As filed with the Securities and Exchange Commission on May 15, 2024.

Registration No. 333-278938

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

Amendment No. 1 to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**86-3329066**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number*)*

455 E. Medical Center Blvd.
Suite 300
Houston, Texas 77598
(281) 671-5150
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Pete O'Heeron
Chief Executive Officer
FibroBiologics, Inc.
455 E. Medical Center Blvd.
Suite 300
Houston, Texas 77598
(281) 671-5150
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Norton Rose Fulbright US LLP	**General Counsel**	**Thompson Hine LLP**
1301 McKinney Street	**FibroBiologics, Inc.**	**300 Madison Avenue**
Suite 5100	**455 E. Medical Center Blvd.**	**27th Floor**
Houston, Texas 77010	**Suite 300**	**New York, New York 10017**
(713) 651-5151	**Houston, Texas 77598**	**(212) 344-5680**
	(281) 671-5150	

Approximate date of commencement of proposed sale to the public: **As soon as practicable after this registration statement becomes effective.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 7(a)(2)(B) of the Securities Act. □

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as

amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION, DATED MAY 15, 2024**

FibroBiologics, Inc.

Up to 1,801,801 Units, each consisting of
One Share of Common Stock and
One Warrant to purchase One Share of Common Stock

Up to 1,801,801 Shares of Common Stock Underlying the Warrants

We are offering on a best efforts basis up to 1,801,801 units (the "Units"), of FibroBiologics, Inc., each Unit consisting of one share of our common stock, par value $0.00001 per share (the "common stock"), and one warrant to purchase one share of common stock ("Warrant"). We have assumed a public offering price of $11.10 per Unit, which was the last reported sale price of our common stock on The Nasdaq Global Market on April 23, 2024.

Our common stock is listed on The Nasdaq Global Market ("Nasdaq") under the symbol "FBLG". There is no established public trading market for the Warrants. We do not intend to apply for listing of the Warrants on any securities exchange or recognized trading system.

The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The Warrants will have an exercise price of $11.10 (100% of the public offering price per Unit) and will be exercisable for a period of five years commencing upon issuance. The shares of common stock and the Warrants included in the Units can only be purchased together in this offering, but are immediately separable and will be issued separately. The Warrants will be exercisable, at the option of the holder, in whole or in part. Each Warrant will entitle the holder thereof to purchase one share of common stock, and the Warrants are not exercisable for a fractional share. A holder of a Warrant may not exercise any portion of a Warrant to the extent that the holder, together with its affiliates and any other person or entity acting as a group, would own more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding shares of common stock after exercise, as such ownership percentage is determined in accordance with the terms of the Warrants, except that upon notice from the holder to us, the holder may waive such limitation up to a percentage, not in excess of 9.99%. To better understand the terms of the Warrants, you should carefully read the "Description of Our Securities" section on page 83 of this prospectus.

Our founder and Chief Executive Officer, Pete O'Heeron, beneficially owns approximately 60% of the voting power of our outstanding voting securities, and we are a "controlled company" within the meaning of the listing rules of The Nasdaq Stock Market LLC. We do not intend to rely on any exemptions from the corporate governance requirements that are available to controlled companies.

The public offering price per Unit will be determined at the time of pricing and may be at a discount to the then current market price. The assumed public offering price used throughout this prospectus may not be indicative of the final offering price. The final public offering price will be determined through negotiation between us and investors based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and the general condition of the securities markets at the time of this offering.

The Units will be offered at a fixed price and are expected to be issued in a single closing. We expect this offering to be completed no later than two business days following the commencement of this offering. This offering will terminate on May 31, 2024, unless the offering is fully subscribed before that date or we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will deliver all securities to be issued in connection with this offering delivery versus payment/receipt versus payment upon receipt of investor funds received by us. Accordingly, neither we nor the placement agent have made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged Maxim Group LLC as our exclusive placement agent ("Maxim" or the "placement agent") to use its reasonable best efforts to solicit offers to purchase our securities in this offering. The placement agent is not purchasing or selling any of the securities we are offering and is not required to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering the actual public offering amount, placement agent's fee, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above and throughout this prospectus. We have agreed to pay the placement agent the placement agent fees set forth in the table below. See "Plan of Distribution" in this prospectus for more information.

	Per Unit	Total
Public offering price	$	$
Placement Agent Fees[(1)]	$	$
Proceeds, before expenses, to FibroBiologics, Inc.[(2)]	$	$

(1) We have agreed to pay to the placement agent a cash fee equal to 7.0% of the gross proceeds received by us in the offering. We have also agreed to reimburse the placement agent for certain expenses and closing costs. See "Plan of Distribution" for additional information and a description of the compensation payable to the placement agent.
(2) The amount of offering proceeds to us presented in this table does not give effect to any exercise of the Warrants.

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. See the "*Risk Factors*" section beginning on page 10 of this prospectus for the risks and uncertainties you should consider before investing in our common stock.

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

Delivery of the securities offered hereby is expected to be made on or about May , 2024, subject to satisfaction of certain customary closing conditions.

Sole Placement Agent

Maxim Group LLC

The date of this prospectus is , 2024

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You should rely only on the information contained in this prospectus or contained in any free writing prospectus filed with the Securities and Exchange Commission. Neither we nor the placement agent have authorized anyone to provide any information different from, or in addition to, the information contained in this prospectus and in any free writing prospectuses we have prepared or that have been prepared on our behalf or to which we have referred you. Neither we nor the placement agent take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, the securities only under the circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since such date.

For investors outside the United States: Neither we nor the placement agent have done anything that would permit the use of or possession or distribution of this prospectus or any related free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission, or the SEC. We may provide a prospectus supplement to add information to, or update or change information contained in, this prospectus, including the section titled "*Plan of Distribution*". You may obtain this information without charge by following the instructions under the "*Where You Can Find Additional Information*" section of this prospectus. You should read this prospectus and any prospectus supplement before deciding to invest in our securities.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or will be filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described under "*Where You Can Find Additional Information*."

PROSPECTUS SUMMARY

This summary highlights select information contained elsewhere in this prospectus and does not contain all the information you should consider before making an investment decision. You should read the entire prospectus carefully, including the sections entitled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the accompanying notes included elsewhere in, or incorporated by reference into, this prospectus before making an investment decision. Unless otherwise indicated or the context otherwise requires, all references in this prospectus to "we," "us," "our," the "Company," "FibroBiologics" and similar terms refer to FibroBiologics, Inc.

Overview

We are a clinical-stage cell therapy company focused on developing and commercializing fibroblast-based therapies for patients suffering from chronic diseases with significant unmet medical needs, including degenerative disc disease, multiple sclerosis, wound healing, and certain cancers, and for potential extension of life applications including thymic and splenic involution reversal.

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 (doing business as FibroGenesis), or FibroGenesis, in return for rights to certain intellectual property through a patent assignment agreement and an intellectual property cross-licensing 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 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, and 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 has historically been believed to produce an extracellular matrix responsible for maintaining the structural integrity of the tissue. Fibroblasts also play an important role in maintaining stem cell niches in organs and are involved in every stage of wound healing.

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 or simple biopsy punch;
- have a faster doubling time in culture than stem cells;
- possess superior immune modulatory activity compared with 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 and additives.

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*. 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. Because allogeneic fibroblasts do not cause an immune response, we are planning to build our own current Good Manufacturing Practices, or cGMP, manufacturing facility to source allogeneic fibroblast cells for clinical testing of our product candidates and for commercial sales if our product candidates receive marketing approval.

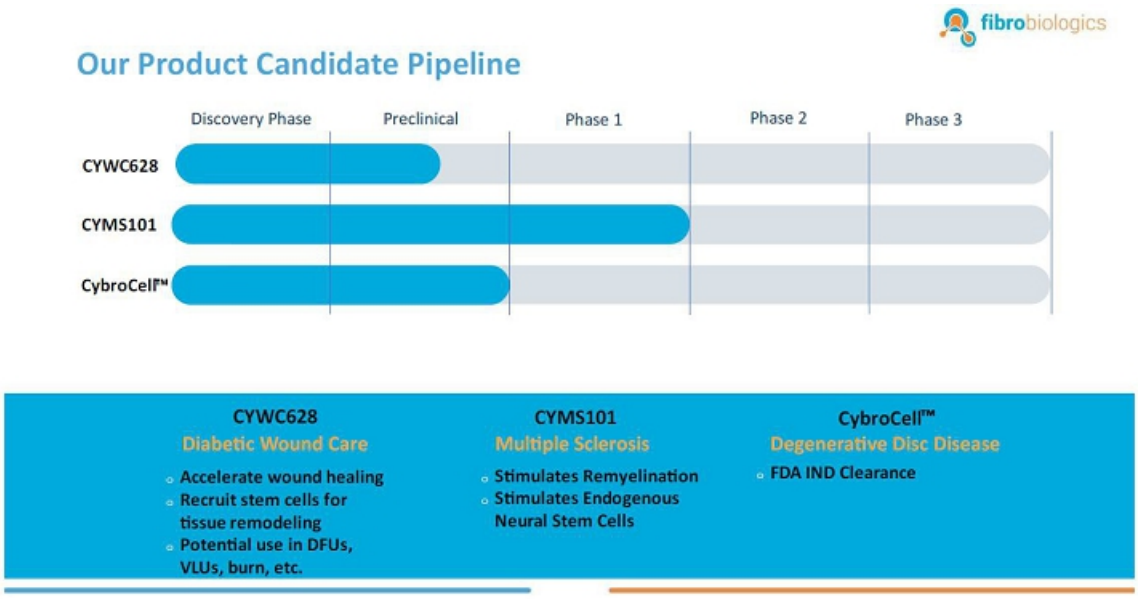
To date, however, no fibroblast therapy products have been approved and there have only been a few clinical trials involving fibroblasts. The costs to develop, manufacture, and commercialize product candidates utilizing our fibroblasts technology platform may exceed our estimates. Furthermore, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates so any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Additional information regarding risks and uncertainties relating to our product candidates technology and business are set forth in the sections titled "—*Summary of Risk Factors*" and "*Risk Factors*" in this prospectus.

Our Management Team and Oversight

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, with combined successful track records 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 relevant expertise on our scientific advisory board to help guide our research and development efforts.

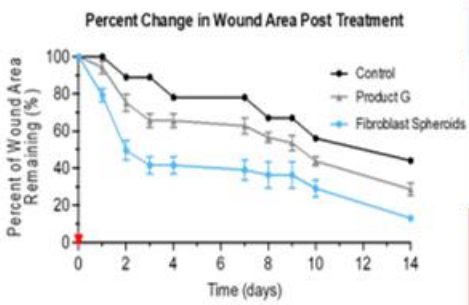
Our Current Pipeline

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



CYWC628 for Wound Healing: We are in the late pre-clinical stages of developing CYWC628 as an allogeneic fibroblast cell-based therapy for wound healing. Our studies are presently focused on utilizing fibroblasts and fibroblast-derived cells to treat wounds in diabetic mice. Our data to date is compiled from four separate animal model studies (manuscript for publication in progress). Each study utilized 16 wild type as well as leptin mutated NONcNZO10LTJ mouse that develops type 2 diabetes when fed a high fat diet. Wound size and area for all our experiments were measured using an eKare inSight™ device which is FDA approved for measuring and monitoring wound size, area and depth. Phase 1 of our pre-clinical study studied the subcutaneous and topically administered single cell mouse dermal fibroblasts (both treatments administered every two days), as well as mouse dermal fibroblast derived exosomes. The results of this study indicated significant improvement in wound healing ($p < 0.0005$) for topically administered mouse fibroblasts and mouse fibroblast exosomes as compared to untreated control, and significant improvement in wound healing with subcutaneous inject of fibroblast in the wound periphery ($p < .005$). Our Phase 2 pre-clinical study studied the impact of using frozen and thawed single cell mouse fibroblasts administered every two days, as well as mouse spheroid fibroblasts, one-time topical administration, measuring 250 um and each containing approximately 10,000 mouse dermal fibroblasts. In total 100 spheroids were topically administered on to an 8 millimeter diameter wound on the back of the wild type and leptin mutated mice. The results of the study indicated significant improvement in wound healing with the frozen thawed single cell mouse fibroblasts ($p < 0.005$), as well as 4°C stored mouse fibroblast spheroids ($p < 0.0005$) with both mouse types. Our objective was to test the feasibility of using spheroid fibroblasts as an extended-release mechanism on wound surfaces. The results indicated that spheroid fibroblasts are easier to use and more viable than single cell fibroblasts, and generate more significant results. Our Phase 3 pre-clinical study tested the effect of using a single topical administration of human dermal fibroblast (CYWC628) spheroids compared to a single administration of mouse dermal spheroids, in addition to comparing with a commercially available and FDA approved diabetic foot ulcer treatment called Grafix™. The results of our study indicated that CYWC628 significantly improved wound healing rate ($p < 0.0005$) as compared to untreated control as well as significant improvement ($p < 0.05$) over mouse fibroblast spheroids and Grafix™. For our Phase 4 pre-clinical study we studied the impact of a single topical treatment of CYWC628 spheroids and Grafix™ on a chemically induced chronic wound model often used to mimic diabetic foot ulcers in animal models. The results of our study indicated a 58.5% reduction in wound area three days after a single topical administration of CYWC628 as compared to 34.5% for Grafix™ ($p < 0.005$). The untreated saline control group had an 11% improvement in wound healing which was not statistically significant ($p < 0.06$). Our results also indicated that with multiple topical administration of CYWC628, the rate of wound closure will likely be more rapid.

The following graph and chart summarize the results of our Phase 4 pre-clinical study.



Comparison	D1	D2	D3	D4	D7	D8	D9	D10	D14
Product G vs. Control	ns	ns	ns	ns	ns	ns	ns	ns	ns
Fibroblast Spheroids vs. Control	**	****	****	****	****	****	****	***	****
Fibroblast Spheroids vs. Product G	*	****	****	***	***	**	**	*	*

- 58.5% reduction in wound size within 4 days of treatment with fibroblast spheroids
- 34.5% reduction in wound size with 4 days of treatment with Product G

Note: * indicates level of statistical significance with a p value of ≤ 0.05
** indicates level of statistical significance with a p value of ≤ 0.01
*** indicates level of statistical significance with a p value of ≤ 0.001
**** indicates level of statistical significance with a p value of ≤ 0.0001

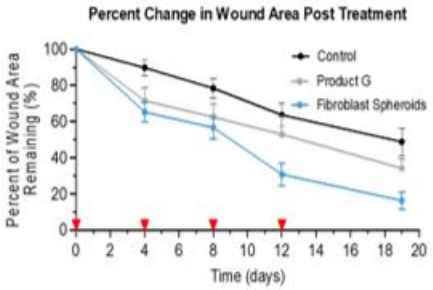
CYMS101 for Multiple Sclerosis: We are developing CYMS101 as an allogeneic fibroblast cell-based therapy to treat multiple sclerosis, or MS. After completing animal studies using CYMS101 (allogeneic fibroblast cells), we received approval from Mexico to conduct clinical investigations using the fibroblast cell composition for patients with MS and have completed a Phase 1 clinical trial called "Feasibility Study of Tolerogenic Fibroblasts in Patients with Refractory Multiple Sclerosis." 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 results of the study for safety were no adverse effects during intravenous injection of the tolerogenic fibroblasts, no short or long-impact in complete blood count test during the 16-week monitoring period, and no short or long impact in electrocardiogram results during the 16-week monitoring period. In addition, the results of the study for efficacy included general improvement of Paced Auditory Serial Addition Test, or PASAT, score for all patients during the 16-week monitoring period, general improvement of 9-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, or EDSS, test, and no patient exhibited further deterioration during the trial. We are currently conducting further research to determine the mode of action of fibroblasts in oligodendrocyte expansion and expect to file an IND application for a Phase 2 clinical trial in MS. We will likely seek a strategic partner to collaborate with us on the development of CYMS101 either before initiating the Phase 2 clinical trial, or after its completion, if successful, and prior to commencing with a Phase 3 clinical trial.

CybroCell™ for Degenerative Disc Disease: CybroCell™ is an allogeneic fibroblast cell-based therapy for degenerative disc disease This new technology 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 will prove superior to existing treatments because we expect it will be less invasive, and will regenerate the disc, restore function and reduce pain without debilitating long-term effects. We have completed two rounds of animal studies. The results from the studies were positive and resulted in "first in human" trial approval in our investigational new drug, or IND, submission to the U.S. Food and Drug Administration, or FDA. We have received IND clearance from the FDA, conditional upon approval of our master cell bank, to run a Phase 1/2 clinical trial for patients suffering from degenerative disc disease. We will be conducting this trial within the United States. A timeline will be determined through discussions with the FDA.

Business Update and Recent Developments

CYWC628 for Wound Healing: For our Phase 5 pre-clinical study, using a diabetic mouse model (BKS.Cg-Dock7m), we studied the impact of multiple administrations of CYWC628 spheroids and Grafix™ on a chemically induced chronic wound often used to mimic diabetic foot ulcers in animal models. The CYWC628 spheroids were administered on Day 0, Day 4, Day 8 and Day 12. The results of our study with this mouse model of a chronic wound indicated (i) a 34.8% reduction in wound area four days after the first administration (day 4) of CYWC628 as compared to 28.6 % for Grafix™ ($p > 0.05$), which was not statistically significant, and 10.2% for the untreated saline control group ($p < 0.05$); (ii) a 43.4% reduction in wound area four days after the second administration (day 8) of CYWC628 as compared to 37.6 % for Grafix™ ($p > 0.05$), which was not statistically significant, and 21.7% for the untreated saline control group ($p < 0.05$); (iii) a 69.3% reduction in wound area four days after the third administration (day 12) of CYWC628 as compared to 47.13% for Grafix™ ($p < 0.05$), which was statistically significant, and 36.4% for the untreated saline control group ($p < 0.05$), which was also statistically significant.; and (iv) an 83.8% reduction in wound area four days after the fourth administration (Day 19) of CYWC628 as compared to 66% for Grafix™ ($p< 0.05$), which was statistically significant, and 55.2% for the untreated saline control group ($p<0.01$), which was also statistically significant. Grafix™ results as compared to saline control were not statistically significant at any of the measured timepoints, whereas CYWC628 as compared to saline control was statistically significant at all measured timepoints.

The following graph and chart summarize the results of our Phase 5 pre-clinical study.



	1st dose	2nd dose	3rd dose	4th dose
Product G vs. Control	ns	ns	ns	ns
Fibroblast spheroids vs. Control	*	**	**	**
Fibroblast spheroids vs. Product G	ns	ns	*	*

n=10 for each cohort

At day 19: **83.8% average wound closure for fibroblast spheroids** compared with 66.0% for Product G and 51.2% for Control

Note: * indicates level of statistical significance with a p value of ≤ 0.05
** indicates level of statistical significance with a p value of ≤ 0.01

Effective wound healing is not only determined by the efficiency of wound closure, but also by the quality of the healed wound. For our multiple CYWC628 administration study, we also looked at several metrics essential to the quality of wound healing. These metrics are re-epithelialization, granulation, cell proliferation, neo-vascularization, and fibroblast recruitment. The results of the study indicated that at day 19 after the final treatment, CYWC628 had a significantly improved epithelization, granulation, cell proliferation (as measured using Ki67), neo-vascularization (as measured by CD31 and VEGF), and fibroblast recruitment (as measured by αSMA and IL-6) compared to control and Grafix™.

For our remaining pre-clinical studies, we will investigate multiple administrations of CYWC628 on a chemically induced chronic wound NONcNZO10/LtJ mouse model, complete a dose titration study to provide information on effective dose range of CYWC628, and complete an acute and chronic toxicity study. We expect to complete these studies in the 3rd quarter of 2024. Based upon our results achieved to date and the expected timing of these additional pre-clinical studies, we are planning to initiate a Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers in 2025 with results expected in the third quarter of 2025.

Manufacturing: We are planning to complete a technology transfer of our cell manufacturing processes to a contract development and manufacturing organization, or CDMO, and conduct feasibility studies for our fibroblast spheroid-based drug product, with the intent to enter into a master services agreement with that CDMO to supply drug product for clinical trials. We expect to produce a master cell bank, working cell bank, and drug product for use in clinical trials by year end 2024.

Our Competitive Strengths

Our strengths lie in our technology platform centered around the power of fibroblasts and in our experienced leadership team. Fibroblasts are the most common cell found in the human body and we believe they are more robust and potent than stem cells. Our intellectual property portfolio includes 48 issued patents and 108 pending patents for the use of fibroblasts in diverse therapeutic areas. We also have an experienced leadership team with successful track records in entrepreneurial startup companies and the life sciences industry, a board of directors with life sciences operational leadership experience, and a world-renowned scientific advisory board with relevant expertise.

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 will focus our efforts on the following strategy:

- Prioritize our initial clinical development efforts on product candidates with the combination of significant unmet treatment needs, lower risk and high market potential.

- Partner with contract 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 risk and significant unmet treatment needs as funding allows.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "*Risk Factors*" in this prospectus. These risks include, but are not limited to, the following:

- There is substantial doubt about our ability to continue as a going concern.
- The successful development of biopharmaceutical products is highly uncertain.
- We have a limited operating history and none of our current product candidates have been approved for commercial sale.
- 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.
- The regulatory approval processes of the FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable.
- 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.
- 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.
- Our refrigerated product candidates require specific storage, handling and administration at the clinical sites.
- We intend to identify and develop novel cell therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development.

- 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.
- We have limited experience in designing clinical trials.
- Our long-term prospects 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.
- 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.
- 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.
- 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.
- We are subject to risks related to our dependence on third parties (i) to conduct certain aspects of our preclinical studies and clinical trials and (ii) for certain portions of our manufacturing process.
- We are highly dependent on our Houston, Texas facility and any failure to maintain the use of this facility would have a material and adverse effect on our business.
- We are subject to extensive government regulations.
- Our business entails a significant risk of product liability.
- 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, and we are subject to various risks relating to our intellectual property.
- We may not be able to continue to meet Nasdaq's continued listing requirements.
- The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.
- We are a "controlled company" within the meaning of The Nasdaq Stock Market Rules because our insiders beneficially own more than 50% of the voting power of our outstanding voting securities.
- We have 2,500 shares of Series C Preferred Stock with super voting rights.
- We have identified a material weakness in our internal controls over financial reporting due to lack of segregation of duties.
- Our shares of common stock have a very short trading history on Nasdaq. An active trading market may not develop or continue to be liquid and the market price of our shares of common stock may be volatile.

Reverse Stock Split

On October 6, 2023, our board of directors and our stockholders each approved a 1-for-4 reverse stock split of all classes of our issued and outstanding capital stock (the "Reverse Stock Split"), and on October 31, 2023, we filed an amended and restated certificate of incorporation with the State of Delaware to immediately effect the Reverse Stock Split. All share and per share information in this prospectus have been adjusted to reflect the Reverse Stock Split, unless otherwise stated.

Implications of being a Controlled Company

Our founder and Chief Executive Officer, Pete O'Heeron, collectively beneficially owns approximately 60% of the voting power of our outstanding voting securities and we are a "controlled company" within the meaning of the listing rules of The Nasdaq Stock Market LLC.

As long as our principal shareholder owns at least 50% of the voting power of our Company, we will continue to be a "controlled company" as defined under Nasdaq Listing Rules. As a controlled company, we are permitted to rely on certain exemptions from Nasdaq's corporate governance rules, including:

- an exemption from the rule that a majority of our board of directors must be independent directors;
- an exemption from the rule that the compensation of our chief executive officer must be determined or recommended solely by independent directors; and
- an exemption from the rule that our director nominees must be selected or recommended solely by independent directors.

Although we currently do not intend to rely on the "controlled company" exemption under the Nasdaq listing rules, we could elect to rely on this exemption in the future. As a result, you may not in the future have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements.

Implications of being an emerging growth company and a smaller reporting company

We are an "emerging growth company" as defined in the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take, and intend to take, advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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 Securities Exchange Act of 1934, as amended, or 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

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.

Corporate Information

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. Our principal executive offices are located at 455 E. Medical Center Blvd., Suite 300, Houston, Texas 77598. Our telephone number is (281) 671-5150, and our website address is www.fibrobiologics.com. Information contained on or that can be accessed through our website is neither a part of nor incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

THE OFFERING

The summary below describes the principal terms of this offering.

Issuer	FibroBiologics, Inc.
Units Offered	1,801,801 Units on a best-efforts basis at an assumed offering price of $11.10 per Unit, which is equal to the closing price of our common stock on The Nasdaq Global Market on April 23, 2024. Each Unit consists of one share of our common stock and one Warrant. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of common stock and the Warrants are immediately separable and will be issued separately in this offering.
Warrants Offered	The 1,801,801 Warrants will have an exercise price of $11.10 per share of common stock (100% of the offering price per Unit), will be immediately exercisable and will expire five years from the date of issuance. The registration statement of which this prospectus forms a part also registers the shares of common stock issuable upon exercise of the Warrants. To better understand the terms of the Warrants, you should carefully read the "Description of Our Securities" section on page 83 of this prospectus. You should also review the form of Warrant, which is filed as an exhibit to the registration statement of which this prospectus forms a part.
Shares of common stock outstanding prior to the offering	32,719,125 shares
Common stock to be outstanding immediately after this offering	Up to 34,520,926 shares, assuming no exercise of the Warrants
Assumed public offering price per Unit	$11.10 per Unit
Use of Proceeds	Assuming the maximum number of Units are sold in this offering at an assumed public offering price of $11.10 per Unit, which represents the last reported sale price of our common stock on The Nasdaq Global Market on April 23, 2024, we estimate the net proceeds from this offering will be approximately $18.4 million, after deducting the placement agent discounts and commissions and estimated offering expenses payable by us. However, this is a best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds. We currently intend to use the net proceeds received from this offering for general corporate purposes, including to hire key personnel, conduct research and development, and for working capital. See "Use of Proceeds" on page 67.
Market for Common Stock and Warrants	Our common stock is listed on Nasdaq Global Market under the symbol FBLG. No public market exists for the Warrants and we do not intend to list the Warrants.
Risk Factors	Any investment in the securities offered hereby is speculative and involves a high degree of risk. You should carefully consider the information set forth under "Risk Factors" beginning on page 10 of this prospectus and elsewhere in this prospectus for a discussion of factors to consider before deciding to purchase our securities.
Lock-up Agreements	We, along with our directors and officers, have agreed with the placement agent to enter into agreements not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of ninety (90) days after this offering is completed, without the prior written consent of Maxim Group LLC. See "Shares Eligible for Future Sale" and "Plan of Distribution" for additional information.
Transfer Agent and Registrar	The transfer agent and registrar for our shares of common stock is VStock Transfer, LLC, with its business address at 18 Lafayette Place, Woodmere, NY 11598.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the Warrants being offered in this offering.

SUMMARY FINANCIAL AND OTHER DATA

The summary financial and other data set forth below should be read together with our financial statements and the related notes to those statements, as well as the "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" section incorporated by reference into this prospectus. The statements of operations and cash flows data for the years ended December 31, 2023 and 2022, have been derived from our audited financial statements incorporated by reference into this prospectus. The statements of operations and cash flows data for the three months ended March 31, 2024 and 2023, and the balance sheet data as of March 31, 2024, have been derived from our unaudited interim condensed financial statements incorporated by reference into this prospectus. The unaudited interim condensed financial statements were prepared on a basis consistent with our audited financial statements and include in management's opinion, all adjustments, consisting of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected in any future period.

All share numbers and per share amounts in the tables below have been adjusted to reflect the Reverse Stock Split.

	For the three months ended March 31,		For the years ended December 31,	
	2024	2023	2023	2022
	(unaudited, in thousands, except shares and per share data)		(in thousands, except shares and per share data)	
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 960	$ 478	$ 2,368	$ 1,147
General, administrative and other	2,490	1,787	6,521	3,320
Total operating expenses	3,450	2,265	8,889	4,467
Loss from operations	(3,450)	(2,265)	(8,889)	(4,467)
Other income/(expense):				
Change in fair value of liability instrument	(3,104)	—	(7,236)	—
Commitment fee expense	(1,941)	—	—	—
Other income/(expense)	—	(15)	(213)	—
Interest income	39	—	—	—
Interest expense	(4)	(135)	(147)	(654)
Net loss	$ (8,460)	$ (2,415)	$ (16,485)	$ (5,121)
Deemed dividend	—	(2,573)	(2,573)	—
Net loss attributable to common stockholders	$ (8,460)	$ (4,988)	$ (19,058)	$ (5,121)
Net loss per share, basic and diluted	$ (0.27)	$ (0.18)	$ (0.68)	$ (0.18)
Weighted-average shares outstanding, basic and diluted	31,133,762	28,230,842	28,230,842	28,230,842
Statements of Cash Flows Data:				
Net cash used in operating activities	$ (4,275)	$ (2,036)	$ (6,401)	$ (4,066)
Net cash used in investing activities	$ (8)	$ (56)	$ (495)	$ —
Net cash provided by financing activities	$ 3,278	$ 14,566	$ 13,793	$ 5,925

	As of March 31, 2024
	(unaudited, in thousands)
Balance Sheet Data:	
Cash and cash equivalents	$ 8,158
Working capital[1]	$ (5,063)
Total assets	$ 11,399
Total liabilities	$ 15,262
Total stockholders' equity/(deficit)	$ (3,863)

[1] We define working capital as current assets less current liabilities.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this prospectus, including our financial statements and related notes appearing elsewhere in this prospectus, before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event you could lose all or part of your investment. The risks and uncertainties described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those described below.

Risks Related to this Offering

This is a best-efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available or available on terms acceptable to us.

You will experience immediate dilution as a result of this offering and may experience additional dilution in the future.

The public offering price for the Units offered hereby will be substantially higher than the net tangible book value per share of our common stock immediately after this offering. If you purchase Units in this offering, you will incur substantial and immediate dilution in the net tangible book value of your investment. Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our common stock then outstanding. After giving effect to the sale by us of 1,801,801 Units in this offering at an assumed public offering price of $11.10 per Unit, and after deducting placement agent fees and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $10.68 per share. To the extent that options and warrants that are currently outstanding are exercised, there will be further dilution to your investment. We may also issue additional common stock, options, warrants and other securities in the future that may result in further dilution of your shares of our common stock.

Future sales of our common stock, or the perception that such sales may occur, could depress the trading price of our common stock.

After the completion of this offering, we expect to have up to 34,537,007 shares of our common stock outstanding. We and each of our officers and directors have signed lock-up agreements for a period of 90 days following the date of closing of this offering, subject to specified exceptions. See "Plan of Distribution."

The placement agent may, in its sole discretion and without notice, release all or any portion of the shares of our common stock subject to lock-up agreements. As restrictions on resale end, the market price of our common stock could drop significantly if the holders of these shares of our common stock sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our common stock or other securities.

We have broad discretion in the use of the net proceeds we receive from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

The Warrants are speculative in nature.

The Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, holders of the Warrants may exercise their right to acquire the common stock and pay an exercise price of $11.10 per share, prior to five years from the date of issuance, after which date any unexercised Warrants will expire and have no further value.

Holders of Warrants will have no rights as a common stockholder unless such holders exercise their Warrants and acquire our common stock.

Until holders of Warrants acquire shares of our common stock upon exercise of the Warrants, holders of Warrants will have no rights with respect to the shares of our common stock underlying such Warrants. Upon exercise of the Warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

There is no public market for the Warrants in this offering, which may limit your ability to resell the Warrants.

There is no established public trading market for the Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Warrants on any securities exchange or recognized trading system. As a result, the Warrants may not be widely distributed and purchasers of the Warrants may be unable to resell them or sell them only at an unfavorable price for an extended period of time, if at all.

The market price of our common stock may never exceed the exercise price of the Warrants issued in connection with this offering.

The Warrants being issued in connection with this offering become exercisable upon issuance and will expire five years from the date of issuance. The market price of our common stock may never exceed the exercise price of the Warrants prior to their date of expiration. Any warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the warrant holder.

Risks Related to Our Financial Condition and Capital Requirements

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

In connection with the preparation of our quarterly report on Form 10-Q for the quarter ended March 31, 2024, or the Quarterly 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 Quarterly Report. 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 condensed 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 condensed consolidated financial statements included in the Quarterly Report 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.

The successful development of biopharmaceutical products is highly uncertain.

Successful development of biopharmaceutical products 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 NDA preparation, discussions with the FDA, an FDA 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.

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 and 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.

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 cell therapy company with a limited operating history upon which you can evaluate our business and prospects. None of our current product candidates are approved for commercial sale and we have not generated any revenue from such product candidates. 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. In relation to our current product candidates, we have not yet demonstrated our ability to successfully complete any Phase 3 clinical trials, 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 biopharmaceutical 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 private financings. For the years ended December 31, 2023 and 2022, we incurred net losses of $16.5 million and $5.1 million, respectively. As of December 31, 2023, we had an accumulated deficit of $24.4 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates, from management and administrative costs and other expenses that we have incurred while building our business infrastructure, and from a loss due to the change in fair value of liability instrument. 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 lead 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.

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 drug 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 develop. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2023, we had approximately $9.2 million in cash and cash equivalents. Based on our current business plans, we believe that our existing capital will enable us to fund our operations through at least February 28, 2025. Our estimate as to how long we expect our existing capital to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

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, in-licensed or otherwise;
- 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.

Advancing the development of our product candidates will require a significant amount of capital. In order to fund all of the activities that are necessary to complete the development of our product candidates, we will be required to obtain further funding through equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional funding may not be available to us on acceptable terms, or at all.

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 or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through equity, debt financings, or other sources, including up-front payments and milestone payments from strategic collaborations. 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder.

Such financing 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 are party to a share purchase agreement, dated November 12, 2021, with certain investors (the "GEM SPA"), pursuant to which we may elect to issue and sell to such investors, and if so elected, such investors will be obligated to purchase, for a period commencing on the first day on which our common stock trade on a principal U.S. securities exchange and ending 60 months from such date, up to $100,000,000 worth of shares of our common stock, or the Aggregate Limit, subject to a 10% discount for the investors for shares acquired pursuant to the GEM SPA. The GEM SPA was contingent upon our achieving a public listing of our common stock, which was satisfied by the direct listing of our common stock on Nasdaq (the "Direct Listing"). However, it is possible that we may not be able to obtain access to the full amount potentially available to us under the GEM SPA due to a variety of factors outside of our control.

The GEM SPA prohibits the investors and their affiliates from:

(1) selling any of our securities during its term except for the shares that it owns or has the right to purchase pursuant to the provisions of a Draw Down Notice or the Warrant (as defined in the GEM SPA);

(2) entering into a short position, engaging in any short sales or equivalent transactions, establishing or increasing a put equivalent position or liquidating or decreasing any call equivalent position with respect to our shares, or taking, directly or indirectly, any action designed or intended to cause the manipulation of the price of our shares to facilitate the sale or resale of any of the shares; and

(3) granting any option to purchase or acquiring any right to dispose or otherwise dispose for value of any of our shares, or any securities convertible into, or exchangeable for, or warrants to purchase, any of our shares, respectively, or entering into any swap, hedge or other agreement that transfers, in whole or in part, the economic risk of ownership of our shares (except for shares that it has the right to purchase pursuant to the provisions of a Draw Down Notice or the Warrant).

The investors under the GEM SPA have further agreed to comply in all material respects with all applicable laws, rules, regulations and orders, including, without limitation, the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Regulation M and Rule 10b-5 under the Exchange Act, where applicable. GEM and GYBL have informed us that they did not engage in any short selling of our securities or other hedging activities prior to entering into the GEM SPA.

On January 31, 2024, in conjunction with the Direct Listing, we issued a draw-down notice under the GEM SPA to have GEM purchase up to 900,000 shares of our common stock at a draw-down threshold price of no less than $15.00 per share. GEM submitted two closing notices after 65,447 shares and 76,851 shares of our common stock were purchased at $13.50 per share. The net proceeds from these two closing notices under this draw-down were approximately $1.8 million. We then authorized a reduction of the draw-down threshold price to no less than $13.50 per share, and GEM submitted one additional closing notice after 84,759 shares of our common stock were purchased pursuant to the GEM SPA at $12.15 per share for net cash proceeds of approximately $1.0 million. Pursuant to the GEM SPA, we are required to pay the investors a commitment fee equal to 2% of the Aggregate Limit, payable in cash or shares of our common stock. The commitment fee is payable even if we do not utilize any drawdowns.

In addition, the GEM SPA required us to issue to GYBL, on our public listing date, a warrant to purchase up to the number of shares of our common stock that is equal to 4% of our total equity interests outstanding immediately after the completion of our public listing, at a price per share equal to the lesser of (i) the public offering price per share (in the case of an initial public offering) or the closing bid price per share on the public listing date (in the case of a public listing other than an initial public offering) or (ii) the quotient obtained by dividing $700,000,000 by the total number of equity interests. With approval from our Board of Directors, we issued 1,299,783 warrants with an initial exercise price of $21.54 per share to GYBL.

Our election to issue and sell to the investors, shares of our common stock pursuant to the GEM SPA, or the exercise of the warrant we were obligated to issue upon consummation of the Direct Listing, will result in further dilution to our existing stockholders and investors who purchase shares of our common stock in this offering.

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. 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.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

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.

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. 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;

- 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 institutional review boards, or IRBs;

- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

- delays in enrollment due to travel or quarantine policies, or other factors related 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 drug-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; or
- 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.

Conducting clinical trials in foreign countries, as we may do for our 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 has substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

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. 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, some of our planned clinical trials may utilize an "open-label" trial design. 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. This is particularly true for clinical trials in rare diseases, where the very small patient population makes it difficult to conduct two traditional, adequate and well-controlled studies, and therefore the FDA, the EMA or comparable foreign regulatory authorities are often required to exercise flexibility in approving therapies for such diseases. 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.

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, 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, operating results, 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.

Additionally, if any of our product candidates receives regulatory approval and becomes a product, 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 Risk Evaluation and Mitigation Strategy, or 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, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. 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.

Even if 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. 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;
- 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.

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

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

Our refrigerated drug product candidates must be stored at low temperatures in specialized refrigerated containers until immediately prior to use. For administration, the drug 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.

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.

The regulatory requirements that will govern any novel cell therapy product candidates we develop are not entirely clear and are subject to change. Within the broader genetic medicine field, very few therapeutic products have received marketing authorization from the FDA or the EMA. 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. Moreover, there is substantial overlap in those responsible for regulation of existing cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research to consolidate the review of cell therapy and related products. 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.

Our cell therapy product candidates will need to meet safety and efficacy standards applicable to any new biologic under the regulatory framework administered by the FDA. In addition to FDA oversight and oversight by IRBs, under the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines, cell therapy clinical trials are also subject to review and oversight by an Institutional Biosafety Committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving National Institutes of Health, or NIH, funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether individual cell therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

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 future 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 large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA, the EMA or any other regulatory authority with respect to our current 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 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. Furthermore, any regulatory approval to market a product candidate may be subject to significant limitations on the approved uses or indications for which we may market the product candidate or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving an NDA or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product candidate. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the product candidate and affect reimbursement by third-party payors.

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 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. 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biological products.

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.

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 focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. 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. 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.

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.

We intend to identify and develop novel cell therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development.

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 been a few number of clinical trials involving fibroblasts as compared to other, more conventional forms of therapy.

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

The estimates in this prospectus of the annual addressable markets for our product candidates are based on a number of third-party estimates. 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.

Our long-term prospects 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 are 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;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- 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.

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.

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—Competition*" for additional details. 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 also may 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. 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 will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We will be 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, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 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 will increase our legal and financial compliance costs, make certain activities more time-consuming and costly, and require our management and other personnel to devote a substantial amount of time to compliance initiatives.

Despite our best efforts, we may not be able to produce reliable financial statements or file such financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, beginning with the first full year after we become a public company. However, 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. To achieve compliance with Section 404 of the Sarbanes-Oxley Act, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. We will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We could also become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources. See the risk factor below captioned "*We have identified a material weakness in our internal control 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*."

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 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. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and any design may not succeed in achieving its stated goals under all potential future conditions. 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 control 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 financial statements for the fiscal year ended December 31, 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 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 financial statements prior to our Chief Financial Officer joining us in June 2022 when all financial functions were handled by a single individual, and afterward, through December 31, 2023, 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.

With the addition of our Chief Financial Officer and the changes made to our accounting and financial reporting processes and internal controls during the last half of fiscal year 2022 and through December 31, 2023, we have strengthened our internal controls and 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.

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. 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 and prospects.

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.

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. 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, 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.

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

We currently purchase our cell therapy product candidates from a contract development and manufacturing organization, or CDMO. We are in the process of contracting with a CDMO, for the transfer of our experimental cell bank to produce our master cell bank, working cell bank and our fibroblast cell-based product candidates to enable clinical trials. If the transfer of our experimental cell bank to the CDMO is not successful, we may encounter delays, additional costs, or technical failure of one or more of our product candidates. Similarly, if the CDMO is unable to produce from the experimental cell bank our master cell bank, working cell bank and our 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.

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.

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 others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. 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 for use in development and commercialization under the guidance of members of our organization. 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 was 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, which went into effect on January 1, 2020, establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the sale of personal information, and creating a new and potentially severe statutory damages framework 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.

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 from outside of the United States, including, for example, the European Union General Data Protection Regulation and the UK Data Protection Act 2018, or, 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 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 may be or 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 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. For example, states, such as California, Virginia, Colorado, Utah and Connecticut have recently enacted consumer privacy laws that grant rights to data subjects and places privacy and security obligations on entities handling personal data of consumers or households. Some observers note that the CCPA and similar legislation could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

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, we may 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. We will be subject to the data protection laws of the European Union and United Kingdom in relation to personal data we collect from these territories. These laws impose additional obligations and risk upon our business, including substantial expenses and changes to business operations that are required to comply with these laws. The withdrawal of the United Kingdom from the European Union, or Brexit, and the subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the European Union and United Kingdom, which may lead to additional compliance costs and could increase our overall risk.

The GDPR, which deals with the processing of personal data and on the free movement of such data, imposes a broad range of strict requirements, 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 details to those 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, appointing data protection officers, conducting data protection impact assessments and record-keeping.

The GDPR imposes strict rules on the transfer of personal data out of the EEA/UK to countries not regarded by European Commission and the United Kingdom government as providing adequate protection, or the third countries, including the United States. These transfers are prohibited unless an appropriate safeguard specified by data protection laws is implemented, such as the Standard Contractual Clauses, or the SCCs, approved by the European Commission, or a derogation applies. The UK has published its own transfer mechanism, the International Data Transfer Agreement and International Data Transfer Addendum, which enables transfers from the UK and has implemented a similar Transfer Equivalence Test. The international transfer obligations under the EU and UK data protection regimes require effort and cost and may result in us needing to make strategic considerations around where EEA/UK personal data is located and which service providers we utilize for the processing of EEA/UK personal data, particularly as the enforcement around GDPR international transfer compliance obligations is currently unclear. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process with the intention for this bill to reform the UK's data protection regime. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime. This may lead to additional compliance costs and could increase our overall risk.

We cannot assure you that any efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our reputation and materially harm our business.

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 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. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to 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.

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.

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.

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.

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 also may 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.

We may choose to 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 mean. 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. 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 and become products, 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;
- 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 previous U.S. administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions, including the Executive Orders, will be implemented, or whether they will be rescinded or replaced under the new U.S. administration. 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 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, all of which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

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 or our licensors 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 and our licensors 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 in-licensed 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 in-licensed 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 and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our or our licensors' rights or permit us or our licensors to gain or keep any competitive advantage. These uncertainties and/or limitations in our and our licensors' 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 may in-license issued patents in the United States and foreign countries, we cannot be certain that the claims in our other in-licensed 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 our in-licensed 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 our licensors 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 or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;

- 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 or our licensors 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 or our licensors may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those from our licensors and from third parties. We also may require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. 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 by our licensors 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 they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, 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, although we enter 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.

If the scope of any patent protection our licensors obtain is not sufficiently broad, or if our licensors lose any of the patent protection we license, 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 in-licensed patent rights are highly uncertain. Our pending and future in-licensed 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 patent applications we license currently or in the future 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 license 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 licensed-in 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 in-licensed 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 in-licensed patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, 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 in-licensed patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of licensed 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 or license;
- we or our licensors 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 or license;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our licensors' pending patent applications will not lead to issued patents;
- issued patents that we own or license 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 the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- 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 prospectus, 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 operating results.

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 or the patents of our licensors, which could be expensive, time-consuming and unsuccessful. Further, our in-licensed issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our patents or other intellectual property rights or the intellectual property rights of our licensors. To cease such infringement or unauthorized use, we and/or our licensors may be required to file infringement claims, which can be expensive and time-consuming. Further, our licensors may need to file infringement claims, and our licensors may elect not to file such claims. 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 license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or 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 or those of our licensors 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 our licensors, 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 or our licensors' 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 or our licensors' 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 and licensed 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 or our licensors may be subject to claims challenging the inventorship or ownership of our or our in-licensed 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 in-licensed 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 or our licensors 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 or our licensors 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 or our licensors 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 or our licensors 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 in-licensed 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 in-licensed inventions in all countries outside the United States or from selling or importing products made using our in-licensed inventions in and into the United States or other jurisdictions. Competitors may use our in-licensed 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 or our licensors 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 or our licensors 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 or our licensors' patents or other intellectual property rights, or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our licensors' 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 or our licensors' patents at risk of being invalidated, held unenforceable, or interpreted narrowly and our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors 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 or our licensors' efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 and our licensors may have limited remedies if patents are infringed or if we or our licensors 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 or our licensors 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 confidential information and inventions 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 confidentiality 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 or our licensors 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 we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

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. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently 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

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.

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 and medical 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 operating results. 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, 2023, we had ten 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.

Risks Related to This Offering and Ownership of Our Common Stock

We may not be able to maintain compliance with Nasdaq's listing standards, which could limit stockholders' ability to trade our common stock.

On January 31, 2024, we completed the Direct Listing, pursuant to which we registered 4,806,226 shares of our common stock held by certain stockholders, or their permitted transferees (the "Registered Stockholders"). As a listed company on the Nasdaq, we are required to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order 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.

Our common stock have a very short trading history on Nasdaq. An active trading market may not develop or continue to be liquid and the market price of shares of our common stock may be volatile.

Our common stock is listed and traded on Nasdaq. Prior to the listing on Nasdaq, there was not a public market for any of our securities, and an active market for our common stock may not develop or 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. 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.

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.

The public price of our common stock could be subject to wide fluctuations in response to the risk factors described in this prospectus and others beyond our control, including:

- changes in the industries in which we operate;
- 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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following the listing of our common stock on Nasdaq as a result of the supply and demand forces described above. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations and financial condition.

Future sales of common stock by our Registered Stockholders and other stockholders could cause our share price to decline.

Our common stock is listed and traded on Nasdaq. Prior to listing on Nasdaq, there was no public market for our common stock and there has not been a sustained history of trading in our common stock in "over-the-counter" markets. While our common stock may be sold by the Registered Stockholders pursuant to this prospectus or by our stockholders pursuant to other current or future effective registration statements or in accordance with Rule 144 under the Securities Act or other exemption from registration, there can be no assurance that any Registered Stockholders or other existing stockholders will sell any of their shares of common stock and there may initially be a lack of supply of, or demand for, our common stock on Nasdaq. As described herein, certain shares of our common stock outstanding as of the date hereof will be registered under this registration statement. There can be no assurance that the Registered Stockholders and other stockholders will not sell all of their shares of common stock (including, upon exercise by GYBL, the shares of common stock underlying the warrants we issued to GYBL), resulting in an oversupply of our common stock on Nasdaq. In the case of a lack of supply of our common stock, the trading price of our common stock may rise to an unsustainable level. 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 existing stockholders to sell a sufficient amount of common stock at the price offered by such institutional investors and the greater influence individual investors have in setting the trading price. If institutional investors are unable to purchase our common stock, the market for our common stock may be more volatile without the influence of long-term institutional investors holding significant amounts of our common stock. In the case of a lack of market demand for our common stock, the trading price of our common stock could decline significantly and rapidly after our listing. Therefore, an active, liquid and orderly trading market for our common stock may not initially develop or be sustained, which could significantly depress the public price of our common stock and/or result in significant volatility, which could affect your ability to sell your shares of common stock.

We have 2,500 shares of Series C Preferred Stock with super voting rights.

Our board of directors and stockholders have each approved the creation and issuance of an aggregate of 2,500 (after giving effect to the Reverse Stock Split) Series C Preferred Stock, all of which Series C Preferred Stock were issued to Pete O'Heeron, our founder and Chief Executive Officer, in conjunction with the 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 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 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 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.

See *"Description of Capital Stock—Series C Preferred Stock"* for additional information regarding our Series C Preferred Stock.

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.

We are a "controlled company" within the meaning of The Nasdaq Stock Market Rules because our insiders beneficially own more than 50% of the voting power of our outstanding voting securities.

Our founder and Chief Executive Officer, Pete O'Heeron, collectively beneficially owns approximately 60% of the voting power of our outstanding voting securities and we are a "controlled company" within the meaning of the listing rules of The Nasdaq Stock Market LLC. We may rely on certain exemptions from corporate governance rules, including an exemption from the rule that a majority of our board of directors must be independent directors. Although we currently do not intend to rely on the "controlled company" exemption under the Nasdaq listing rules, we could elect to rely on this exemption in the future. In the event that we elected to rely on the "controlled company" exemption, a majority of the members of our board of directors might not be independent directors, and our governance and nominating and compensation committees might not consist entirely of independent directors. Our status as a controlled company could cause our shares of common stock to be less attractive to certain investors or otherwise harm our trading price. As a result, you would not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements.

You may be diluted by future issuances of preferred stock or additional common stock in connection with our incentive plans, acquisitions or otherwise; future sales of such shares in the public market, or the expectations that such sales may occur, could lower our stock price.

Our amended and restated certificate of incorporation authorizes us to issue shares of common stock and options, rights, warrants and appreciation rights relating to our common stock for the consideration and on the terms and conditions established by our board of directors in its sole discretion. We could issue a significant number of shares of common stock in the future in connection with investments or acquisitions. Any of these issuances could dilute our existing stockholders, and such dilution could be significant. Moreover, such dilution could have a material adverse effect on the market price for the shares of our common stock.

The future issuance of shares of preferred stock with voting rights 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.

The future issuance of shares of preferred stock with dividend or conversion rights, liquidation preferences or other economic terms favorable to the holders of preferred stock could adversely affect the market price for our common stock by making an investment in the common stock less attractive. For example, investors in the 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.

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 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, operating results, 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 in this offering 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 this prospectus and our periodic reports and proxy 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 operating results and financial statements may not be comparable to the operating results and 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.

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 December 31, 2023, our executive officers, directors and five percent or greater stockholders and their respective affiliates, beneficially own, in the aggregate, approximately 19% of our outstanding common stock on an as converted basis. To the extent that the same group continue to own a significant percentage of our common stock following this offering, 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 of our organizational documents and approval of any merger, sale of substantially all our assets or other significant corporate transactions. This concentration of ownership 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.

Provisions of our amended and restated certificate of incorporation and bylaws may delay or prevent a take-over that may not be in the best interests of our stockholders.

Provisions of our amended and restated certificate of incorporation and 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, as more particularly described elsewhere in this prospectus, (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 authorize the issuance of shares of preferred stock which will have such rights and preferences determined from time to time by our board of directors. 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 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. Pursuant to our planned 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 planned 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 Risks

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 may establish and publish 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, manufacturers, other contractors, consultants, collaborators or potential future collaborators, 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, our internal computer systems and those of our current and any future CROs 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. 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 (violating certain privacy laws such as HIPAA and GDPR), it could result in a material disruption of our drug 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 in any event, 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 facility is located in 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 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, 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, plans and objectives of management 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 prospectus 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 prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "*Risk Factors*" and elsewhere in this prospectus. 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. 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 prospectus, 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 prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

MARKET AND INDUSTRY DATA

This prospectus includes estimates regarding market and industry data. Unless otherwise indicated, information concerning our industry and the markets in which we operate, including our general expectations, market position, market opportunity, and market size, are based on our management's knowledge and experience in the markets in which we operate, together with currently available information obtained from various sources, including publicly available information, industry reports and publications, surveys, our customers, trade and business organizations, and other contacts in the markets in which we operate. Certain information is based on management estimates, which have been derived from third-party sources, as well as data from our internal research.

In presenting this information, we have made certain assumptions that we believe to be reasonable based on such data and other similar sources and on our knowledge of, and our experience to date in, the markets in which we operate. While we believe the estimated market and industry data included in this prospectus is generally reliable, such information is inherently uncertain and imprecise. Market and industry data is subject to change and may be limited by the availability of raw data, the voluntary nature of the data gathering process, and other limitations inherent in any statistical survey of such data. In addition, projections, assumptions, and estimates of the future performance of the markets in which we operate are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "*Risk Factors*" and "*Cautionary Note Regarding Forward-Looking Statements*." These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us. Accordingly, you are cautioned not to place undue reliance on such market and industry data or any other such estimates.

The source of certain statistical data, estimates, and forecasts contained in this prospectus are the following independent industry publications or reports:

- **"Degenerative Disc Disease Therapeutics Global Market Analysis, Insights and Forecast, 2022-2029"** Fortune Business Insights;
- **"Global Regenerative Medicine Market 2022-2029"** Fortune Business Insights;
- **"Global Multiple Sclerosis Drugs Market 2022-2029"** Fortune Business Insights; and
- **"Global Wound Care Market 2022-2029"** Fortune Business Insights.

The content of the above sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We own or otherwise have rights to the trademarks, including those mentioned in this prospectus, used in conjunction with the operation of our business. This prospectus includes our own trademarks, which are protected under applicable intellectual property laws, as well as trademarks, service marks and tradenames of other entities, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, TM or SM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks, service marks and tradenames. We do not intend our use or display of other entities' trademarks, service marks or tradenames to imply a relationship with, or endorsement or sponsorship of us by, any other entities.

USE OF PROCEEDS

We estimate that the net proceeds of this offering, after deducting placement agent fees and estimated expenses payable by us, will be approximately $18.4 million, assuming the sale of all Units offered hereby at an assumed offering price of $11.10 per Unit, which represents the closing sale price of our common stock on The Nasdaq Global Market on April 23, 2024, and further assuming no exercise of the Warrants issued in connection with this offering.

We currently intend to use the net proceeds received from this offering for general corporate purposes, including to hire key personnel, conduct research and development, and for working capital.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. The amounts and timing of our actual expenditures will depend upon numerous factors, including the development efforts and the overall economic environment. Therefore, our management will retain broad discretion over the use of the proceeds from this offering. We may ultimately use the proceeds for different purposes than what we currently intend. Pending any ultimate use of any portion of the proceeds from this offering, if the anticipated proceeds will not be sufficient to fund all the proposed purposes, our management will determine the order of priority for using the proceeds, as well as the amount and sources of other funds needed.

Pending our use of the net proceeds from this offering, we may invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. 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 as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors. Any such determination will also depend upon our business prospects, operating results, financial condition, 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**.**

DILUTION

If you invest in our Units in this offering, your interest will be diluted to the extent of the difference between $11.10, the assumed offering price per share of our common stock included as part of the Units (without assigning any value to the Warrants), and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of March 31, 2024, was a deficit of approximately $3.9 million, or $(0.12) per share.

Net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of common stock.

After giving effect to our sale of 1,801,801 Units in this offering at an assumed offering price of $11.10 per Unit, and after deducting estimated placement agent discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the Warrants, our as adjusted net tangible book value as of March 31, 2024, would have been approximately $14.5 million or $0.42 per share. This represents an immediate dilution in net tangible book value of $10.68 per share to purchasers of common stock included in the Units sold in this offering, as illustrated in the following table:

Assumed public offering price per Unit attributable to common stock		$ 11.10
Net tangible book value per share as of March 31, 2024		(0.12)
Increase in net tangible book value per share attributable to new investors in this offering	$ 0.54	
As adjusted for this offering, net tangible book value per share as of March 31, 2024		$ 0.42
Dilution per share to new investors		$ 10.68

A $1.00 increase or decrease in the assumed public offering price of $11.10 per Unit would increase or decrease our as adjusted net tangible book value of common stock after this offering by $1.7 million and the dilution per share of common stock to new investors by $0.95, assuming the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated placement agent discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of Units we are offering. An increase or decrease of 100,000 in the number of Units offered by us would increase or decrease our as adjusted net tangible book value after this offering by approximately $1.0 million and increase or decrease as adjusted net tangible book value per share of common stock after this offering by $0.03 per share of common stock and would increase or decrease the dilution per share of common stock to new investors by $0.03, assuming the assumed public offering price remains the same, and after deducting estimated placement agent discounts and commissions and estimated offering expenses payable by us.

To the extent that shares are issued upon the exercise of outstanding options and warrants or shares are issued under our equity incentive plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2024, as follows.

- on an actual basis; and
- on an as adjusted basis to give effect to our sale of 1,801,801 Units in this offering at an assumed offering price of $11.10 per Unit, and after deducting estimated placement agent discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the Warrants.

This table should be read in conjunction with, and is qualified in its entirety by reference to, our financial statements and related notes incorporated by reference into this prospectus.

	As of March 31, 2024	
	Actual	As Adjusted
	(in thousands, except for share and per share amounts)	
Cash and cash equivalents	$ 8,158	$ 26,532
Stockholders' equity:		
Preferred Stock, $0.00001 par value per share; 8,750,000 Series A Preferred shares authorized, actual and as adjusted; no Series A Preferred shares issued and outstanding, actual and as adjusted	—	—
Preferred Stock, $0.00001 par value per share; 5,000,000 Series B Preferred shares authorized, actual and as adjusted; no Series B Preferred shares issued and outstanding, actual and as adjusted	—	—
Preferred Stock, $0.00001 par value per share; 5,000,000 Series B-1 Preferred shares authorized, actual and as adjusted; no Series B-1 Preferred shares issued and outstanding, actual and as adjusted	—	—
Preferred Stock, $0.00001 par value per share; 2,500 Series C Preferred shares authorized, issued and outstanding, actual and as adjusted	—	—
Non-voting Common stock, $0.00001 par value per share; 30,000,000 shares authorized, actual and as adjusted; no shares issued and outstanding, actual and as adjusted	—	—
Voting Common Stock, $0.00001 par value per share; 100,000,000 shares authorized, actual and as adjusted; 32,719,125 shares issued and outstanding, actual; 34,520,926 shares issued and outstanding, as adjusted	—	—
Additional paid-in capital	28,954	47,328
Accumulated deficit	(32,817)	(32,817)
Total stockholders' equity/(deficit)	$ (3,863)	$ 14,511
Total capitalization	$ (3,863)	$ 14,511

The number of shares of our voting common stock reflected in our actual and as adjusted information set forth in the table above excludes:

- 4,005,375 shares of common stock issuable upon exercise of stock options outstanding under our 2022 Stock Plan (as defined herein) as of March 31, 2024;
- 8,494,625 shares of common stock reserved for issuance under our 2022 Stock Plan;
- 10,321 shares of common stock underlying warrants that were issued in connection with the issuance of certain shares of the Series B-1 Preferred Stock;
- 1,299,783 shares of common stock underlying warrants to purchase common stock that were issued to GYBL upon the Direct Listing pursuant to the GEM SPA; and
- 1,801,801 shares of common stock underlying Warrants to purchase common stock that will be issued to investors in this offering.

MANAGEMENT

Executive Officers

The following table sets forth certain information, as of the date of this prospectus, concerning our executive officers:

Name	Age	Position
Pete O'Heeron, MSHA	60	Founder, Chairperson and Chief Executive Officer
Mark Andersen, CPA CFA	53	Chief Financial Officer
Hamid Khoja, Ph.D.	54	Chief Scientific Officer
Ruben A. Garcia	47	General Counsel

The following is a biographical summary of the experience of our executive officers.

Pete O'Heeron, MSHA. Pete O'Heeron founded our company and has served as our Chief Executive Officer, and the Chairperson and member of our board of directors since our inception in April 2021. Mr. O'Heeron is also the founder of FibroGenesis, our affiliate, and has served as the Chief Executive Officer of FibroGenesis since January 2006. Mr. O'Heeron is a preeminent biopharma inventor, with over 300 patents issued and pending in the areas of biologics, cell therapy and medical devices. Mr. O'Heeron is a seasoned leader in his field, with over 25 years of experience in medical technology and biotech development. As Chief Executive Officer, he aims to position us to become a global leader in fibroblast-based cell therapies with the development and commercialization of therapies that can cure and treat patients suffering from chronic diseases. Mr. O'Heeron brings together multi-disciplinary teams and resources necessary to commercialize unique technologies. Prior to founding our company and FibroGenesis, he founded an operational investment group, Advanced Medical Technologies, LLC, that identified early-stage opportunities in the medical field with strong intellectual property potential in 2006. He also founded in 1998 NeoSurg Technologies, which developed the T2000 Minimally Invasive Access System. NeoSurg Technologies was sold to Cooper Surgical in 2006. Mr. O'Heeron also previously served in a variety of executive-level positions at Christus Health Care Corporation from 1988 until 1995 and has provided strategic advisory services to healthcare companies in the areas of biologics, advanced surgical instrumentation and telemedicine. Mr. O'Heeron received his Bachelor's Degree in Healthcare Administration from Texas State University, his Masters in Healthcare Administration from the University of Houston Clear Lake, and his Executive Management Certification in Mergers and Acquisition from the University of Chicago. We believe Mr. O'Heeron is qualified to serve as a member of our board of directors based on our review of his experience, qualifications, attributes and skills, including co-founding our company and his executive leadership experience in the biotechnology industry.

Mark Andersen, CPA CFA. Mark Andersen has served as our Chief Financial Officer since June 2022. Prior to joining us, Mr. Andersen most recently served as Chief Financial Officer and Vice President of Administration for the Indiana Biosciences Research Institute in Indianapolis, Indiana, from May 2016 until May 2022. In that role, he was responsible for finance, human resources, legal, and information technology for the institute. Mr. Andersen helped create the operating infrastructure for the institute, assisted with fundraising and provided oversight for the endowment investment portfolio, which grew to nearly $150.0 million. Prior to that, from August 2015 until February 2016, Mr. Andersen served as Vice President Finance and Corporate Controller for MiMedx with responsibility for SEC reporting and finance functions. Previously, from January 2004 to August 2015, Mr. Andersen held multiple financial leadership roles at Eli Lilly and Company, including Investments Director for the company's pension plan, Finance Director for Mergers and Acquisitions, and Controller for Lilly USA. Mr. Andersen received his Bachelor of Science degree in accounting and Master of Science in accountancy from Southern Utah University, and his MBA from the University of Michigan Ross School of Business.

Hamid Khoja, Ph.D. Hamid Khoja has served as our Chief Scientific Officer since August 2021. Dr. Khoja has more than 25 years of experience as a leader of scientific teams, development of cell-based genomic, proteomic, epigenetics assays, and tools, protocols and technologies for use in drug discovery and development and clinical diagnostics. Prior to joining us, Dr. Khoja most recently served from March 2009 to August 2021 as the Principal Scientist as Covaris, LLC, a privately-held scientific tools company with emphasis in genomics, epigenetics, and proteomics, where he provided long-term strategic applications proposals to the Chief Executive Officer, managed external collaborations for product and applications development, assessed new technologies for acquisition and OEM opportunities, and presented posters and presentations at numerous scientific conferences. Dr. Khoja led the effort in successfully incorporating Covaris technology into the Illumina Next Generation Sequencing technology protocols leading to over 15,000 citations. Dr. Khoja also developed the Covaris chromatin immunoprecipitation methodology with over 3,000 citations in peer-reviewed publications, as well as leading the effort in using Covaris technology for simplifying epigenetics assay workflows for use in drug development and discovery, and clinical use. Dr. Khoja also led collaborations with the U.S. National Cancer Institute for successful development of microbiome DNA extraction using acoustics, and completion of FDA EUA SARA-CoC-2 bridge study design for approval of new sample collection and viral ribonucleic acid (RNA) extraction using Covaris technology. Dr. Khoja also developed a patented workflow for the manufacturing of synthetic cell-free DNA for use as reference standard in sequencing based liquid biopsy clinical oncology-based assays. Prior to Covaris, Dr. Khoja was a Senior Applications Scientist at Genomic Solutions, a startup scientific tools company later acquired by Harvard Apparatus, from March 2022 to March 2009, where he led the development of a high throughput protein crystallization platform used in pharmaceutical industry for drug development, managed the scientific applications group, presented company resources at scientific meetings and assessed new technologies for acquisition and OEM opportunities. During the startup phase of Sequenom, Inc., from January 2000 to March 2003, Dr. Khoja established the methodology for highly multiplexed polymerase chain reaction, or PCR, used in the development of Sequenom's massEXTEND technology for MALDI-TOF MS-based analysis of single nucleotide polymorphisms and genetic disease. Dr. Khoja led the effort in developing diagnostic MS-based assays for hemochromatosis, cystic fibrosis and ten predominantly Jewish genetic diseases using Sequenom's massEXTEND technology which were then transferred to a large clinical diagnostic company. Dr. Khoja also previously worked at Eli Lilly and Company from November 1998 to September 1999 and Chiron Corporation from October 1995 to October 1998. During his career at Eli Lilly, Dr. Khoja established a high throughput PCR and sequencing strategy using a variety of sequencing strategies and bioinformatic tools available in 1999 for obtaining high coverage genome sequencing which led to the finalizing of the first ever complete sequence of the S. pneumoniae genome. At Chiron Corporation, which was subsequently acquired by Novartis, Dr. Khoja helped in the design, development and optimization of HTP binding assays for FGFR, VEGF, PDGF, and EPO receptors, identification of novel g-protein coupled seven transmembrane receptors, and identification of novel proteins involved in the TNF signaling pathway, and development of branched-DNA based HTP screening for ligand-induced oncogene quantification.

Dr. Khoja received his Bachelor of Science in Molecular Biology from the University of Southern California and his Ph.D. in Molecular Biology from Boston University.

Ruben Garcia. Ruben Garcia has served as our General Counsel since March 1, 2024. Prior to FibroBiologics, Mr. Garcia most recently served as Senior Vice President, General Counsel and Corporate Secretary at AcelRx Pharmaceuticals, Inc. (n/k/a Talphera, Inc.), a pharmaceutical company, from April 2019 to February 2022. In that role, he was responsible for all legal and compliance matters. Prior to AcelRx, Mr. Garcia was Senior Corporate Counsel and Assistant Secretary at Ultragenyx Pharmaceutical Inc., a biopharmaceutical company, from November 2016 to April 2019, with responsibility for SEC and governance matters. Prior to Ultragenyx, Mr. Garcia was an attorney at Vinson & Elkins LLP and Jones Day, where he practiced in the areas of capital markets, securities offerings, corporate governance and mergers and acquisitions. Mr. Garcia holds a B.A. in Government and Economics from Georgetown University and a J.D. from Stanford Law School.

Non-Employee Directors

The following table sets forth certain information, as of the date of this prospectus, concerning our non-employees who serve on our board of directors:

Name	Age	Position
Robert Hoffman	58	Director
Victoria Niklas, M.D.	65	Director
Richard Cilento, Jr., MBA	62	Director
Stacy Coen, MBA	53	Director
Matthew Link	49	Director

The following is a biographical summary of the experience of our non-employee directors.

Robert Hoffman. Robert Hoffman has served on our board of directors since April 2021. Mr. Hoffman currently serves as President, Chief Executive Officer and Chairperson of the board of directors of Kintara Therapeutics, Inc. (Nasdaq: KTRA), a clinical stage, biopharmaceutical company focused on the development and commercialization of new cancer therapies, a member of the board of directors of ASLAN Pharmaceuticals Limited (Nasdaq: ASLN), an oncology-focused biotechnology company developing a portfolio of immuno-oncology agents and targeted therapies, and Chairperson, and a member, of the board of directors of Antibe Therapeutics Inc., a Toronto, Canada-based pharmaceutical company listed on the Toronto Stock Exchange. Mr. Hoffman previously served as Senior Vice President and Chief Financial Officer of Heron Therapeutics, Inc., (Nasdaq: HRTX), a commercial-stage biotechnology company, from April 2017 to October 2020, and as Chief Financial Officer of AnaptysBio, Inc. (Nasdaq: ANAB), a specialty pharmaceutical company, from July 2015 to September 2016. From June 2012 to July 2015, Mr. Hoffman served as the Senior Vice President, Finance and Chief Financial Officer of Arena Pharmaceuticals, Inc., or Arena, a biopharmaceutical company, prior to its acquisition by Pfizer Inc. in March 2022. From August 2011 to June 2012 and previously from December 2005 to March 2011, Mr. Hoffman served as Arena's Vice President, Finance and Chief Financial Officer and in a number of various roles of increasing responsibility from 1997 to December 2005. Mr. Hoffman formerly served as a member of the board of directors of Saniona AB, a biopharmaceutical company, from September 2021 to May 2022, and as a member of the board of directors of Kura Oncology, Inc. (Nasdaq: KURA), a cancer research company, from March 2015 to August 2021. He also previously served as a member of the board of directors of CombiMatrix Corporation, a molecular diagnostics company, MabVax Therapeutics Holdings, Inc., a biopharmaceutical company, and Aravive, Inc. (Nasdaq: ARAV), a clinical stage biotechnology company. Mr. Hoffman serves as a member of the steering committee of the Association of Bioscience Financial Officers. Mr. Hoffman formerly served as a director and President of the San Diego Chapter of Financial Executives International and was an advisor to the Financial Accounting Standard Board, or FASB, from 2010 to 2020, advising the U.S. accounting rulemaking organization on emerging issues and new financial guidance. Mr. Hoffman holds a B.B.A. from St. Bonaventure University. We believe Mr. Hoffman's financial and executive business experience qualifies him to serve on our board of directors.

Victoria Niklas, M.D. Victoria Niklas has served on our board of directors since April 2021. Dr. Niklas has a distinguished career spanning more than two decades in translational research, clinical care and teaching at academic health centers, and is currently the Chief Medical Officer of Oak Hill Bio, a clinical-stage neonatology and rare disease therapeutics company, a position she has held since 2022. Prior to joining Oak Hill Bio, Dr. Niklas served in Global Medical Affairs and as Global Program Leader of the OHB-607 program in Rare Disease and Hematology at Takeda Pharmaceuticals. Before Takeda, she was Chief Medical and Scientific Officer at Prolacta Bioscience, a neonatal nutritional product development company based on human donor milk. Dr. Niklas has over 20 years of experience as an academic neonatologist with expertise in developmental and acquired inflammatory disorders of the gut, the lung and the mucosal immune system with relevance to diseases across the lifespan. She has held positions as Chief, Division of Newborn Medicine at Nemours Children's Hospital, Chief of Neonatology at UCLA Olive View Medical Center, and Visiting Professor of Clinical Pediatrics at the David Geffen School of Medicine at UCLA. Dr. Niklas is board certified in Perinatal and Neonatal Medicine and holds a California medical license. In addition to being a co-author on numerous scientific and clinical publications, she has helped lead the development of patented products and has served as a board member for multiple biotech and early-stage companies in functional foods. Dr. Niklas received her MD from Harvard Medical School, her MA in Biochemistry and Molecular Biology from Harvard University, and her bachelor's in Biological Sciences from Goucher College. We believe Dr. Niklas' extensive experience and knowledge in the biotechnology sector qualifies her to serve on our board of directors.

Richard Cilento, Jr., MBA. Richard Cilento has served on our board of directors since April 2021. Mr. Cilento is the founder, Chairperson of the board of directors and Chief Executive Officer of GlycosBio Inc., a life sciences research and development company. Mr. Cilento was the founder, President and Chief Executive Officer of FuelQuest, Inc., a provider of information technology, supply chain management and tax automation technologies, which was acquired by Saracen Energy Advisors LP in May 2007. Mr. Cilento has held senior-management positions with several technology firms, including Xerox Corporation, where he served as Vice President of Strategic Services of Xerox Connect. Prior to that, he was the Vice President of Corporate Services for XLConnect Solutions, where he served as the lead technologist for advanced systems and supported the organization through its initial public offering and its eventual merger with Xerox. An aeronautical and astronomical engineer, Mr. Cilento began his career at the U.S. National Aeronautics and Space Administration (NASA), where he and his team built space shuttle flight plans for the U.S. Department of Defense Star Wars program and a diverse set of government-funded technology and life science experimentation. Mr. Cilento was a lead engineer who designed and planned the space station assembly sequences for the construction of the International Space Station. Mr. Cilento holds a BS degree in Aeronautical and Astronomical Engineering from the University of Illinois and an MBA at the University of Houston, Clear Lake. We believe Mr. Cilento's business experience across a broad set of technical industries and executive-level knowledge of capital markets, including venture capital, private equity and public markets, qualifies him to serve on our board of directors.

Stacy Coen, MBA. Stacy Coen has served as a member of our board of directors since July 2021. Ms. Coen has over 25 years of business and corporate development experience from leading oncology and rare disease companies. She most recently served as the Chief Business Officer for ImmunoGen, Inc., a company that is developing the next generation of antibody-drug conjugates to improve outcomes for cancer patients. Prior to ImmunoGen, Ms. Coen worked at Editas Medicine, Inc., a biotechnology company developing therapies for rare diseases, where she served as Vice President, Business Development and was responsible for business development, strategy, transactions and alliance management. Prior to joining Editas, Ms. Coen served in multiple roles of increasing responsibility at Genzyme Corporation (now known as Sanofi Genzyme), including as Vice President, Head of Rare Disease Business Development and Licensing, and as Vice President, Global Head of Strategy and Business Development, Multiple Sclerosis, among others. Ms. Coen currently serves on the Huntington's Disease Society of America's Center Programs & Education Advisory Committee. Ms. Coen received a BS in Finance and Economics from the University of Massachusetts and an MBA from the Darden Graduate School of Business at the University of Virginia. We believe Ms. Coen's extensive executive-level experience in the biotechnology industry qualifies her to serve on our board of directors.

Matthew Link. Matthew Link has served on our board of directors since April 2021. Mr. Link has more than 20 years of experience in the healthcare and medical technology industries and currently serves as Chief Commercial Officer for Sight Sciences (SGHT). From 2021 to 2023 he served as managing partner at Orion Healthcare Advisors, LLC, a consulting services provider. From 2006 to 2021 Mr. Link served in regional and executive leadership positions at NuVasive Inc., a global leader in surgical implants and enabling technology for spine surgery and orthopedics. As President of NuVasive, Inc., his responsibilities included oversight of global business units in spine, neurophysiology, and orthopedics. Prior to NuVasive, Inc., Mr. Link held commercial leadership roles at Depuy Orthopedics and Depuy Spine. He also currently serves as chairman of the board of directors at Galen Robotics and as a member of the board of directors of Springbok Analytics and DinamicOR, and the Coulter Translational Research Endowment at the University of Virginia. Mr. Link received a BSEd in Physical Education and Sports Medicine from the University of Virginia. We believe Mr. Link's extensive medical technology industry and executive experience qualifies him to serve on our board of directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Scientific Advisory Board

We have a scientific advisory board, comprised of the following world-renowned scientists with relevant expertise, which helps guide our research and development efforts.

- Claudia Lucchinetti, M.D., Ph.D.
- S. Thomas Carmichael, M.D., Ph.D.
- Kate Rubins, Ph.D.
- Elizabeth Shpall, M.D.
- Neil Bhowmick, Ph.D.

Board of Directors

Our board of directors currently consists of six directors. Our amended and restated certificate of incorporation provides that, subject to the rights of holders of any series of our preferred stock to elect directors, the number of directors on our board of directors shall be fixed from time to time solely by resolution of the majority of the total number of authorized directors, whether or not there exist any vacancies in previously authorized directorships.

Pursuant to our amended and restated certificate of incorporation, subject to the preferential rights of holders of any series of our preferred stock, any newly created directorship that results from an increase in the number of directors or any vacancy on our board of directors can only be filled 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 cannot be filled by the stockholders. Further, any member of our board of directors or our entire board of directors 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.

When considering whether directors have the experience, qualifications, attributes or skills, taken as a whole, to enable our board of directors to satisfy its oversight responsibilities effectively in light of our business and structure, the board of directors focuses primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

Director Independence

Our board of directors has determined that all members of our board of directors, except Pete O'Heeron, are independent directors for purposes of the rules of Nasdaq and the SEC. In making this determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant, including the beneficial ownership of our common stock by each non-employee director.

The composition and functioning of our board of directors and each of our committees complies with all applicable requirements of Nasdaq and the rules and regulations of the SEC.

Staggered Board

In accordance with the terms of our amended and restated certificate of incorporation, our board of directors is divided into three staggered classes of directors and each is assigned to one of the three classes. At each annual meeting of our stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of shareholders to be held during the years 2024 for Class I directors, 2025 for Class II directors and 2026 for Class III directors and will be subject to their earlier death, disqualification, resignation or removal.

- Our Class I directors are Robert Hoffman and Richard Cilento, Jr.;
- Our Class II directors are Mathew Link and Victoria Niklas; and
- Our Class III directors are Stacy Coen and Pete O'Heeron.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in our control.

Board Leadership Structure

Our board of directors is currently chaired by our founder, Pete O'Heeron. Our board of directors can modify our leadership structure in the future as it deems appropriate.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a governance and nominating committee, each of which operates pursuant to a charter adopted by our board of directors. Our board of directors may also establish other committees from time to time to assist the board of directors. The composition and functioning of all of our committees complies with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations. Each committee's charter is available on our website at www.fibrobiologics.com.

Audit Committee

The members of our audit committee are Mr. Hoffman, Dr. Niklas, and Mr. Cilento. Mr. Hoffman serves as the chairperson of the committee. Our board of directors has determined that each member of the audit committee is "independent" as that term is defined in Nasdaq rules and has sufficient knowledge in financial and auditing matters to serve on the audit committee. In addition, our board of directors has determined that each member of the audit committee meets the heightened independence requirements for audit committees required under Section 10A of the Exchange Act and related SEC and Nasdaq rules. Our board of directors has determined that Mr. Hoffman is an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our annual report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving, or recommending to the board of directors for approval, all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

The members of our compensation committee are Mr. Hoffman, Ms. Coen and Mr. Link. Mr. Hoffman serves as the chairperson of the committee. Our board of directors has determined that each member of the compensation committee is "independent" as that term is defined in Nasdaq rules and is a "non-employee director" under Rule 16b-3 under the Exchange Act. In addition, our board of directors has determined that each member of the compensation committee meets the heightened independence requirements for compensation committee purposes under Section 10C of the Exchange Act and related SEC and Nasdaq rules. The compensation committee's responsibilities include:

- reviewing and approving our philosophy, policies and plans with respect to the compensation of our chief executive officer;
- making recommendations to our board of directors with respect to the compensation of our chief executive officer and making recommendations to our board of directors with respect to the compensation of our other executive officers or approving such compensation of our other executive officers;
- reviewing and assessing the independence of compensation advisors;
- overseeing and administering our equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation; and
- preparing the compensation committee reports required by the SEC, including our "compensation discussion and analysis" disclosure.

Governance and Nominating Committee

The members of our governance and nominating committee are Ms. Coen, Dr. Niklas and Mr. Link. Ms. Coen serves as the chairperson of the committee. Our board of directors has determined that each member of the governance and nominating committee is "independent" as defined in Nasdaq rules. The governance and nominating committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying and screening individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a corporate governance framework and related governance documents; and
- overseeing the evaluation of our board of directors and management.

Code of Conduct

We have adopted a written code of ethics and business conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on our website at www.fibrobiologics.com. If we make any substantive amendments to, or grant any waivers from, the code of ethics and business conduct for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

This section discusses the material components of the executive compensation program for our executive officers who are named in the "*—2023 Summary Compensation Table*" below. For the fiscal year ended December 31, 2023, our "named executive officers" and their positions were as follows:

- Pete O'Heeron, Chairperson and Chief Executive Officer;
- Hamid Khoja, Ph.D., Chief Scientific Officer; and
- Mark Andersen, Chief Financial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion. As an "emerging growth company" and a "smaller reporting company," each as defined under SEC rules, we are not required to include a compensation discussion and analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies and/or smaller reporting companies.

2023 Summary Compensation Table

The following table represents information regarding the total compensation awarded to, earned by or paid to our named executive officers during the fiscal years ended December 31, 2022 and 2023:

Name and Principal Position	Year	Salary ($)	Bonus ($) (2)	Option Awards ($) (3)	All Other Compensation ($)(4)	Total ($)
Pete O'Heeron	2022	600,000	—	—	22,485	622,485
Chairperson and Chief Executive Officer	2023	600,000	300,000	3,335,400	50,723	3,452,273
Hamid Khoja, Ph.D.	2022	300,208	101,500	23,900	20,505	446,113
Chief Scientific Officer	2023	325,000	47,396	818,100	50,723	1,241,219
Mark Andersen(1)	2022	189,583	15,000	20,100	88,401	313,084
Chief Financial Officer	2023	325,000	66,354	820,350	70,523	1,282,227

(1) Mark Andersen joined us in June 2022.
(2) Bonus amounts reflect actual bonus payments made during the calendar year.
(3) In accordance with SEC rules, amounts in this column reflect the aggregate grant date fair value of stock options granted computed in accordance with ASC 718, rather than the amounts paid or realized by the named individual. We provide information regarding the assumptions used to calculate the value of the stock options granted in Note 12 to our audited financial statements included elsewhere in this prospectus.
(4) Amounts in the "All Other Compensation" column consist of the amounts set forth in the table below:

Named Executive Officer (2022)	401(k) Plan Matching Contributions ($)	Healthcare Benefits ($)	Relocation ($)
Pete O'Heeron	—	22,485	—
Hamid Khoja, Ph.D.	—	20,505	—
Mark Andersen	6,500	20,512	61,389

Named Executive Officer (2023)	401(k) Plan Matching Contributions ($)	Healthcare Benefits ($)	Relocation ($)
Pete O'Heeron	—	50,723	—
Hamid Khoja, Ph.D.	—	50,723	—
Mark Andersen	19,800	50,723	—

2022 Salaries

In 2022, our named executive officers received an annual base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities.

For fiscal year 2022, Mr. O'Heeron's annual base salary was $600,000 and Mr. Andersen's annual base salary was $325,000. Dr. Khoja's annual base salary was increased from $290,000 to $325,000 during fiscal year 2022.

2023 Salaries

In 2023, our named executive officers received an annual base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities.

For fiscal year 2023, Mr. O'Heeron's annual base salary was $600,000, Mr. Andersen's annual base salary was $325,000, and Dr. Khoja's annual base salary was $325,000.

2022 Bonuses

In fiscal year 2022, each named executive officer was eligible to earn his bonus based on the attainment of pre-established annual company and individual performance objectives, as determined by our board of directors in their discretion. Mr. O'Heeron was eligible to receive an annual cash bonus targeted at 50% of his base salary, and was paid a $300,000 bonus in 2023 based on 2022 performance. Dr. Khoja was eligible to earn an annual cash bonus targeted at 35% of base salary and was paid a bonus of $101,500 in 2022 after his first anniversary in 2022, and was paid a $47,396 bonus in 2023 based upon 2022 performance pro rata from the date of his first anniversary with us. Future bonuses will be based upon calendar years. Mr. Andersen was eligible to earn an annual cash bonus targeted at 35% of base salary, and was paid a $66,354 bonus in 2023 based on 2022 performance and prorated for 2022 based upon the beginning of his employment with us in June 2022.

2023 Bonuses

For fiscal year 2023, each named executive officer is eligible to earn his bonus based on the attainment of pre-established annual company and individual performance objectives, as determined by our board of directors in their discretion. Mr. O'Heeron is eligible to receive an annual cash bonus targeted at 50% of his base salary, or $300,000, Dr. Khoja is eligible to earn an annual cash bonus targeted at 35% of base salary, or $113,750, and Mr. Andersen is eligible to earn an annual cash bonus targeted at 35% of base salary, or $113,750.

Annual bonuses are determined based upon both company performance and individual contributions for the fiscal year and are generally determined and awarded in January of the subsequent year.

Equity Compensation

Dr. Khoja and Mr. Andersen each received commitments in their employment agreements for the equivalent of 7,500 stock options. These options were granted in 2022 after the 2022 Stock Plan (as defined herein) was approved and authorized. Dr. Khoja was also awarded the equivalent of 1,250 shares of non-voting common stock in 2022 prior to establishment of the 2022 Stock Plan. The stock options granted to named executives in 2022 vest 1/3 on the first anniversary date of employment and 1/36th each month thereafter until fully vested, subject to continued service, and will accelerate in full upon the occurrence of a "change in control" of the Company (as defined in the 2022 Stock Plan).

In 2023, Mr. O'Heeron, Dr. Khoja, and Mr. Andersen each received a grant of stock options under the 2022 Stock Plan. Mr. O'Heeron was awarded the equivalent of 1,853,000 shares, Dr. Khoja was awarded the equivalent of 454,500 shares, and Mr. Andersen was awarded the equivalent of 455,750 shares. The stock options granted in 2023 vest 1/4th on the first anniversary of the vesting start date, which was January 1, 2023, with the remainder to vest monthly over 36 months.

For additional information about the 2022 Stock Plan, please see the section titled "—Equity Compensation Plans" below.

Other Elements of Compensation

Retirement Plans

We participate in the Insperity 401(k) retirement savings plan, sponsored by Insperity Holdings, Inc., or the Insperity 401(k) plan, for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the Insperity 401(k) plan on the same terms as other full-time employees. In 2022 and 2023, contributions made by participants in the 401(k) plan were matched up to a specified percentage of the employee contributions on behalf of the named executive officers. These matching contributions are fully vested as of the date on which the contribution is made. Our named executive officers continue to participate in this Insperity 401(k) plan on the same terms as other full-time employees.

Employee Benefits and Perquisites

Health/Welfare Plans. All of our full-time employees, including our named executive officers, are eligible to participate in Insperity's health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We believe that the employee benefits described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

Employment Agreements with our Executive Officers

Pete O'Heeron Employment Agreement

On December 1, 2023, we entered into an employment agreement with Mr. Pete O'Heeron, pursuant to which Mr. O'Heeron agreed to serve as our President and Chief Executive Officer. Mr. O'Heeron's employment pursuant to the agreement is "at-will" and is terminable by either party for any reason and with or without notice.

Pursuant to the employment agreement, Mr. O'Heeron is entitled to receive an initial base salary of $600,000, which is to be reviewed annually by the Board of Directors or Compensation Committee but may not be reduced without Mr. O'Heeron's consent. In addition, the agreement provides that Mr. O'Heeron is eligible to receive an annual performance bonus, as reasonably determined by the Board of Directors or, to the extent delegated by the board, the Compensation Committee, based on one or more performance targets annually determined by the board or the committee, provided that to the extent all performance targets are met, the bonus is required to equal not less than 50% of his base salary. The percentage bonus target is to be reviewed periodically by the board or Compensation Committee.

The agreement also provides that Mr. O'Heeron is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Pursuant to the agreement, if Mr. O'Heeron's employment is terminated by the Company without cause (as defined in the agreement) or by Mr. O'Heeron for good reason (as defined in the agreement), then he will be eligible to receive severance in an amount equal to twelve months' base salary, paid as if he was still employed during such 12 month period, and the amount of the target bonus that would have been due during such 12 month period (payable 60 days after notice of termination). Additionally, Mr. O'Heeron shall continue to vest options during such 12 month period. If the agreement is terminated for any reason, Mr. O'Heeron is due all compensation earned through the date of termination, including unused and accrued vacation, any unpaid bonus which he is due, and a prorated portion of the bonus which would have accrued for the year of termination (with such bonus amounts being paid at the same time as bonuses are paid to other Company executives).

In the event an involuntary termination of Mr. O'Heeron's employment occurs during the 12 months following a change in control (as defined in the agreement), or within two months prior to a change in control, or in the event Mr. O'Heeron terminates his employment for any reason not sooner than six months after the occurrence of a change in control, and subject to Mr. O'Heeron entering into a release with the Company, all stock options and stock-based awards held by Mr. O'Heeron, as of the date of notice of such termination are to vest and become exercisable or nonforfeitable.

The agreement contains customary assignment of inventions and confidentiality obligations of Mr. O'Heeron, and a 12 months non-compete/non-solicitation prohibition, following the termination of his employment.

The compensation under the employment agreement (including bonus target) may be increased from time to time, by the Compensation Committee, or the Board of Directors (with the recommendation of the Compensation Committee), which increases do not require the entry into an amended employment agreement.

The Compensation Committee, or the board, with the recommendation of the Compensation Committee, may also pay or grant discretionary cash bonuses or equity bonuses from time to time in their discretion, at any time, in its/their discretion. The equity bonus may be in the form of common stock, stock options or other equity consideration, in such amounts and with such terms as may be determined by the Compensation Committee or the board, with the recommendation of the Compensation Committee, from time to time.

Hamid Khoja, Ph.D. Employment Agreement

We have entered into an employment agreement with Dr. Khoja, dated July 20, 2021, pursuant to which Dr. Khoja serves as our Chief Scientific Officer. Dr. Khoja's employment pursuant to the agreement is "at-will" and is terminable by either party for any reason and with or without notice.

Pursuant to his agreement, Dr. Khoja is entitled to receive an initial base salary of $290,000, which was increased to $325,000 in 2022. In addition, the agreement provides that Dr. Khoja is eligible to receive an annual performance bonus of up to 35% of his base salary, to be paid based on the achievement of company and individual performance goals. In connection with his entry into the offer letter, Dr. Khoja was granted a stock option award for the equivalent of 7,500 shares of common stock, which vests as to 1/3 of the shares underlying the stock option on the first anniversary of employment date and $1/36^{th}$ per month thereafter until fully vested, subject to continued employment through the applicable vesting date. Pursuant to the agreement, Dr. Khoja was also paid a one-time cash bonus equal to $15,000 in connection with his commencement of employment and was entitled to payment of up to $45,000 of relocation expenses. The agreement also provides that Dr. Khoja is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Pursuant to the agreement, if Dr. Khoja's employment is terminated by the Company without cause, then he will be eligible to receive severance in an amount equal to nine months' base salary.

Mark Andersen Employment Agreement

We have entered into an employment agreement with Mr. Andersen, dated May 20, 2022, pursuant to which Mr. Andersen serves as our Chief Financial Officer. Mr. Andersen's employment pursuant to the agreement is "at-will" and is terminable by either party for any reason with or without notice.

Pursuant to his agreement, Mr. Andersen is entitled to receive an initial base salary of $325,000. In addition, the agreement provides that Mr. Andersen is eligible to receive an annual performance bonus of up to 35% of his base salary, to be paid based on the achievement of company and individual performance goals. In connection with his entry into the agreement, Mr. Andersen was granted a stock option award for the equivalent of 7,500 shares of common stock, which vests as to 1/3 of the shares underlying the stock option on the first anniversary of employment date and $1/36^{th}$ per month thereafter, subject to continued employment through the applicable vesting date. Pursuant to the agreement, Mr. Andersen was also paid a one-time cash bonus equal to $15,000 in connection with his commencement of employment and was entitled to payment of up to $45,000 of relocation expenses. The agreement also provides that Mr. Andersen is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Pursuant to the agreement, if Mr. Andersen's employment is terminated by the Company without cause, then he will be eligible to receive severance in an amount equal to nine months' base salary.

Ruben Garcia Employment Agreement

We have entered into an employment agreement with Mr. Garcia, dated February 29, 2024, pursuant to which Mr. Garcia serves as our General Counsel. Mr. Garcia's employment pursuant to the agreement is "at-will" and is terminable by either party for any reason with or without notice.

Pursuant to his agreement, Mr. Garcia is entitled to receive an initial base salary of $325,000. In addition, the agreement provides that Mr. Garcia is eligible to receive an annual performance bonus of up to 35% of his base salary, to be paid based on the achievement of company and individual performance goals. In connection with his entry into the

agreement, Mr. Garcia was granted a stock option award for the equivalent of 180,000 shares of common stock, which vests as to 1/4 of the shares underlying the stock option on the first anniversary of employment date and 1/48th per month thereafter, subject to continued employment through the applicable vesting date. Pursuant to the agreement, Mr. Garcia was also paid a one-time cash bonus equal to $15,000 in connection with his commencement of employment and was entitled to payment of up to $30,000 of relocation expenses. The agreement also provides that Mr. Garcia is eligible to participate in the health and welfare benefit plans and programs maintained by us for the benefit of our employees.

Pursuant to the agreement, if Mr. Garcia's employment is terminated by the Company without cause, then he will be eligible to receive severance in an amount equal to nine months' base salary.

Equity Compensation Plans

The following summarizes the material terms of the FibroBiologics, Inc. 2022 Stock Plan, or the 2022 Stock Plan.

2022 Stock Plan

Our board of directors adopted on August 10, 2022, and our stockholders approved on August 18, 2022, our 2022 Stock Plan. The 2022 Stock 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. The 2022 Stock Plan, through the grant of stock awards, is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and provide a means by which the eligible recipients may benefit from increases in value of our common stock. Through March 31, 2023, we have issued the equivalent of 101,250 options with a strike price of the equivalent of $3.28 per share to employees, directors, and scientific advisory board members, and the equivalent of 3,689,750 options with a strike price of the equivalent of $2.28 per share to employees and directors, and 216,875 options with an exercise price of $13.00 per share to employees under the 2022 Stock Plan. In August 2023, a total of 2,500 options with a strike price of $3.28 per share were forfeited. Generally, awards granted by us vest over four years and, prior to public listing, have an exercise price equal to the estimated fair value of our common stock as determined by our board of directors with consideration given to contemporaneous valuations of our common stock prepared by an independent third-party valuation firm. After public listing, the exercise price is equal to the closing bid price per share on the date of grant.

As of December 31, 2023, there were the equivalent of 8,711,500 shares available for future issuance under the 2022 Stock Plan.

Outstanding Equity Awards at December 31, 2023

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2023. Other than the equivalent of 1,250 shares of non-voting common stock awarded to Dr. Khoja in 2022 prior to establishment of the 2022 Stock Plan, all awards were granted under our 2022 Stock Plan.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Pete O'Heeron	—	1,853,000	2.28	February 16, 2033
Hamid Khoja, Ph.D.	4,861	2,639	3.28	September 25, 2032
Hamid Khoja, Ph.D.	—	454,500	2.28	February 16, 2033
Mark Andersen	3,472	4,028	3.28	September 25, 2032
Mark Andersen	—	455,750	2.28	February 16, 2033

Director Compensation

Non-employee Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2022. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2022 for their services as members of our board of directors. Pete O'Heeron, our Chairperson and Chief Executive Officer, received no additional compensation for his service as a director. See the section titled "Executive Compensation" for more information on the compensation paid to or earned by O'Heeron as an employee for the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) [1] [3]	Option Awards ($)[2] [3]	Total ($)
Robert Hoffman	50,000	24,600	12,800	87,400
Victoria Niklas	43,000	24,600	12,800	80,400
Richard Cilento, Jr.	43,000	24,600	12,800	80,400
Stacy Coen	41,000	24,600	12,800	78,400
Matthew Link	41,000	24,600	12,800	78,400

(1) In January 2022, each of our non-employee directors was awarded the equivalent of 7,500 shares of stock.

(2) In September 2022, each of our non-employee directors was granted the equivalent of 5,000 stock options with an exercise price of the equivalent of $3.28 per share.

(3) The amounts reported represent the aggregate grant date fair value of the stock and stock options awarded to the non-employee directors during fiscal year 2022, calculated in accordance with ASC Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock and stock options and do not correspond to the actual economic value that may be received upon exercise of the stock options or any sale of any of the underlying shares of common stock.

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2023. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2023 for their services as members of our board of directors. Pete O'Heeron, our Chairperson and Chief Executive Officer, received no additional compensation for his service as a director. See the section titled "Executive Compensation" for more information on the compensation paid to or earned by O'Heeron as an employee for the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)[1] [2]	Total ($)
Robert Hoffman	55,000	—	333,540	388,540
Victoria Niklas	48,000	—	333,540	381,540
Richard Cilento, Jr.	43,000	—	333,540	376,540
Stacy Coen	51,000	—	333,540	384,540
Matthew Link	46,000	—	333,540	379,540

(1) In February 2023, each of our non-employee directors was granted the equivalent of 185,300 stock options with an exercise price of the equivalent of $2.28 per share.

(2) The amounts reported represent the aggregate grant date fair value of the stock options awarded to the non-employee directors during fiscal year 2023, calculated in accordance with ASC Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and do not correspond to the actual economic value that may be received upon exercise of the stock options or any sale of any of the underlying shares of common stock.

As of December 31, 2022, the non-employee members of our board of directors held the following aggregate number of unexercised options:

Name	Number of Securities Underlying Unexercised Options
Robert Hoffman	5,000
Victoria Niklas	5,000
Richard Cilento	5,000
Stacy Coen	5,000
Matthew Link	5,000

Except as set forth above, no non-employee member of our board of directors held unexercised options or unvested shares of our common stock as of December 31, 2022.

As of December 31, 2023, the non-employee members of our board of directors held the following aggregate number of unexercised options:

Name	Number of Securities Underlying Unexercised Options
Robert Hoffman	190,300
Victoria Niklas	190,300
Richard Cilento	190,300
Stacy Coen	190,300
Matthew Link	190,300

Except as set forth above, no non-employee member of our board of directors held unexercised options or unvested shares of our common stock as of December 31, 2023.

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy. The policy is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee is paid cash compensation as set forth below:

Position	Annual Retainer
Board of Directors:	
Members (other than chair)	$ 35,000
Audit Committee:	
Members (other than chair)	$ 8,000
Retainer for chair	$ 10,000
Compensation Committee:	
Members (other than chair)	$ 6,000
Retainer for chair	$ 10,000
Governance and Nominating Committee:	
Members (other than chair)	$ 5,000
Retainer for chair	$ 10,000

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an equity award the equivalent of 7,500 shares of common stock, or the Initial Grant. Furthermore, on the date of each of our annual meeting of stockholders, each non-employee director who continues as a non-employee director following such meeting will be granted an annual equity award of stock options, to purchase the equivalent of 5,000 shares, or the Annual Grant. The Annual Grant will vest in full upon the earlier of (i) the first anniversary of the date of grant or (ii) the date of the next annual meeting; provided, however, that all vesting shall cease if the director resigns from the board of directors or otherwise ceases to serve as a director, unless the board of directors determines that the circumstances warrant continuation of vesting. In addition, all vested options remain exercisable for 12 months if the director resigns from the board of directors or otherwise ceases to serve as a director. Notwithstanding the foregoing, if an outside director was initially elected to the board of directors within 12 months preceding the annual meeting, then such outside director shall receive an Annual Grant that is pro-rated on a monthly basis for time serving as an outside director.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a summary of transactions or series of transactions since inception, or currently proposed transactions or series of transactions, to which we were, or will be, a party, in which the amount involved exceeded, or will exceed, $120,000, and in which any of our directors, executive officers, or to our knowledge, beneficial owners of 5% or more of our capital stock, or 5% Security Holders, or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

Series A Preferred Stock

In May 2021, as part our formation, we issued the equivalent of 8,750,000 shares of our Series A Preferred Stock to FibroGenesis in exchange for a Patent Assignment Agreement, which assigns certain patents/applications to us, and an Intellectual Property Cross-License Agreement, which provides to us an exclusive license within defined fields of use for patents/applications retained by FibroGenesis and provides to FibroGenesis an exclusive license to the patents/applications assigned to FibroBiologics for all other fields of use.

In connection with the Direct Listing, all of our outstanding Series A Preferred Stock were automatically canceled, without the payment of additional consideration by or to the holder thereof.

Series C Preferred Stock

In January 2024, in conjunction with our Direct Listing, we issued 2,500 shares of Series C Preferred Stock with super voting rights to our CEO for no consideration.

FibroGenesis Loans

In July 2022, we loaned $300,000 to FibroGenesis at 0% interest and one year maturity date. In October 2022, we loaned an additional $60,000 to FibroGenesis at 0% interest and one year maturity. The $60,000 was fully repaid in December 2022 and the $300,000 was fully repaid in April 2023.

ROFN Agreement

In January 2023, we entered into an Agreement Regarding Right of First Negotiation with FibroGenesis, or the ROFN Agreement. In exchange for FibroGenesis' consent to amend our certificate of incorporation to (i) eliminate upon our underwritten initial public offering or the direct listing of our common stock on a securities exchange (which we collectively refer to as an IPO) or sale of our company, the liquidation preference for the Series A Preferred Stock, (ii) make the Series B Preferred Stock liquidation preference equal to Series A Preferred Stock and (iii) to provide that upon an IPO or sale of our company, the Series A Preferred Stock will be canceled for no consideration, we agreed to pay to FibroGenesis 15% of the gross proceeds from any equity investments in us prior to an IPO or sale of our company. In addition, we received a five-year right of first negotiation if FibroGenesis decides to license externally any of its technology. Through March 31, 2024, we have paid a total of $2.8 million to FibroGenesis under the ROFN Agreement based upon gross proceeds from equity investments received through January 31, 2024, the date of our direct listing, which was an IPO, and no further payments are due to FibroGenesis pursuant to the ROFN Agreement.

2021 and 2022 Convertible Notes

In December 2021, we issued and sold to investors, some of whom hold more than 5% shares, in a private placement $1.3 million of our convertible promissory notes, or the 2021 Notes. The 2021 Notes bore interest at an initial interest rate of 6.0% per annum and would have automatically converted into shares of our common stock in the event of a qualified financing. The conversion price of the 2021 Notes was equal to $200.0 million divided by the total number of equity interests prior to the dilution from the offering. The 2021 Notes were unsecured and subordinated in right of payment to the prior payment in full to all of our commercial finance lenders, insurance companies, lease financing institutions or other lending institutions approved by our board of directors and regularly engaged in the business of lending money. In April 2023, $1.3 million of these notes were converted into shares of our Series B Preferred Stock and none of the 2021 Notes are outstanding.

In January 2022 and April 2022, we issued and sold to investors, some of whom hold more than 5% of shares, in a private placement $0.35 million and $3.95 million, respectively, of our convertible promissory notes, or the 2022 Notes. The 2022 Notes bore interest at an initial interest rate of 6.0% per annum, had a one-year maturity, and could have been converted at the holder's request into shares of our common stock in the event of a qualified financing. The conversion price of the 2022 Notes was the lesser of (i) a 15% discount to the offering price of our common stock in the event of an IPO or (i) the quotient of $200.0 million divided by total equity interests prior to the dilution from the offering. The 2022 Notes were unsecured and subordinated in right of payment to the prior payment in full to all of our commercial finance lenders, insurance companies, lease financing institutions or other lending institutions approved by our board of directors and regularly engaged in the business of lending money. In February 2023 through June 2023, $4.3 million of these notes were converted into shares of our Series B Preferred Stock and none of the 2022 Notes are outstanding.

Equity and Compensation Arrangements

We adopted on August 10, 2022, and our stockholders approved on August 18, 2022, our 2022 Stock Plan, or the 2022 Plan. The 2022 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards. We issued in 2022 a total of the equivalent of 101,250 options with an exercise price the equivalent of $3.28 per share to employees, directors, and scientific advisory board members under the 2022 Plan. In February 2023, we issued an additional equivalent of 3,689,750 options with an exercise price the equivalent of $2.28 per share to employees and directors. In March 2024, we issued an additional 216,875 options with an exercise price of $13.00 per share to employees. Generally, awards granted by the Company vest over three years and, prior to public listing, have an exercise price equal to the estimated fair value of the common stock as determined by our board of directors with consideration given to contemporaneous valuations of our common stock prepared by an independent third-party valuation firm. After public listing the exercise price is equal to the closing bid price per share on the date of grant.

PRINCIPAL STOCKHOLDERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth as of April 23, 2024:

- certain information regarding the beneficial ownership of our voting securities (being our voting common stock and our Series C Preferred Stock) by (i) each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our voting securities, (ii) each of our executive officers, (iii) each of our directors and (iv) all of our directors and executive officers as a group. Except as otherwise indicated, all persons listed below have (a) sole voting power and investment power with respect to their common stock, except to the extent that authority is shared by spouses under applicable law, and (b) record and beneficial ownership with respect to their common stock.

In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the common stock issuable pursuant to options and warrants that are exercisable or settled within 60 days of April 23, 2024. Shares of common stock issuable pursuant to options and warrants are deemed outstanding for computing the percentage of the class beneficially owned by the person holding such securities but are not deemed outstanding for computing the percentage of the class beneficially owned by any other person.

In the table below, the percentage of beneficial ownership prior to the effectiveness of the registration statement of which this prospectus forms a part is based on, as applicable: (i) 32,719,125 shares of our common stock outstanding as of April 23, 2024; and (ii) 2,500 shares of our Series C Preferred Stock outstanding as of January 23, 2024, after giving effect to the Reverse Stock Split.

Each share of our Series C Preferred Stock is entitled to 13,000 votes per share. The percentage of total voting power in the table below is based on, after giving effect to the transactions described in clauses (i) and (ii) in the immediately preceding paragraph and the 13,000 votes per share of Series C Preferred Stock, the sum of (a) 32,719,125 votes, being the total number of votes associated with the 32,719,125 shares of our common stock (with each share of common stock having one vote) and (b) 32,500,000 votes, being the total number of votes associated with the 2,500 shares of Series C Preferred Stock (with each share of Series C Preferred Stock having 13,000 votes).

Unless otherwise indicated, the business address of each of the individuals and entities named below is c/o FibroBiologics, Inc., 455 E. Medical Center, Blvd., Suite 300, Houston, Texas 77598.

	Beneficial Ownership Prior to the Offering					
	Common Stock		Series C Preferred Stock			
Name and address of Beneficial Owner	Shares	%	Shares	%	Percentage of Total Voting Power[1]	Shares of Common Stock Being Registered Pursuant to this Prospectus
5% Stockholders:						
Golden Knight Incorporated, L.P.[2]	2,125,001	6.0%	—	—	3.3%	—
Executive Officers and Directors						
Pete O'Heeron, MSHA[3]	6,704,418	19.0%	2,500	100%	60.1%	—
Mark Andersen, CPA CFA[4]	165,578	*	—	—	*	—
Hamid Khoja, Ph.D. [5]	167,774	*	—	—	*	—
Ruben A. Garcia	—	—	—	—	—	—
Robert Hoffman [6]	78,127	*	—	—	*	—
Victoria Niklas, M.D.[7]	78,127	*	—	—	*	—
Richard Cilento, Jr., MBA[8]	163,852	*	—	—	*	—
Stacy Coen, MBA[9]	78,127	*	—	—	*	—
Matthew Link[10]	78,127	*	—	—	*	—
Directors and Executive Officers as a Group (9 persons)[11]	7,514,130	21.2%	2,500	100%	61.4%	—

	Beneficial Ownership After the Offering				
	Common Stock		Series C Preferred Stock		
Name and address of Beneficial Owner	Shares	%	Shares	%	Percentage of Total Voting Power[1]
5% Stockholders:					
Golden Knight Incorporated, L.P.[2]	2,125,001	5.5%	—	—	3.2%
Executive Officers and Directors					
Pete O'Heeron, MSHA[3]	6,704,418	17.2%	2,500	100%	58.5%
Mark Andersen, CPA CFA[4]	165,578	*	—	—	*
Hamid Khoja, Ph.D.[5]	167,774	*	—	—	*
Ruben A. Garcia	—	—	—	—	—
Robert Hoffman [6]	78,127	*	—	—	*
Victoria Niklas, M.D.[7]	78,127	*	—	—	*
Richard Cilento, Jr., MBA[8]	163,852	*	—	—	*
Stacy Coen, MBA[9]	78,127	*	—	—	*
Matthew Link[10]	78,127	*	—	—	*
Directors and Executive Officers as a Group (9 persons)[11]	7,514,130	19.3%	2,500	100%	59.7%

* Less than 1%.

(1) After giving effect to the rights of the Series C Preferred Stock, upon the Direct Listing, to 13,000 votes per share.
(2) Michael F. Newlin and Cindy L. Newlin, as General Partners of Golden Knight Incorporated, L.P., share discretionary authority to vote and dispose of the shares directly held by Golden Knight Incorporated, L.P. and may be deemed to be the beneficial owners of such shares. The address for Golden Knight Incorporated, L.P. is 3773 Howard Hughes Pkwy, Suite 500S, Las Vegas, NV 89189-6014.
(3) Common Stock shares include 6,048,147 shares of common stock and 656,271 vested stock options to purchase common stock. The 2,500 shares of Series C Preferred Stock held constitute the maximum number of Series C Preferred Stock we are authorized to issue. Each share of Series C Preferred Stock is entitled to 13,000 votes. For as long as they remain outstanding, the Series C Preferred Stock are subject to an irrevocable proxy issued by Pete O'Heeron in favor and for the benefit of our board of directors, as more particularly described in this prospectus.
(4) Common Stock shares include 165,578 vested stock options to purchase common stock.
(5) Common Stock shares include 1,250 shares of common stock and 166,524 vested stock options to purchase common stock.
(6) Common Stock shares include 7500 shares of common stock and 70,627 vested stock options to purchase common stock.
(7) Common Stock shares include 7,500 shares of common stock and 70,627 vested stock options to purchase common stock.
(8) Common Stock shares include 93,225 shares of common stock and 70,627 vested stock options to purchase common stock.
(9) Common Stock shares include 7,500 shares of common stock and 70,627 vested stock options to purchase common stock.
(10) Common Stock shares include 7,500 shares of common stock and 70,627 vested stock options to purchase common stock.
(11) The 2,500 shares of Series C Preferred Stock held constitute the maximum number of Series C Preferred Stock we are authorized to issue. Each share of Series C Preferred Stock is entitled to 13,000 votes. For as long as they remain outstanding, the Series C Preferred Stock are subject to an irrevocable proxy issued by Pete O'Heeron in favor and for the benefit of our board of directors, as more particularly described in this prospectus.

DESCRIPTION OF OUR SECURITIES

General

The following description summarizes certain important terms of our capital stock. We adopted an amended and restated certificate of incorporation that became effective in connection with the Direct Listing, and this description summarizes the provisions included in such document. 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 titled "*Description of Capital Stock*," you should refer to our amended and restated certificate of incorporation and our bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

In connection with the Direct Listing, (i) all of our outstanding Series A Preferred Stock, all of which were held by FibroGenesis, were automatically canceled without the payment of additional consideration by or to the holder thereof, (ii) all of our outstanding non-voting common stock automatically converted, without the payment of additional consideration by or to the holder thereof, into voting common stock, on a one-for-one basis, (iii) all of our outstanding Series B Preferred Stock and all of our outstanding Series B-1 Preferred Stock automatically converted, without the payment of additional consideration by or to the holder thereof, into common stock, on a one-for-one basis and (iv) all of our outstanding Series C Preferred Stock remained Series C Preferred Stock. Immediately after the Direct Listing, our issued and outstanding capital stock consisted of voting common stock and Series C Preferred Stock.

Our amended and restated certificate of incorporation and our bylaws, authorize us to issue 150,000,000 shares of capital stock, which may consist of: (i) 100,000,000 shares of voting common stock, par value $0.00001 per share, (ii) 30,000,000 shares of non-voting common stock, par value $0.00001 per share, and (iii) 20,000,000 shares of preferred stock, par value $0.00001 per share, of which 2,500 shares are designated as Series C Preferred Stock.

After giving effect to the Reverse Stock Split and the automatic conversion, in connection with the Direct Listing, of all of our outstanding non-voting common stock and convertible preferred stock (being our Series B Preferred Stock and Series B-1 Preferred Stock), as of January 31, 2024, there were 32,492,068 shares of our voting common stock outstanding, held by 1,169 stockholders of record, and 2,500 shares of our Series C Preferred Stock, being all of the authorized Series C Preferred Stock, outstanding, held by one stockholder of record. Pursuant to our amended and restated certificate of incorporation, our board of directors will have the authority, without stockholder approval except as required by Nasdaq rules, to issue additional shares of our capital stock.

Common Stock

Our amended and restated certificate of incorporation provides that**:**

- holders of common stock have voting rights for the election 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 amended and restated 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.

Warrants Being Offered in this Offering

The following summary of certain terms and provisions of the Warrants included in the Units offered hereby and the Warrant Agency Agreement is not complete and is subject to, and qualified in its entirety by the provisions of the form of Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Warrant and such Warrant Agency Agreement.

Exercisability. The Warrants are exercisable immediately and at any time up to the date that is five years after their original issuance. The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the Warrants under the Securities Act is not effective and an exemption from registration is not available, the holder may elect to exercise the Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Warrants. No fractional shares of common stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, we will in our election either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the investor, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

Exercise Price. The exercise price per whole share of common stock purchasable upon exercise of the Warrants is equal to 100% of the offering price per Unit. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Cashless Exercise. If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of common stock underlying the Warrants under the Securities Act is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrants.

Call option. We have the right to "call" any portion of a holder's Warrants by delivering a call notice to the holder within 30 days after we publicly announce [ ]. After delivery of a call notice, the Warrants will continue to be exercisable. Each Warrant will be canceled and no longer exercisable to the extent the holder fails to timely exercise the Warrant for the called portion thereof within 20 trading days following our issuance of a call notice, provided that to the extent the exercise of a called portion of a Warrant would cause the holder to hold shares of our common stock in excess of a specified beneficial ownership limitation, upon exercise of such portion, as set forth in the Warrant, instead of shares being issued, the exercise would result in the modification of the terms of such portion to be consistent with certain specified terms .

Transferability. Subject to applicable laws, the Warrants may be offered for sale, sold, transferred or assigned without our consent.

Adjustments; Fundamental Transactions. The exercise price and the number of shares underlying the Warrants are subject to appropriate adjustment in the event of stock splits, stock dividends on our shares of common stock, stock combinations or similar events affecting our shares of common stock. In addition, in the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power of our outstanding capital stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding capital stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Warrant.

Exchange Listing. We do not intend to apply for the listing of the Warrants offered in this offering on any stock exchange. Without an active trading market, the liquidity of the Warrants will be limited.

Amendment. The Warrants may be modified or amended with the written consent of the Company and the holders thereof.

Anti-Takeover Effects of our Certificate of Incorporation, Bylaws and Delaware Law

Our amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 amended and restated 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 bylaws provide 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 commenced trading on The Nasdaq Global Market under the symbol "FBLG" on January 31, 2024.

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.

PLAN OF DISTRIBUTION

We are offering up to a maximum of 1,801,801 Units, based on an assumed public offering price of $11.10 per Unit, which represents the closing price of our common stock on The Nasdaq Global Market on April 23, 2024, for gross proceeds of up to $20.0 million before deduction of placement agent commissions and offering expenses, in a best-efforts offering. There is no minimum amount of proceeds that is a condition to closing of this offering. The actual amount of gross proceeds, if any, in this offering could vary substantially from the gross proceeds from the sale of the maximum amount of securities being offered in this prospectus.

Pursuant to a placement agency agreement, dated as of , 2024, we have engaged Maxim Group LLC to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its "best efforts" to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agent may engage one or more subagents or selected dealers in connection with this offering.

The placement agency agreement provides that the placement agent's obligations are subject to conditions contained in the placement agency agreement.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement and the Units will be offered at a fixed price and are expected to be issued in a single closing. We expect to deliver the securities being offered pursuant to this prospectus on or about , 2024.

Placement Agent Fees, Commissions and Expenses

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to 7.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. We paid the placement agent $15,000 (the "Advance") as an advance against certain out-of-pocket expenses upon execution of an engagement letter and agreed to reimburse reasonable and documented out-of-pocket expenses of the placement agent, including fees and expenses of outside counsel, up to $85,000 (including the Advance). Any portion of the Advance not offset by actual expenses will be returned to us in accordance with Financial Industry Regulation Authority Rule 5110(g)(4)(A).

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us.

	Per Unit	Total
Public offering price	$	$
Placement agent fees[(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) Does not include additional compensation the Placement Agent will receive and reimbursement for out-of-pocket expenses incurred in connection with this offering as described above.

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the placement agent commission, will be approximately $0.2 million, all of which are payable by us. This figure includes, among other things, the placement agent's fees and expenses (including the legal fees, costs and expenses for the placement agent's legal counsel) up to $85,000.

Upon consummation of this offering, we agreed to pay to the placement agent a tail fee equal to the cash compensation in this offering, if we receive proceeds from any investor who was contacted or introduced by the placement agent in connection with this offering in any other financing of equity or equity-linked capital-raising activity during the 12-month period following the completion of this offering.

Lock-Up Agreements

We and our officers and directors have agreed, subject to limited exceptions, including issuances by us of securities in accordance with the GEM SPA, for a period of ninety (90) days after the closing of this offering, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the placement agent agreement or thereafter acquired without the prior written consent of the placement agent, provided, however, that we shall not file publicly a registration statement on Form S-1 related to the GEM SPA until thirty (30) days after the closing of this offering. The placement agent may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the placement agent may be required to make for these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Right of First Refusal

For a period of nine months after the closing of this offering, Maxim has a right of first refusal to act as sole managing underwriter and sole book runner, sole placement agent, or sole sales agent, for any and all future public or private equity, equity-linked or debt (excluding commercial bank debt) offerings for which we retain the service of an underwriter, agent, advisor, finder or other person or entity in connection with such offering during such nine-month period for us, or any successor to us or any of our subsidiaries. We shall not offer to retain any entity or person in connection with any such offering on terms more favorable than terms on which we offer to retain Maxim. Such offer shall be made in writing in order to be effective. Maxim shall notify us within ten business days of its receipt of the written offer contemplated above as to whether or not it agrees to accept such retention. If Maxim should decline such retention, we shall have no further obligations to Maxim with respect to the offering for which we have offered to retain Maxim.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as placement agent and should not be relied upon by investors.

Certain Relationships

The placement agent and its affiliates have provided and may in the future provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

Determination of Offering Price and Warrant Exercise Price

The actual offering price of the securities we are offering, and the exercise price of the Warrants included in the Units that we are offering, were negotiated between us, the placement agent and the investors in the offering based on the trading of our shares of common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering, as well as the exercise price of the Warrants that we are offering include our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is vStock Transfer LLC, at 18 Lafayette Place, Woodmere, NY 11598. The transfer agent's telephone number is (212) 828-8436.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the placement agent that would permit a public offering by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that country or jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the placement agent is not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area-Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code Monétaire et Financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-1 to D.411-3, D.744-1, D.754-1 ;and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1; and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The securities may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societ-$$-Aga e la Borsa, "CONSOB" pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors"); and

- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such securities, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA") has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a general discussion of certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of Units, consisting of shares of common stock and Warrants, the acquisition, ownership, and disposition of shares of common stock acquired as part of the Units, the exercise, disposition, or expiration of Warrants acquired as part of the Units, the acquisition, ownership, and disposition of shares of common stock received upon exercise of the Warrants (the "warrant shares"), all as acquired pursuant to this prospectus. Because the shares of common stock and Warrants are immediately separable and will be issued separately, the holder of a Unit generally should be treated, for U.S. federal income tax purposes, as the owner of the underlying share of common stock and one Investor Warrant that comprise the Unit, as the case may be. As a result, the discussion below with respect to actual holders of shares of common stock and Warrants should also apply to holders of Units (as the deemed owners of the underlying common stock and Warrants that comprise the Units).

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation that, if enacted, could be applied on a retroactive or prospective basis. We have not sought and will not seek any rulings from the Internal Revenue Service (the "IRS"), regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders (each as defined below) who are initial purchasers of a Unit pursuant to this offering and hold Units, shares of common stock, Warrants, or warrant shares, as applicable, as a capital asset within the meaning of Section 1221 of the Internal Revenue Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate and gift taxes. Except as provided below, this summary does not address tax reporting requirements. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations and governmental organizations;
- banks or other financial institutions;
- brokers or dealers in securities or foreign currency;
- traders or dealers in securities who elect to apply a mark-to-market method of accounting;
- real estate investment trusts, regulated investment companies or mutual funds;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations organized outside the United States, any state thereof, or the District of Columbia that are nonetheless treated as U.S. persons for U.S. federal income tax purposes;
- persons that own (directly, indirectly or constructively) more than 5% of the total voting power or total value of our common stock;
- corporations that accumulate earnings to avoid U.S. federal income tax;

- persons subject to the alternative minimum tax;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- U.S. holders (as defined below) that have a "functional currency" other than the U.S. dollar;
- persons that acquire Units, shares of common stock, Warrants or warrant shares as compensation for services;
- owners that hold our stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- holders subject to special accounting rules;
- S corporations (and shareholders thereof);
- partnerships or other entities or arrangements treated as partnerships or other "pass-through" entities for U.S. federal income tax purposes (and partners or other owners thereof); and
- U.S. holders that are subject to taxing jurisdictions other than, or in addition to, the United States with respect to their Units, shares of common stock, Warrants or warrant shares, or that hold such securities in connection with a trade or business, permanent establishment or fixed base outside the United States.

If an entity or arrangement taxable as a partnership (or other pass-through" entity) for U.S. federal income tax purposes holds our Units, shares of common stock, Warrants or warrant shares, the U.S. federal income tax treatment of such entity (or arrangement) and the partners (or other owners) of such entity generally will depend on the status of the partners, the activities of the entity and certain determinations made at the partner level. This summary does not address the tax consequences to any such owner. Partners (or other owners) of entities or arrangements that are classified as partnerships or as "pass-through" entities for U.S. federal income tax purposes should consult their own tax advisors regarding the U.S. federal, U.S. federal net investment income, U.S. federal alternative minimum, U.S. federal estate and gift, U.S. state and local, and non-U.S. tax consequences arising from and relating to the acquisition, ownership, and disposition our Units, shares of common stock, Warrants or warrant shares.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of our Units, shares of common stock, Warrants or warrant shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A "non-U.S. holder" is a beneficial owner of our Units, shares of common stock, Warrants or warrant shares that is neither a U.S. holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT, AND IS NOT INTENDED TO BE, LEGAL OR TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. INCOME, ESTATE AND OTHER TAX CONSIDERATIONS OF ACQUIRING, HOLDING AND DISPOSING OF OUR UNITS, SHARES OF COMMON STOCK, WARRANTS OR WARRANT SHARES.

U.S. Federal Income Tax Consequences of the Acquisition and Disposition of Units

No statutory, administrative or judicial authority directly addresses the treatment of a Unit or any instrument similar to a Unit for U.S. federal income tax purposes and, therefore, that treatment is not entirely clear. For U.S. federal income tax purposes, the acquisition by a U.S. holder or a non-U.S. holder of a Unit should be treated as the acquisition of one share of common stock and one Investor Warrant that comprise the Unit. The purchase price for each Unit will be allocated among these two components in proportion to their relative fair market values at the time the Unit is purchased. Under U.S. federal income tax law, each investor must make his or her own determination of such value based on all the relevant facts and circumstances. Therefore, we strongly urge each investor to consult his or her tax advisor regarding the determination of value for these purposes. This allocation of the purchase price for each Unit will establish a U.S. holder's or non-U.S. holder's initial tax basis for U.S. federal income tax purposes in the one share of common stock and the one Investor Warrant that comprise each Unit.

For U.S. federal income tax purposes, the disposition of a Unit will be treated for U.S. federal income tax purposes as a disposition of the one share of common stock and the one Investor Warrant that comprise the Unit, and the amount realized on the disposition will be allocated among these two components in proportion to their relative fair market values (as determined by each such holder based on all the relevant facts and circumstances) at the time of disposition. The separation of the shares of common stock and Warrants comprising the Units should not be a taxable event for U.S. federal income tax purposes.

The foregoing treatment of the Units, shares of common stock and Warrants and a holder's allocation are not binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the Units, no assurance can be given that the IRS or a U.S. court will respect the characterization of the Units or a holder's allocation set forth above. Each U.S. holder and non-U.S. holder should consult its own tax advisor regarding the tax consequences of an investment in a Unit (including alternative characterizations of a Unit). The balance of this
discussion assumes that the characterization of the Units described above will be respected for U.S. federal income tax purposes.

U.S. Holders

U.S. Federal Income Tax Consequences of the Exercise, Disposition or Expiration of Warrants or Certain Adjustments to the Warrants

Exercise of Warrants

A U.S. holder should not recognize gain or loss on the exercise of Warrants and related receipt of warrant shares (unless cash is received in lieu of the issuance of a fractional warrant share). A U.S. holder's initial tax basis in the warrant shares received on the exercise of Warrants should be equal to the sum of (a) such U.S. holder's tax basis in such Warrants plus (b) the exercise price paid by such U.S. holder on the exercise of such Warrants. It is unclear whether a U.S. holder's holding period for the warrant shares received on the exercise of Warrants would commence on the date of exercise of the Warrants or the day following the date of exercise of the Warrants.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of Warrants into warrant shares. The U.S. federal income tax treatment of a cashless exercise of Warrants into warrant shares is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of Warrants described in the preceding paragraph. A cashless exercise may not be taxable, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either situation, a U.S. holder's basis in the warrant shares received would equal the holder's basis in the Warrants exercised therefor. If the cashless exercise were treated as not being a realization event, it is unclear whether a U.S. holder's holding period for the warrant shares received on the cashless exercise of Warrants would commence on the date of exercise of the Warrants or the day following the date of exercise of the Warrants. If the cashless exercise were treated as a recapitalization, the holding period of the warrant shares would include the holding period of the Warrants exercised therefor.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered a number of Warrants having a fair market value equal to the exercise price for the total number of Warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the Warrants deemed surrendered and the U.S. holder's tax basis in the Warrants deemed surrendered. In this case, a U.S. holder's aggregate tax basis in the warrant shares received would equal the sum of the U.S. holder's tax basis in the Warrants deemed exercised and the exercise price of such Warrants. It is unclear whether a U.S. holder's holding period for the warrant shares received would commence on the date of the deemed exercise of the Warrants or the day following the date of the deemed exercise of the Warrants.

Because of the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a U.S. court. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Warrants.

Disposition of Warrants

A U.S. holder will recognize gain or loss on the sale or other taxable disposition of an Investor Warrant in an amount equal to the difference, if any, between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in the Investor Warrant sold or otherwise disposed of. Any such gain or loss generally will be a capital gain or loss, which will be long-term capital gain or loss if the Investor Warrant is held for more than one year. Deductions for capital losses are subject to complex limitations under the Internal Revenue Code.

Expiration of Warrants Without Exercise

Upon the lapse or expiration of an Investor Warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the Investor Warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the Investor Warrant is held for more than one year. Deductions for capital losses are subject to complex limitations under the Internal Revenue Code.

Certain Adjustments to the Warrants

Under Section 305 of the Internal Revenue Code, an adjustment to the number of warrant shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a U.S. holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. holder's proportionate interest in the "earnings and profits" or our assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of Warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. (See more detailed discussion of the rules applicable to distributions made by us at "*Distributions on Shares of Common Stock and Warrant Shares*" below).

U.S. Federal Income Tax Consequences of the Ownership, and Disposition of Shares of Common Stock and Warrant Shares

Distributions on Shares of Common Stock and Warrant Shares

A U.S. holder that receives a distribution, including a constructive distribution, with respect to a share of common stock or warrant share (as well as any constructive distribution on an Investor Warrant as described above) will be required to include the amount of such distribution in gross income as a dividend to the extent of our current and accumulated "earnings and profits", as computed under U.S. federal income tax principles. To the extent that a distribution exceeds our current and accumulated "earnings and profits", such distribution will be treated first as a tax-free return of capital to the extent of a U.S. holder's tax basis in the shares of common stock or warrant shares and thereafter as gain from the sale or exchange of such shares of common stock or warrant shares (see "*Sale or Other Taxable Disposition of Shares of Common Stock and/or Warrant Shares*" below). Dividends received on shares of common stock or warrant shares may be eligible for a dividends received deduction, subject to certain restrictions relating to, among others, the corporate U.S. holder's holding period. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), dividends paid by us to non-corporate U.S. holders, including individuals, generally will be eligible for the preferential tax rates applicable to long-term capital gains for dividends, provided certain holding period and other conditions are satisfied. The dividend rules are complex, and each U.S. holder should consult its own tax advisor regarding the application of such rules.

Sale or Other Taxable Disposition of Shares of Common Stock and/or Warrant Shares

Upon the sale or other taxable disposition of shares of common stock or warrant shares, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such shares of common stock or warrant shares sold or otherwise disposed of. Gain or loss recognized on such sale or other taxable disposition generally will be long-term capital gain or loss if, at the time of the sale or other taxable disposition, the shares of common stock or warrant shares have been held for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. There are no preferential tax rates for long-term capital gain of a U.S. holder that is a corporation. Deductions for capital losses are subject to significant limitations under the Internal Revenue Code.

Non-U.S. Holders

U.S. Federal Income Tax Consequences of the Exercise, Disposition or Expiration of Warrants or Certain Adjustments to the Warrants

Exercise or Expiration (Without Exercise) of Warrants

The U.S. federal income tax treatment of a non-U.S. holder's exercise of an Investor Warrant, or the expiration (without exercise) of an *Investor Warrant* held by a non-U.S. holder, will correspond to the U.S. federal income tax treatment of the exercise of an Investor Warrant by a U.S. holder or the expiration (without exercise) of an Investor Warrant held by a U.S. holder , as described above under "U.S. Holders—Exercise of Warrants" and "U.S. Holders—Expiration of Warrants Without Exercise," respectively, although to the extent of a cashless exercise results in a taxable exchange of Warrants, the consequences would be similar to those described below in "Non-U.S. Holders—*Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Warrants and Warrant Shares*."

Certain Adjustments to the Warrants

Under Section 305 of the Internal Revenue Code, an adjustment to the number of warrant shares that will be issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a non-U.S. holder of the Warrants if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of a Investor Warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the Warrants should generally not result in a constructive distribution. See the more detailed discussion of the rules applicable to distributions made by us under the heading "*Distributions on Shares of Common Stock and Warrant Shares*" below.

U.S. Federal Income Tax Consequences of the Acquisition, Ownership, and Disposition of Shares of Common Stock and Warrant Shares

Distributions on Shares of Common Stock and Warrant Shares

If we pay distributions of cash or property with respect to our shares of common stock or warrant shares, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of common stock or warrants shares, as applicable. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "- *Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Warrants and Warrant Shares*." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, shares of common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations. If we are a USRPHC (as defined below) and we do not qualify for the Regularly Traded Exception (as defined below), distributions that exceed our current and accumulated earnings and profits will be subject to a 15% withholding tax unless an application for a withholding certificate is filed to reduce or eliminate such withholding.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States (or, if an income tax treaty applies, attributable to a permanent establishment maintained by the non-U.S. holder in the United States) are generally not subject to the 30% (or lower rate as may be specified by an applicable tax treaty) withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business (or, if an income tax treaty applies, the distribution is attributable to a permanent establishment maintained by the non-U.S. holder in the United States), the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income (or, under an applicable income tax treaty, income attributable to a permanent establishment maintained by a non-U.S. holder in the United States) received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Sale, Exchange or Other Taxable Disposition of Shares of Common Stock, Warrants and Warrant Shares

Subject to the discussions below in *"-Information Reporting and Backup Withholding*" and *"-Foreign Account Tax Compliance Act*," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our shares of common stock, Warrants, or warrant shares unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

- the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or

- we are or have been a "U.S. real property holding corporation" ("**USRPHC**") for U.S. federal income tax purposes at any time during the shorter of the non-U.S. holder's holding period or the 5-year period ending on the date of disposition of shares of common stock, Warrants or warrant shares; provided, with respect to the shares of common stock and warrant shares, that as long as our shares of common stock are regularly traded on an established securities market as determined under the U.S. Treasury Regulations (the "**Regularly Traded Exception**"), a non-U.S. holder would not be subject to taxation on the gain on the sale of shares of common stock or warrant shares under this rule unless the non-U.S. holder has owned: (i) more than 5% of our shares of common stock at any time during such 5-year or shorter period; (ii) Warrants with a fair market value on the date acquired by such holder greater than the fair market value on that date of 5% of our shares of common stock; or (iii) aggregate equity securities of ours with a fair market value on the date acquired in excess of 5% of the fair market value of our shares of common stock on such date (in any case, a "**5% Shareholder**"). Since the Warrants are not expected to be listed on a securities market, the Warrants are unlikely to qualify for the Regularly Traded Exception. In determining whether a non-U.S. holder is a 5% Shareholder, certain attribution rules apply in determining ownership for this purpose. We can provide no assurances that we are not currently, or will not become , a USRPHC, or if we are or become a USRPHC, that the shares of common stock, Warrants or warrant shares will meet the Regularly Traded Exception at the time a non-U.S. holder purchases such securities or sells, exchanges or otherwise disposes of such securities. Non-U.S. holders should consult with their own tax advisors regarding the consequences to them of investing in a USRPHC. If we are a USRPHC, a non-U.S. holder will be taxed as if any gain or loss were effectively connected with the conduct of a trade or business as described above in "*Distributions on Shares of Common Stock and Warrant Shares*" and a buyer of our common stock, Warrants or warrant shares from such holder may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized by the non-U.S. holder, in the event that (i) such holder is a 5% Shareholder, or (ii) the Regularly Traded Exception is not satisfied during the relevant period. We will be classified as a USRPHC if the fair market value of our "United States real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes.

Information Reporting and Backup Withholding

Distributions on our common stock and warrant shares, and the payment of the proceeds of a disposition of, our Units, shares of common stock, Warrants and warrant shares generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements. Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

Foreign Account Tax Compliance Act

Sections 1471 through 1474 of the Internal Revenue Code (commonly referred to as "**FATCA**") impose a separate reporting regime and potentially a 30% withholding tax on certain payments, including payments of dividends (including constructive dividends) on our shares of common stock and warrant shares. Withholding under FATCA generally applies to payments made to or through a foreign entity if such entity fails to satisfy certain disclosure and reporting rules. These rules generally require (i) in the case of a foreign financial institution, that the financial institution agree to identify and provide information in respect of financial accounts held (directly or indirectly) by U.S. persons and U.S.-owned entities, and, in certain instances, to withhold on payments to account holders that fail to provide the required information, and (ii) in the case of a non-financial foreign entity, that the entity either identify and provide information in respect of its substantial U.S. owners or certify that it has no such U.S. owners. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits.

FATCA withholding also potentially applies to payments of gross proceeds from the sale or other disposition of our shares of common stock and warrant shares. Proposed U.S. Treasury Regulations, however, would eliminate FATCA withholding on such payments, and the U.S. Treasury Department has indicated that taxpayers may rely on this aspect of the proposed U.S. Treasury Regulations until final U.S. Treasury Regulations are issued.

Non-U.S. holders typically will be required to furnish certifications (generally on the applicable IRS Form W-8) or other documentation to provide the information required by FATCA or to establish compliance with or an exemption from withholding under FATCA. FATCA withholding may apply where payments are made through a non-U.S. intermediary that is not FATCA compliant, even where the non-U.S. holder satisfies the holder's own FATCA obligations.

The United States and a number of other jurisdictions have entered into intergovernmental agreements to facilitate the implementation of FATCA. Any applicable intergovernmental agreement may alter one or more of the FATCA information reporting and withholding requirements. You are encouraged to consult with your own tax advisor regarding the possible implications of FATCA on your investment in our shares of common stock or warrant shares, including the applicability of any intergovernmental agreements.

THE ABOVE SUMMARY IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO PROSPECTIVE INVESTORS WITH RESPECT TO THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF UNITS, SHARES OF COMMON STOCK, WARRANTS OR WARRANT SHARES. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE TAX CONSIDERATIONS APPLICABLE TO THEM IN LIGHT OF THEIR OWN PARTICULAR CIRCUMSTANCES.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Norton Rose Fulbright US LLP, Houston, Texas. The placement agent is being represented by Thompson Hine LLP, New York, New York in connection with this offering.

EXPERTS

The financial statements of FibroBiologics, Inc. as of and for the years ended December 31, 2023 and 2022 have been audited by Withum Smith+Brown, PC, an independent registered public accounting firm, as stated in their report incorporated by reference herein. Such audited financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with such law, will file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may obtain documents that we file with the SEC at www.sec.gov. Our website address is www.fibrobiologics.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

SEC rules permit us to "incorporate by reference" certain information into this prospectus, which means that we can disclose important information about us by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except for information superseded by information contained in this prospectus or in any subsequently filed incorporated document. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must carefully review all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. However, we undertake no obligation to update or revise any statements we make, except as required by law.

This prospectus incorporates by reference the documents listed below and any filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents furnished and not filed with the SEC) on or after the date of this prospectus and prior to the termination of the offering covered by this prospectus:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 29, 2024;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 14, 2024; and
- our Current Reports on Form 8-K, filed with the SEC on February 2, 2024, February 6, 2024, February 8, 2024, February 14, 2024 , February 20, 2024 and April 26, 2024 (except, in each case, any information, including exhibits, furnished and not filed with the SEC).

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or in any subsequently filed document which is or is deemed to be incorporated by reference in this prospectus modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. Any such request may be made by writing or calling us at the following address or phone number:

FibroBiologics, Inc.
455 E. Medical Center Blvd.
Suite 300
Houston, Texas 77598
(281) 671-5150

FibroBiologics, Inc.

Up to 1,801,801 Units, each consisting of
One Share of Common Stock and
One Warrant to Purchase One Share of Common Stock

1,801,801 Shares of Common Stock Underlying the Warrants

PRELIMINARY PROSPECTUS

, 2024

Sole Placement Agent

Maxim Group LLC

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. ***Other Expenses of Issuance and Distribution***

The following table sets forth the costs and expenses payable by us in connection with this registration statement and the listing of our common stock. All amounts shown are estimates except for the SEC registration fee.

	Amount
SEC registration fee	$ 5,904
Legal fees and expenses	185,000
Accounting fees and expenses	20,000
Printing and engraving expenses	5,000
Transfer agent fees and expenses	5,000
FINRA fees	3,500
Miscellaneous expenses	1,500
Total	$ 225,904

Item 14. ***Indemnification of Directors and Officers***

We are incorporated under the laws of the State of Delaware. Section 145 of the DGCL provides that a Delaware corporation may indemnify any person who was or is, or is threatened to be made, a party to any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Section 145 of the DGCL also provides that a Delaware corporation may indemnify any person who was or is, or is threatened to be made, a party to any threatened, pending, or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification of any claim, issue or matter is permitted without judicial approval if such person is adjudged to be liable to the corporation.

Under the DGCL, where a present or former officer or director is successful on the merits or otherwise in the defense of any action referred to above, or in defense of any claim, issue or matter therein, the corporation must indemnify such present or former officer or director against the expenses (including attorney's fees) which such present or former officer or director actually and reasonably incurred in connection with such action (or claim, issue or matter therein).

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director or officer, except for liability for any:

- breach of a director's or officer's duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- in the case of a director, unlawful payment of dividends or unlawful stock purchase or redemption;
- transaction from which the director or officer derived an improper personal benefit; or
- in the case of an officer, any action by or in the right of the corporation.

Our amended and restated certificate of incorporation contains a provision that precludes any director or officer of ours from being personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director or officer, except for the aforementioned liabilities which we are not permitted to eliminate or limit under Section 102(b)(7) of the DGCL.

In addition, our amended and restated certificate of incorporation and bylaws, in each case, require us to indemnify, and advance expenses to, to the fullest extent permitted by law, any person who was or is, or is threatened to be made, a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative by reason of the fact that the person is or was our director, officer, employee or agent, or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise.

Our bylaws authorize us to purchase and maintain insurance on behalf of any person who is or was our director, officer, employee or agent, or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, enterprise or nonprofit entity against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not we would have the power to indemnify such person against such liability under the provisions of the DGCL.

We maintain an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act. In addition, we entered into separate indemnification agreements with each of our directors and executive officers.

Item 15. ***Recent Sales of Unregistered Securities***

The following sets forth information regarding all unregistered securities we have issued since our inception. Unless stated otherwise, the sale of the securities listed below were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering.

Series A Preferred Stock

In connection with our formation, on April 8, 2021, we issued the equivalent of 8,750,000 shares of our Series A Preferred Stock to FibroGenesis in return for rights to certain intellectual property through the Patent Assignment Agreement and the Intellectual Property Cross-License Agreement. See "*Business—Intellectual Property*" for additional details. No underwriters were involved in the sale of the securities.

Non-Voting Common Stock

In January 2022, we issued an aggregate of the equivalent of 37,500 shares of our non-voting common stock for no cash consideration to five of our independent directors, the equivalent of 7,500 shares each, for their service on our board of directors.

In March 2022, we issued the equivalent of 12,500 shares and 1,250 shares, respectively, of our non-voting common stock for no cash consideration to Dr. An and Dr. Khoja for services provided.

In August 2022, we issued the equivalent of 28,179,592 of our nonvoting common stock to our parent company, FibroGenesis.

Series B Preferred Stock

In December 2022, we issued an aggregate of the equivalent of 381,658 shares of Series B Preferred Stock to investors in a private placement, at a price the equivalent of $6.76 with respect to the equivalent of 318,049 shares, with the remaining equivalent of 63,609 shares being bonus shares.

From February 2023 through April 2023, we issued an aggregate of the equivalent of 890,310 shares of our Series B Preferred Stock to investors in a Regulation Crowdfunding offering, at a price the equivalent of $6.76 as to the equivalent of 724,937 shares, with the remaining equivalent of 143,225 shares and equivalent of 22,148 shares being bonus and commission shares, respectively. The sales of the foregoing securities were issued pursuant to the exemption provided by Section 4(a)(6) of the Securities Act.

In March and April 2023, we issued an aggregate of the equivalent of 1,680,084 shares of our Series B Preferred Stock to investors in private placements, at a price the equivalent of $6.76 as to the equivalent of 1,527,349 shares, with the remaining equivalent of 152,735 shares being bonus shares.

Series B-1 Preferred Stock

From April 2023 through September 2023, we issued an aggregate of the equivalent of 74,922 shares of our Series B-1 Preferred Stock to investors in a private placement, at prices ranging from the equivalent of $18.00 to $20.00 per share as to the equivalent of 64,070 shares, with the remaining equivalent of 10,852 shares being bonus shares. In connection with a portion of such private placement of our Series B-1 Preferred Stock, we also agreed to issue warrants, exercisable for a period of three years from their issuance date, to purchase an aggregate of the equivalent of an aggregate of 8,890 shares of our common stock at an exercise price of the equivalent of $20.00 per share. In November 2023, the Company issued a total of 14,859 additional shares of Series B-1 Preferred Stock and 1,431 additional warrants to purchase shares of common stock to investors who subscribed to purchase shares of Series B-1 Preferred Stock at a price per share that exceeded the reference price per share expected in the Direct Listing.

Series C Preferred Stock

In January 2024, in conjunction with our Direct Listing, we issued 2,500 shares of Series C Preferred Stock with super voting rights to our CEO for no consideration.

Voting Common Stock

In February 2024, we issued 142,298 shares of our voting common stock to GEM for approximately $1.8 million of net proceeds, pursuant to the draw-down notice we issued under the GEM SPA to have GEM purchase up to 900,000 shares of the Company's common stock at a draw-down threshold price of no less than $15.00 per share, which was closed after 142,298 shares of our common stock were purchased at $13.50 per share. We then authorized a reduction of the draw-down threshold price to no less than $13.50 per share, and GEM submitted one additional closing notice in March 2024 after 84,759 shares of our common stock were purchased pursuant to the GEM SPA at $12.15 per share for net cash proceeds of approximately $1.0 million.

Warrants

In January 2024, in accordance with the GEM SPA, we issued a warrant to purchase up to 1,299,783 shares of our voting common stock with an initial exercise price of $21.54 per share to GYBL for no additional consideration.

Item 16. ***Exhibits and Financial Statement Schedules***

Exhibits

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement, which Exhibit Index is incorporated herein by reference.

Financial Statement Schedules

All financial statement schedules are omitted because the information called for is not required or is shown either in the financial statements or in the accompanying notes.

Item 17. ***Undertakings***

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (a)(1)(i), (ii), and (iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit No.	
1.1*	Form of Placement Agent Agreement
3.1	Amended and Restated Certificate of Incorporation of the registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
3.2	Bylaws of the registrant, as currently in effect (incorporated by reference to Exhibit 3.2 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
4.1	Reference is made to exhibits 3.1 through 3.2.
4.2	Form of Warrant of FibroBiologics, Inc. issued pursuant to the GEM Agreement (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A filed on March 15, 2024 (File No. 333-277019).
4.3*	Form of Warrant issued to Series B-1 Holders.
4.4*	Form of Warrant to be issued to Purchasers.
5.1*	Opinion of Norton Rose Fulbright US LLP.
10.1	Intellectual Property Cross-License Agreement dated as of May 17, 2021, between SpinalCyte LLC and FibroBiologics, LLC (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.2	Patent Assignment Agreement dated May 17, 2021, between SpinalCyte LLC and FibroBiologics, LLC (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.3	Share Purchase Agreement dated as of November 12, 2021, by and among FibroBiologics, LLC GEM Global Yield LLC SCS and GEM Yield Bahamas Limited (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.4	Registration Rights Agreement dated November 12, 2021, by and among FibroBiologics, LLC GEM Global Yield LLC SCS and GEM Yield Bahamas Limited (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.5	Bridge Note dated April 1, 2021, between SpinalCyte LLC and FibroBiologics, Inc (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.6	Sublease Agreement between United Fire & Casualty Company and FibroBiologics, Inc., effective October 5, 2022 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.7	License Agreement, dated November 30, 2021, between K2 Biolabs, LLC and FibroBiologics, LLC (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.8	Amendment No. 1, effective July 1, 2022, to the License Agreement between K2 Biolabs, LLC and FibroBiologics, Inc. (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.9	Amendment No. 2, effective August 1, 2022, to the License Agreement between K2 Biolabs, LLC and FibroBiologics, Inc. (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.10	Amendment No. 3, effective October 1, 2022, to the License Agreement between K2 Biolabs, LLC and FibroBiologics, Inc. (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).

10.11	Amendment No. 4, effective January 1, 2023, to the License Agreement between K2 Biolabs, LLC and FibroBiologics, Inc. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.12	2022 Stock Plan (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.13	Employment Agreement effective from July 20, 2021, between FibroBiologics, LLC and Hamid Khoja (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.14	Employment Agreement effective from May 31, 2022, between FibroBiologics, Inc. and Mark Andersen (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.15	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.16	Energy Research Park Industrial Lease between University of Houston System, as Landlord, and FibroBiologics, Inc., as Tenant, effective August 1, 2023 (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.17	IP Transfer Agreement between SpinalCyte, LLC and FibroBiologics, LLC, dated as of May 17, 2021 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.18	Amendment 1 to the Patent Assignment Agreement, effective August 2, 2022 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.19	Agreement Regarding Right of First Negotiation dated January 20, 2023 (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1/A filed on November 30, 2023 (File No. 333-275361)).
10.20	Form of Stock Option Notice and Grant Agreement (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.21	Amendment 1 to Energy Research Park Industrial Lease between University of Houston System, as Landlord, and FibroBiologics, Inc., as Tenant, effective October 1, 2023 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1/A filed on March 15, 2024 (File No. 333-277019).
10.22	Employment Agreement effective from December 1, 2023, between FibroBiologics, Inc. and Pete O'Heeron (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-1/A filed on December 4, 2023 (File No. 333-275361)).
10.23	Employment Agreement effective from March 1, 2024, between FibroBiologics, Inc. and Ruben Garcia (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S-1/A filed on March 15, 2024 (File No. 333-277019).
10.24*	Form of Securities Purchase Agreement
10.25*	Form of Warrant Agent Agreement
23.1*	Consent of Norton Rose Fulbright US LLP (included in Exhibit 5.1).
23.2	Consent of WithumSmith+Brown PC.
23.3*	Consent of Howard An, M.D.
24.1*	Power of Attorney.
107*	Filing Fee Table

*Previously filed

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Houston, State of Texas, on May 15, 2024.

FibroBiologics, Inc.

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons 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)	May 15, 2024
/s/ Mark Andersen Mark Andersen	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 15, 2024
* Robert Hoffman	Director	May 15, 2024
* Victoria Niklas, M.D.	Director	May 15, 2024
* Richard Cilento	Director	May 15, 2024
* Stacy Coen	Director	May 15, 2024
* Matthew Link	Director	May 15, 2024

*By: */s/ Mark Andersen*
Name: Mark Andersen
Title: Attorney-in-fact

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement Amendment No. 1 on Form S-1 of our report dated February 29, 2024, relating to the financial statements of FibroBiologics, Inc. as of and for the years ended December 31, 2023 and 2022, which is incorporated by reference in that Prospectus.

We also consent to the reference to our firm under the caption "Experts" in the Prospectus.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
May 15, 2024