accounted for as an operating lease under the ASC 842 guidance for lease accounting. A right-of-use lease asset and lease liability of $2.3 million each were recorded at inception of the lease term using a discount rate of 7.5%.

In June 2023, the Company entered into a new lease for temporary lab and office space for its research operations. This lease had a term of 12 months and monthly rent of $6,000 and was accounted for as a short-term lease. This lease commenced in August 2023. In September 2023, the Company entered into an amendment of this lease for additional space, and the monthly rent increased to $7,000. In March 2024, the Company entered into a second amendment of this lease for additional space, and effective April 1, 2024, the monthly rent increased to $8,000. In July 2024, the Company signed an amendment of this lease, effective August 1, 2024, to extend the term for an additional 12 months, and the monthly rent decreased to $7,000. The Company terminated this lease effective April 30, 2025.

In March 2025, the Company executed a new lease for 10,693 square feet located in Houston, Texas, to be used in its research and development efforts. This lease commenced on April 1, 2025, terminates on May 31, 2031, and specifies initial base and additional rent totaling $32,000 per month. This lease will be accounted for as an operating lease under the ASC 842 guidance for lease accounting. A right-of-use lease asset and lease liability of $1.6 million each were recorded at inception of the lease term using a discount rate of 6.38%.

Rent expense for the years ended December 31, 2025 and 2024 was $0.8 million and $0.6 million, respectively. As of December 31, 2025, noncancelable lease payments under operating leases were $2.7 million.

Maturities of operating lease liability as of December 31, 2025 were as follows:

(in thousands of dollars)		
2026	$	845
2027		849
2028		347
2029		355
2030		332
Thereafter		—
Total lease payments		2,728
Less: Imputed interest		(318)
Total lease liability		2,410
Less: Current lease liability		(706)
Total non-current lease liability	$	1,704

11. Related Party Transactions

During the years ended December 31, 2025 and 2024, the Company paid an aggregate of $66,950 and $0, respectively, to a member of its Board of Directors pursuant to a consulting agreement effective May 15, 2025. Under the terms of the agreement, the director provided strategic advisory services to the Company, including support for finance and capital raising activities. The statement of work under this agreement pursuant to which these services were provided has expired.

12. Share-Based Compensation

The Company adopted on August 10, 2022, and the stockholders approved on August 18, 2022, the 2022 Stock Plan (the “Plan”). The Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards.

As of December 31, 2025 and 2024, respectively, there were 6,783,761 and 7,934,836 shares available for future issuance under the Plan.

Stock-based compensation expense is recognized in the Statements of Operations as follows:

(in thousands of dollars)	For the Year Ended December 31, 2025	2024
Research and development	$ 418	$ 328
General and administrative	2,268	1,891
Total stock-based compensation expense	$ 2,686	$ 2,219

In addition to the $2.2 million stock-based compensation expense for stock options for the year ended December 31, 2024, a $45,000 stock-based compensation expense was recognized for the grant of 2,500 shares of Series C Preferred Stock to the CEO.

Unrecognized stock-based compensation costs related to unvested awards and the weighted-average period over which the costs are expected to be recognized as of December 31, 2025, are as follows:

	Stock Options
Unrecognized stock-based compensation expense (in thousands)	$ 4,852
Expected weighted-average period compensation costs to be recognized (years)	2.2

A summary of the Company's stock option activity is as follows:

	Stock Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	4,565,164	$ 2.82	8.2	$ 7
Granted	1,391,000	$ 1.00	7.0	$ —
Exercised	—	$ —	—	$ —
Forfeited/canceled	(239,925)	$ 2.83	—	$ —
Outstanding as of December 31, 2025	5,716,239	$ 2.39	8.0	$ —
Exercisable as of December 31, 2025	2,756,930	$ 2.68	7.3	$ —

The fair value of stock options granted to employees, directors, and consultants was estimated on the date of grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

Assumptions:	Year Ended December 31, 2025	Year Ended December 31, 2024
Risk-free interest rate	4.13% - 4.25%	4.4%
Expected volatility	108% - 111%	101%
Expected term (years)	7.0	7.0
Expected dividend	0%	0%

The weighted-average grant date fair value of the options granted during the years ended December 31, 2025 and 2024 was $0.87 per share and $3.82 per share, respectively.

13. Warrants

As of December 31, 2025, the Company accounts for all issued and outstanding warrants to purchase common stock as equity-classified instruments based on the guidance in ASC 480 and ASC 815.

	Number of Warrants		Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)
Outstanding as of December 31, 2024	10,321	$	20.00	1.8
Granted	22,494,434	$	0.33	5.0
Exercised	—	$	—	—
Forfeited/canceled	—	$	—	—
Outstanding as of December 31, 2025	22,504,755	$	—	4.9
Exercisable as of December 31, 2025	22,504,755	$	0.34	0.0

In addition to the common warrants listed above, the Company had pre-funded warrants to purchase up to an aggregate of 8,570,203 shares of Common Stock outstanding at December 31, 2025.

14. Subsequent Events

Related Party Transaction

On January 14, 2026, the Company issued a $400,000 note receivable to Golden Knight Incorporated, LP (the "Note"). The Note is due on January 14, 2027 and has an interest rate of 3.63%.

On January 14, 2026, an investor exercised 1,075,000 pre-funded warrants for $17.50, and the Company issued 1,075,000 shares.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

General

The following description summarizes certain important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this section, you should refer to our amended and restated certificate of incorporation, as amended, or certificate of incorporation, and our bylaws, or bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of Delaware law.

Authorized Capital Stock

Our certificate of incorporation authorizes us to issue 310,000,000 shares of capital stock, which may consist of: (i) 300,000,000 shares of common stock, par value $0.00001 per share, and (ii) 10,000,000 shares of preferred stock, par value $0.00001 per share, of which 2,500 shares are designated as Series C Preferred Stock.

Pursuant to our certificate of incorporation, our board of directors has the authority, without stockholder approval except as required by Nasdaq rules, to issue additional shares of our capital stock.

Common Stock

Our certificate of incorporation and Delaware law, as applicable, provide that**:**

- holders of common stock have voting rights for the election and removal of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment;
- holders of common stock are entitled to one vote per share on matters to be voted on by stockholders and are also entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor;
- the payment of dividends, if any, on the common stock will be subject to the prior payment of dividends on any outstanding preferred stock;
- upon our liquidation or dissolution, the holders of common stock will be entitled to receive *pro rata* all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock outstanding at that time; and
- our stockholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the common stock.

Preferred Stock

Our certificate of incorporation provides that shares of preferred stock may be issued from time to time in one or more series. Our board of directors is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights, if any, and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our board of directors is able to, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the common stock and could have anti-takeover effects. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of our control or the removal of our existing management.

Series C Preferred Stock

There is currently one series of designated preferred stock, being the Series C Preferred Stock, 2,500 total shares of which are authorized and all of which 2,500 authorized shares of Series C Preferred Stock are issued, outstanding and held by Pete O'Heeron, our founder, Chief Executive Officer and Chairperson of our board of directors. The outstanding shares of Series C Preferred Stock are fully paid and nonassessable.

The Series C Preferred Stock rank senior to our common stock upon our liquidation, dissolution, winding up or otherwise.

The Series C Preferred Stock is entitled to vote on any matter to be voted on by our stockholders, in each case voting together with the holders of our common stock as a single class, and each share of Series C Preferred Stock is entitled to 13,000 votes. The Series C Preferred Stock is entitled to receive the same prior notice of any meeting of stockholders as provided to our common stockholders.

The Series C Preferred Stock is not entitled to any dividend, whether payable in cash, stock or property.

Subject to the superior rights of other, then outstanding, classes or series of preferred stock, in the event of any liquidation, dissolution or winding up of our company, the Series C Preferred Stock shall be entitled to receive, prior and in preference to any distribution in such liquidation, dissolution or winding up of any of our assets to the holders of our common stock, a liquidation preference of $18.00 per share (subject to appropriate adjustment in the event of any stock split, combination or other similar recapitalization).

The Series C Preferred Stock may be converted at any time as follows:

- At the option of the holder, a share of Series C Preferred Stock may be converted into one share of our common stock; and
- Upon the election of the holders of a majority of the then outstanding shares of Series C Preferred Stock, all outstanding shares of Series C Preferred Stock may be converted into an equal number of shares of our common stock, on a one-for-one basis.

In addition, the Series C Preferred Stock is subject to a mandatory conversion upon any transfer of the Series C Preferred Stock. Each share of Series C Preferred Stock shall automatically convert, without the payment of additional consideration by or to the holder thereof, into one fully paid and non-assessable share of our common stock, upon any transfer of any share of Series C Preferred Stock, whether or not for value. Any shares of Series C Preferred Stock converted as described above must be retired and cancelled and may not be reissued as shares of such series.

For as long as the Series C Preferred Stock remain outstanding, the aggregate number of shares of Series C Preferred Stock then outstanding shall be proportionately adjusted for any increase or decrease in the number of issued shares of our common stock resulting from a subdivision or combination of our common stock or other similar recapitalization, in each case effected without our receipt of consideration.

The Series C Preferred Stock is subject to an irrevocable proxy issued by Pete O'Heeron, the holder of all of the Series C Preferred Stock, in favor and for the benefit of, our board of directors, granting our board of directors the irrevocable proxy, for as long as the Series C Preferred Stock remains outstanding, to vote all of the Series C Preferred Stock on all matters on which the Series C Preferred Stock are entitled to vote, in any manner that our board of directors may determine in its sole and absolute discretion; provided, however, that such irrevocable proxy shall not, without the written consent of Pete O'Heeron, permit our board of directors to vote the Series C Preferred Stock with respect to any proposal to amend, delete or waive any rights of Pete O'Heeron with respect to the Series C Preferred Stock as set forth in our amended and restated certificate of incorporation. In light of the superior voting rights associated with the Series C Preferred Stock, the irrevocable proxy is intended to ensure that such superior voting rights are utilized in our best interest and to avoid or mitigate conflicts that may arise in the future for Pete O'Heeron as an individual stockholder employee.

Anti-Takeover Effects of our Certificate of Incorporation, Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Classified Board

Our certificate of incorporation requires our board of directors to be divided into three classes serving staggered three-year terms, with one class elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board of directors.

Stockholder Actions by Written Consent

Our certificate of incorporation requires that, any action required or permitted to be taken by our stockholders must be effected at a duly-called annual or special meeting of our stockholders and may not be effected by written consent in lieu of a meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures specify that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken, and define what is considered timely. Our bylaws specify the requirements as to form and content of all stockholder notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Director Removal and Vacancies

Our certificate of incorporation requires that a member of our board of directors, or our entire board, may only be removed for cause, and then only by the affirmative vote of the holders of at least $66^{2/3}$% in voting power of our stock entitled to vote on such removal. In addition, our certificate of incorporation requires that any newly created directorship that results from an increase in the number of directors, or any vacancy on our board of directors, must be filled solely by the affirmative vote of a majority of the total number of directors then in office, even if less than a quorum, or by a sole remaining director and may not be filled by the stockholders.

Supermajority Voting Requirements

Our certificate of incorporation requires the affirmative vote of the holders of at least $66^{2/3}$% in voting power of our stock entitled to vote thereon to (i) amend, alter or repeal our bylaws and adopt new bylaws or (ii) to amend, alter, change or repeal, or adopt any provision inconsistent with, certain provisions of our certificate of incorporation, including the provisions relating to the requirement to have a classified board, the provisions relating to the removal of directors, the provision precluding stockholder action by written consent and the choice of forum provision in our amended and restated certificate of incorporation (as explained below).

Undesignated Preferred Stock

Our certificate of incorporation provides for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our

shareholders, our board of directors could cause shares of preferred stock to be issued without shareholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent shareholder or shareholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in our control.

Exclusive Forum

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the (i) Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (c) any action arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws or (d) any action asserting a claim governed by the internal affairs doctrine and (ii) to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. The foregoing provision would not preclude stockholders that assert claims under the Exchange Act from bringing such claims in federal court, to the extent that the Exchange Act confers exclusive federal jurisdiction over such claims, subject to applicable law. Our choice of forum provision may impose additional litigation costs on stockholders in pursuing claims and may limit a stockholder's ability to bring a claim in a judicial forum that it believes to be favorable for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims.

Limitation of Liability and Indemnification of Directors and Officers

Our certificate of incorporation provides that our directors and officers will be indemnified by us to the fullest extent authorized by Delaware law.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions and insurance are necessary to attract and retain talented and experienced directors and officers. In addition, we entered into separate indemnification agreements with each of our directors and executive officers.

Section 203 of the DGCL

As a Delaware corporation, we are subject to the provisions of Section 203 of the DGCL. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with an "interested stockholder." In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns 15% or more of the outstanding voting stock of the corporation.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 of the DGCL do not apply if:

- the business combination takes place more than three years after the interested stockholder became an "interested stockholder;"

- our board of directors approves the transaction that made the stockholder an "interested stockholder" prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "FBLG".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer LLC. The transfer agent and registrar's address is 18 Lafayette Place, Woodmere, NY 11598. The transfer agent and registrar can be contacted by phone at: (212) 828-8436.

Exhibit 21.1

List of Subsidiaries of the Registrant

Subsidiary	Place of Incorporation
FibroBiologics Australia Pty Ltd.	Australia

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-280303, File No. 333-284077, and File No. 333-292407), Form S-3 (File No. 333-284663), and Form S-8 (File No. 333-279421) of FibroBiologics, Inc. of our report dated February 24, 2026, (which includes an explanatory paragraph relating to FibroBiologics, Inc.'s ability to continue as a going concern) relating to the consolidated financial statements of FibroBiologics, Inc. as of and for the years ended December 31, 2025 and 2024, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
February 24, 2026

Exhibit 31.1

CERTIFICATION

I, Pete O'Heeron, certify that:

1. I have reviewed this Annual Report on Form 10-K of FibroBiologics, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2026

/s/ Pete O'Heeron

Pete O'Heeron
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Jason D. Davis, certify that:

1. I have reviewed this Annual Report on Form 10-K of FibroBiologics, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2026

/s/ Jason D. Davis

Jason D. Davis
Chief Financial Officer
Principal Financial Officer

Exhibit 32.1

STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Annual Report of FibroBiologics, Inc. (the "Company"), on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Pete O'Heeron, Chief Executive Officer of the Company, and Jason D. Davis Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Pete O'Heeron
Pete O'Heeron
Chief Executive Officer

/s/ Jason D. Davis
Jason D. Davis
Chief Financial Officer

Date: February 24, 2026