UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39438

GEMINI THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-1612845**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Address Not Applicable[1]	**Address Not Applicable**[1]
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 401-4400

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	GMTX	The Nasdaq Global Market

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's Common Stock on The Nasdaq Global Market on June 30, 2021, was $173,315,118.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2022 was 43,208,159.

DOCUMENTS INCORPORATED BY REFERENCE

None.

[1] In January 2022, the Company became a remote-first company. Accordingly, the Company does not currently maintain a physical headquarters.

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Gemini Therapeutics, Inc.

As used in this Annual Report on Form 10-K, unless otherwise indicated or the context otherwise requires, references to "Gemini," "we," "us," "our" and other similar terms refer to Gemini Therapeutics, Inc. and its consolidated subsidiaries after giving effect to the Business Combination (as defined herein) with FS Development Corporation (as defined herein) and to Gemini Therapeutics, Inc. as it existed prior to the Business Combination.

On February 5, 2021 (the "Closing Date"), FS Development Corporation, a Delaware corporation ("FSDC"), consummated a business combination (the "Business Combination"), by and among Gemini Therapeutics, Inc., a Delaware corporation ("Old Gemini"), Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the Company Securityholders (the "Stockholders' Representative"), FSDC and FSG Merger Sub Inc., a Delaware corporation ("Merger Sub").

On the day prior to the Closing Date, Old Gemini changed its name to "Gemini Therapeutics Sub, Inc." Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC changed its name to "Gemini Therapeutics, Inc.", and (ii) Old Gemini merged with and into Merger Sub (the "Merger"), with Old Gemini as the surviving company in the Merger and, after giving effect to such Merger, Old Gemini becoming a wholly-owned subsidiary of Gemini. Upon the closing of the Business Combination, and pursuant to the terms of the Merger Agreement, the existing shareholders of Old Gemini exchanged their interests for shares of common stock of Gemini.

For more information regarding the Business Combination, see Note 2, *Business Combination*, to the consolidated financial statements included in this Annual Report on Form 10-K.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements relate to expectations for future financial performance, business strategies or expectations for our business. These forward-looking statements are based on information available as of the date of this report and our management's current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Specifically, forward-looking statements may include, but are not limited to, statements relating to or about:

- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- timing of and costs associated with our restructuring, and the savings benefits we except to receive from the restructuring;
- success in retaining, or changes required in, our officers, key employees or directors;
- our public securities' potential liquidity and trading;
- the ability of our clinical trials and any available data therefrom to demonstrate acceptable safety and efficacy of our product candidates, including GEM103, our lead product candidate;
- the timing, progress and results of any clinical trials for GEM103 and our other product candidates, to the extent relevant, 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, if any, will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings;
- our ability to obtain marketing approvals of our product candidates and to meet existing or future regulatory standards or comply with post-approval requirements, to the extent relevant;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and expectations regarding our ability to obtain and maintain intellectual property protection;
- the impact of laws and government regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding developments and projections relating to our competitors and industry;
- the loss of our executive, financial and strategic alternatives teams;
- our lack of profitability and, to the extent we continue to operate our business, the need for additional capital; and

- the outcome of any known and unknown litigation.

Other statements preceded by, followed by or that include the words “may,” “can,” “should,” “will,” “estimate,” “plan,” “project,” “forecast,” “intend,” “expect,” “anticipate,” “believe,” “seek,” “target” or similar expressions, or the negative of these terms, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any or all forward-looking statements may turn out to be incorrect. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- the risk that any strategic alternative process disrupts current plans and operations;
- the ability to recognize the anticipated benefits of any strategic alternative process or a potential strategic transaction;
- costs related to the strategic alternative process or a potential strategic transaction;
- the risk that the loss of key employees disrupts our operations and our ability achieve our plans and strategy;
- changes in applicable laws or regulations;
- the possibility that we may be adversely affected by other economic, geopolitical, business, and/or competitive factors; and
- other risks and uncertainties described under the section of this Annual Report on Form 10-K entitled “Risk Factors” and our other filings with the U.S. Securities and Exchange Commission (“SEC”).

PART I

Item 1. Business.

BUSINESS

Overview

We are a clinical-stage precision medicine company developing novel therapeutic compounds to treat genetically defined, age-related macular degeneration ("AMD"). Our lead product candidate, GEM103, is a recombinant form of the human complement factor H protein ("CFH") and is designed to address complement hyperactivity and overall dysregulation caused by loss of function mutations thus restoring retinal health in patients with AMD. Native CFH serves multiple functions in maintaining retinal health including regulating lipid metabolism in the retina, protecting the retina against lipid and protein by-products of oxidative stress and regulating the complement system, which is part of the innate immune system. This multifaceted regulation plays an integral role in engagement and maintenance of complement-mediated immune responses that are involved in pathogen defense and cellular debris clearance.

In January 2022, we announced that we discontinued both of our Phase 2a clinical trials of GEM103, the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study.

In February 2022, we announced a corporate restructuring and that we have initiated a process to evaluate strategic alternatives. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize shareholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

Since inception in 2015, we have devoted substantially all our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our product candidates. We do not have any products approved for sale, and we have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product.

To the extent we continue to pursue clinical development of GEM103, GEM307 or any other product candidate, our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We have not yet successfully completed any pivotal clinical trials, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

We believe GEM103 is capable of down-regulating hyperactive complement activity while maintaining a healthy environment for the cellular architecture supporting retinal function in patients with AMD. We believe that this differentiated approach to controlling complement dysregulation may be able to broadly address AMD pathology and potentially treat AMD. In September 2020, we commenced a Phase 2a clinical trial of GEM103 in patients with dry AMD carrying mutations in the CFH gene, and we announced discontinuation of this trial in January 2022. Based on initial data available from the ReGAtta Phase 2a study and the Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study, GEM103 continues to be generally well-tolerated through 510 intravitreal administrations. GEM103 has been granted Fast Track designation by the U.S. Food and Drug Administration ("FDA").

Augmenting CFH activity represents a unique approach to address imbalances in the immune system in a broad array of complement-mediated inflammatory diseases. Restoration of terminal complement pathway regulation avoids the unintended consequences of broad complement inhibition, which can result in safety issues and a reduced therapeutic index. Integration of genetic, biological, and clinical information has identified high-risk, genetically defined subpopulations present within the current broadly defined AMD cohort. In particular, loss of function variants in the gene that encodes CFH can reduce complement regulation and/or adversely affect retinal homeostasis, both of which strongly correlate with an increased risk for developing AMD.

AMD is a disease primarily affecting the macula, the central portion of the retina responsible for high acuity vision, and is the number one cause of irreversible blindness in the United States and Europe. AMD has generally been characterized as either “wet” or “dry,” definitions driven by clinical presentation rather than underlying biology. In dry AMD, the center of the retina slowly degenerates leading to loss of photoreceptors over time. In wet AMD, choroidal vessels grow aberrantly and invade the retina (referred to as choroidal neovascularization (“CNV”)) rapidly degrading central vision. There are approximately 16 million AMD patients in the United States, of whom approximately 90%, or approximately 15 million, have dry AMD. Of these, approximately six million carry a variant in the CFH gene which leads to loss of function in the CFH protein. In these patients, CFH protein is generally expressed at normal levels but the genetic mutations result in functional insufficiency in the CFH expressed. For wet AMD, drugs targeting one of the central proteins in CNV pathogenesis, vascular endothelial growth factor (“VEGF”), have proven effective in its management. No treatment is currently available for the approximately 15 million patients with early, intermediate, or advanced dry AMD.

We were developing GEM103 initially for the treatment of dry AMD in patients with loss of function mutations in CFH. As a complement pathway regulatory protein, GEM103 has the potential to restore appropriate complement function by ameliorating the detrimental effects of excessive complement activation, including inappropriate cell lysis and exaggerated immune responses, while simultaneously preserving the beneficial roles of CFH, including clearance of extracellular debris and repair of oxidative damage. The mechanism of action of GEM103 stands in contrast to that of broad complement pathway inhibitors developed to date which indiscriminately block both the detrimental and beneficial effects of complement activation. To our knowledge, GEM103 is the first recombinant, native complement modulator that has been evaluated in human clinical trials.

GEM103 has been evaluated in a single ascending dose Phase 1 clinical trial of CFH-variant related dry AMD patients. The findings in the Phase 1 clinical trial enabled the initiation of a Phase 2a trial evaluating multiple ascending doses in a genetically enriched patient population carrying mutation(s) in the gene for CFH and suffering from dry AMD. Based on initial data available from the ReGAtta Phase 2a study and the Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study, GEM103 continues to be generally well-tolerated in 510 intravitreal administrations and such preliminary data indicated rapid and sustained increased levels of CFH, supporting GEM103's biological activity to regulate complement in GA patients as indicated by a reduction in complement biomarkers elevated in patients with AMD. In January 2022, we announced that we discontinued the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study.

We are also working to advance GEM307, that could be effective for treatment of systemic diseases, towards an investigational new drug application (“IND”) filing.

Our Strategy

In January 2022, we announced that we discontinued both of our Phase 2a clinical trials of GEM103, the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study. In February 2022, we announced a corporate restructuring that will result in a substantial reduction of our workforce. In addition, we announced that we initiated a process to evaluate strategic alternatives in order to maximize shareholder value.

Introduction to AMD

AMD is a progressive and irreversible disorder of the macula. The macula is the central portion of the retina in the eye and is responsible for both high acuity vision and color perception. AMD may affect vision in one or both eyes and in later stages results in progressive and chronic degeneration of the macula, leading to irreversible vision loss. AMD is a disease associated with advanced age, typically with onset occurring after the age of 50 and slowly progressing over many years. Retinal degeneration from dry AMD is a gradual process characterized by increasing drusen deposition and other extracellular debris accumulation around retinal pigment epithelium (“RPE”), complement hyperactivity and subsequent loss of photoreceptor cells in the retina in proximity to the degenerated RPE. Eventually, geographic atrophy (“GA”) occurs when regions of the macula are replaced by scar tissue. Common symptoms of dry AMD include blurry vision, loss of night vision and loss of central vision, making activities of daily living such as reading, driving and even recognizing faces progressively more difficult. With vision being central to independent living, AMD has a large and growing societal impact as the population ages.

Dry AMD, like many complex diseases, results from the interactions between environmental and genetic risk factors. However, unlike many late-onset conditions, approximately 70% of attributable risk for advanced AMD is explained by genetic risk. Factors such as aging, smoking, diet and UV light exposure confer the strongest non-genetic risks. Research over the last decade has uncovered multiple genetic variants which can increase the risk of developing advanced AMD by up to 30-fold, including many of the loci within the complement system. One such genetic locus that occurs with high frequency and strongly increases the risk of dry AMD is the CFH gene. We were developing GEM103, a recombinant human CFH molecule, to address the

dysregulation resulting from loss of function variants in these patients and also to restore retinal homeostasis disrupted by CFH dysfunction.

Drugs targeting VEGF, one of the key endogenous proteins driving neovascularization, have proven to be successful in the treatment of wet AMD; however, no treatment is currently available for the remaining majority of patients with dry AMD or GA. Current standard-of-care for dry AMD is limited to over-the-counter vitamin and antioxidant supplements, and, in the absence of available therapeutic interventions, physicians can only regularly monitor a patient's progression toward GA, vision loss, and ultimately blindness. There are a number of therapies in development for dry AMD and GA. Apellis Pharmaceuticals, Inc., has announced primary efficacy results from two ongoing Phase 3 studies of pegcetacoplan targeting complement at the level of C3. One study met its primary efficacy endpoint, and the other study did not. Zimura, a C5 inhibitor being developed by IVERIC bio, Inc., is in pivotal clinical trials. Lampalizumab, a complement factor D inhibitor which had been developed by F. Hoffmann-La Roche AG failed to meet its endpoint in its Phase 3 clinical trials. As presented publicly by that sponsor, lampalizumab failed to adequately inhibit factor D and did not have an effect on complement biomarkers of interest as assayed post hoc from in-trial aqueous humor samples. Other approaches for the treatment of dry AMD are under investigation and in earlier stages of development such as programs from Gyroscope Therapeutics Limited and NGM Biopharmaceuticals.

Our Approach to Date

We believe that a precision medicine approach exemplified by those applied to treat cancer and cystic fibrosis, where molecular definitions of disease supplant clinical descriptions or pathological diagnoses, can also be applied to AMD. Precision medicine is intended to more accurately diagnose patients and precisely match therapies to the underlying genetic drivers of disease. Many well-powered and robust studies have demonstrated the significant role that genetics plays in the development of AMD and lay the groundwork for a precision approach in this large population with few options for treatment.

CLARITY Natural History Studies

In December 2018 we initiated CLARITY, a set of natural history studies designed to identify and characterize disease progression in subjects with non-central GA secondary to dry AMD who are carriers of high-risk genetic variants. For this purpose, we developed a custom genetic test and have genetically screened more than 500 patients. The last CLARITY study visit for the last patient occurred in July 2021. Results confirmed the frequency of pathological genotypic mutations of interest in the dry AMD population including previously published results that approximately 80% of patients with dry AMD have a loss of function variant in the CFH gene. The variants result in the expression of a CFH protein which is impaired in its ability to regulate complement in the eye and/or its ability to promote broader retinal health and homeostasis.

CFH, Complement and the Ocular Compartment

The immune system is composed of two distinct responses, innate and adaptive. The complement system, as part of the innate immune system, plays an integral role in maintaining immune-surveillance and homeostasis in the ocular microenvironment. The complement system is the first line of defense against infection and can effectively clear invading microorganisms well before activation of the adaptive immune system. Even apart from this sentinel function, localized complement activation occurs normally within the ocular compartment and is critical to maintaining retinal health, including participating in clearing of cell debris within the retinal cell layers. Complement dysfunction within the ocular compartment results in a diseased eye.

Complement components constitute a complex network of about 30 circulating or membrane-associated proteins, organized into hierarchal proteolytic cascades. The complement system can be activated by three different pathways: the classical pathway, the lectin pathway, and the alternative pathway. The alternative pathway is constitutively activated and is highly regulated on host cells to limit damage while being amplified on non-host or severely damaged cells to provide protection from pathogens and to help clear unwanted material. CFH provides critical functionality for retinal health. CFH binds to markers on the surface of the body's own cells to protect these cells from aberrant or excessive complement activity. CFH also facilitates microbial clearance and other critical activities such as phagocytosis and lipid clearance. In the absence of sufficient levels of functional CFH protein, cells may be permanently and terminally damaged.

CFH is a key protein that is responsible for self-surface recognition as well as maintaining a well-balanced immune response by regulating the activation of the complement system. CFH functions physiologically to restore retinal health by both downregulating inappropriate cell lysis and facilitating clearance of extracellular debris and repair of oxidative damage which results from multiple sources. Immunohistochemical analyses have shown that many complement components, including CFH, are molecular constituents of drusen, a type of cell debris which is a clinical hallmark of dry AMD. Continuous control of the alternative pathway by CFH is necessary due to the amplifying properties of the alternative pathway and its potential to provoke unneeded inflammatory response if not properly controlled. This control is best achieved by maintaining regulatory function

of the complement system by augmenting CFH activity and thereby inhibiting detrimental effects of the overly active complement system.

Our Clinical Development Program to Date

GEM103

Overview

GEM103 is a full length, recombinantly produced human CFH protein which provides a functional level of active CFH in AMD patients with loss of function mutations in the gene encoding CFH. GEM103 imparts physiologic regulation of the complement pathway driving the complement system toward equilibrium in patients where there is incomplete regulation due to insufficient functional CFH protein. This is a unique approach to address over-activation of the innate immune system.

Preclinical and Clinical Development

A series of preclinical studies have been performed to evaluate the pharmacokinetic and pharmacodynamic performance of GEM103. In preclinical pharmacokinetic studies, we observed that GEM103 was detected in all assayed ocular compartments, including aqueous humor, vitreous humor and the retina. Of note GEM103 was distributed to the retina following intravitreal injection in non-human primate radio-labeled distribution studies. Our study shows that after an intravitreal injection of radio-labelled GEM103, the protein is detected in the aqueous humor as well as into the retina, which is the site of action for the protein, for an extended period of time following a single dose.

Actions of endogenous CFH include inhibition of the complement activation cascade while permitting clearance of foreign material, cellular debris and pathogens in the eye. In *in vitro*, cell-based assays, GEM103 was shown to inhibit hyperactive terminal complement activity demonstrating a more potent but comparable maximal ability to inhibit cellular lysis when compared to a broad inhibitor of C3. In addition, we observed the necessary phagocytic activity required to clear lipid and other forms of debris is maintained by GEM103, while it is impaired by a broad inhibitor of C3, a potentially undesirable consequence of current approaches that results in complete suppression of complement activity.

In our Phase 1 clinical trial, single ascending doses of GEM103 were administered via intravitreal injection (IVT) to dry AMD patients enriched for genetic variants of interest. GEM103 was well-tolerated across a range of single doses from 50 to 500 µg/eye in a 50 µL preparation delivered intravitreally, without any dose limiting toxicity or inflammation or anti-drug induced antibody, confirmed by an independent safety review committee.

The findings in the Phase 1 clinical trial enabled the initiation of a Phase 2a trial evaluating multiple ascending doses of 250 to 500 µg/eye GEM103 (in 50 µL) in a genetically enriched patient population carrying mutation(s) in the gene for CFH and suffering from dry AMD. The primary objective of this study was to evaluate the safety and tolerability of monthly IVT GEM103 and provide additional information on pharmacokinetics and exploratory biomarker responses based upon serially obtained aqueous humor samples. This study did not have a defined controlled group was not designed to inform GA efficacy.

Based on initial data available from the ReGAtta Phase 2a study and the Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study, GEM103 continues to be generally well-tolerated through 510 intravitreal administrations with no increased risk for CNV in the GA population, no ocular serious adverse events and no study discontinuations related to GEM103. The majority of adverse events were typical of IVT injections. There was one report of mild inflammation related to GEM103 that resolved without treatment and did not require modification of GEM103 dosing.

Repeat IVT GEM103 dosing resulted in rapid and sustained increased levels of CFH, at least 12-fold above baseline levels with 500 µg/eye GEM103. A regulation of complement in GA patients has been observed with ~40% reduction in Ba and ~20% reduction in C3a, complement biomarkers elevated in patients with AMD. These initial findings support continued development and we have received feedback from the FDA through an end of Phase 2 meeting on a later stage clinical trial design to potentially support approval.

We also evaluated GEM103 as add-on therapy in patients suffering from wet AMD who have been treated with anti-VEGF therapy, as development of macular atrophy in that setting has been associated with a relative insufficiency in CFH. In a Phase 2a clinical trial comparing 500 µg/eye GEM103 (in 50 µL) + standard of care anti-VEGF therapy (aflibercept) to sham IVT injection + standard of care anti-VEGF therapy (aflibercept), we enrolled 50 individuals and dosed every 8 weeks. Initial results for up to 6 months of dosing showed every 8-week IVT GEM103 administration was generally well-tolerated with rapid

and sustained increased levels of CFH and regulation of complement as evidenced by reduction in complement biomarkers elevated in patients with AMD.

As previously described, in January 2022, we announced that we discontinued both of our Phase 2a clinical trials, the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study, as both studies have achieved their intended purpose of evaluating GEM103's safety and tolerability.

Additional Programs

Factor H Potentiating Antibody

In addition to AMD, there are other systemic conditions that have complement dysregulation as part of the underlying disease pathologies. Many of these conditions affect the renal system and include rare diseases such as atypical Hemolytic Urea Syndrome, C3 Glomerulopathy as well as more common disorders like IgA Nephropathy. Many of these diseases have genetic risk factors that include CFH dysregulation and other complement regulatory proteins like the CFH-related proteins. We have developed GEM307 as a factor H potentiating antibody that enhances the activity of endogenous CFH, effectively increasing the effective functional concentration of CFH. We have pre-clinical data supporting improvement of clinical benefit in animal models mimicking these conditions of complement dysregulation. We have received pre-IND feedback from the FDA.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We rely on well-established third-party contract manufacturing organizations ("CMOs") to produce our product candidates, and we have recruited personnel with experience to manage the third-party CMOs producing our product candidates and other product candidates or products that we may develop in the future.

Our lead product candidate, GEM103, is a recombinant version of the endogenous CFH protein that is found most widely in our 'intent to treat' population. Specifically, it contains the amino acids V62, Y402 and E936 which are those most frequently found in the Caucasian population.

The process for manufacturing GEM103 consists of a cell culture and purification processes to achieve a stringent quality, purity, strength and safety criteria in line with a product candidate dosed intravitreally.

We have paused manufacturing of GEM103 as we engage in a process to evaluate strategic alternatives.

The process for manufacturing GEM307 consists of a cell culture and purification processes to achieve a stringent quality, purity, strength and safety criteria in line with regulatory expectations for an IND.

Sales and Marketing

We hold worldwide commercialization rights to each of our product candidates.

In order to market for sale a product, we would need to build focused capabilities to commercialize development programs for certain indications where we believe that the medical specialists for the indications are sufficiently concentrated to allow us to effectively promote the product with a targeted sales team. In other indications, we would need to seek to enter into collaborations that we would believe might contribute to our ability to advance development and ultimately commercialize our product candidates.

We could also seek to enter into collaborations where we believe that realizing the full commercial value of our development programs would require access to broader geographic markets or the pursuit of broader patient populations or indications.

Research Collaboration and License Agreement

In April 2017, we entered into a Research Collaboration and License Agreement with Sanquin Blood Supply Foundation ("Sanquin") (the "2017 License Agreement") to develop antibodies that bind and enhance the activity of CFH. From the effective date of the 2017 License Agreement until the end of April 2019, the parties engaged in a research program based on an agreed upon research plan. The research program was overseen by a joint steering committee, comprised of two members from each of Gemini and Sanquin, with each party having one vote with respect to decisions within the purview of the joint

steering committee. If the joint steering committee was unable to resolve any issues unanimously, then such disputes were subject to a dispute resolution procedures. We funded Sanquin's research during the term of the research program.

Following the conclusion of the research program, we have sole responsibility for the development of licensed products for the treatment and prevention of diseases in humans. Sanquin granted us an exclusive royalty-bearing license, with the right to sublicense through multiple tiers, to Sanquin's patent rights, including patent rights generated during the research program and a non-exclusive license, with the right to sublicense through multiple tiers, to Sanquin's background know-how and materials, in each case to research, develop, commercialize, make, use, sell, offer for sale and import or otherwise exploit licensed products. On March 7, 2022, we entered into an amendment to the 2017 License Agreement (the "2022 Amendment") to clarify that certain patent rights directed to CFH potentiating antibodies are jointly owned by us and Sanquin. Under the 2022 Amendment, Sanquin granted us an exclusive (even as to Sanquin) royalty-bearing license, with the right to sublicense through multiple tiers, to the portion of these patent rights owned by Sanquin. Pursuant to the 2017 License Agreement with the 2022 Amendment incorporated (the "Amended License Agreement"), we are required to use commercially reasonable efforts to conduct development and commercialization of licensed products in accordance with an agreed upon development plan.

As consideration for the license, we paid Sanquin a one-time, non-refundable upfront payment of $100,000. We are required to make milestone payments to Sanquin upon achievement of certain development and commercial milestones (i.e., once net sales targets exceed certain thresholds) totaling up to an aggregate amount of $29.0 million. We are also required to pay Saquin a low double digit percentage of any non-royalty sublicensing income received and are required to make minimum royalty payments to Sanquin on each anniversary date of the effective date of the 2017 License Agreement. We are required to make royalty payments of between 1.25% and 2.50% of net product sales if commercialization is achieved, subject to offset by minimum royalty payments due and up to 50% reduction for royalty stacking.

The Amended License Agreement shall terminate on a country-by-country and licensed product-by-licensed product basis upon the latest of (i) expiration of the last valid claim of a Sanquin patent or a jointly owned patent that covers such licensed product, (ii) seven years after the first commercial sale of such licensed product, or (iii) the date on which there is no longer any marketing exclusivity for such licensed product. The Amended License Agreement may be terminated by either party (i) upon 90 days written notice in the event of the other party's uncured breach of the Amended License Agreement, or (ii) the other party files for bankruptcy protection, makes an assignment for the benefit of its creditors, or files a petition for bankruptcy or insolvency that is not dismissed in 90 days. We have the right to terminate the Amended License Agreement at any time upon 90 days prior written notice, and Sanquin has the right to terminate the Amended License Agreement if we fail to meet our diligence obligations under the Amended License Agreement.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use, including combination therapies. As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use and biomarkers and complementary diagnostic and/or companion diagnostic related claims.

As of March 7, 2022, we own or exclusively license approximately 59 patents and pending patent applications in the United States ("U.S.") and foreign jurisdictions, including one granted U.S. patent, 11 granted foreign patents, four pending U.S. non-provisional patent applications and 43 pending foreign patent applications.

Our patent portfolio relating to GEM103 includes two patent families owned by us. The first patent family includes a pending Patent Cooperation Treaty ("PCT") application directed to dosage regimens for treating inflammatory ocular diseases using GEM103 and certain biomarkers for monitoring responses to the treatment. The statutory expiration for any U.S. and foreign patents issuing from this family is 2041. The second patent family includes a pending PCT application directed to methods of treating age-related macular degeneration using GEM103 in patients who carry certain CFH genetic mutations. The statutory expiration for any U.S. and foreign patents issuing from this family is 2040.

Our patent portfolio relating to our factor H potentiating antibody program includes two patent families that we exclusively license from Sanquin Blood Supply Foundation and one patent family that we jointly own with Sanquin. The two in-licensed

patent families are directed to antibodies that bind the same region of the factor H protein as our GEM307 product candidate. The first in-licensed family includes granted patents in Australia, France, Germany, Italy, the Netherlands, Mexico, Spain, and U.K. that cover GEM307 with statutory expiration in 2035. This family also include pending patent applications in Brazil, Canada, Israel, Japan, and South Korea which, if issued, would have statutory expiration in 2035. The second in-licensed patent family is pending in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, the Republic of Korea, Mexico and the United States. The statutory expiration for any patents issuing from this family is 2039. The patent family jointly owned by us and Sanquin is directed to the specific GEM307 product candidate. This family is pending in the United States, Argentina, Australia, Brazil, Canada, China, Europe, India, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, South Africa and Taiwan. The statutory expiration for any patents issuing from this family is 2040.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see "*Risk factors — Risks related to our intellectual property*."

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

The biotechnology and pharmaceutical industries, including complement therapies, are characterized by rapidly changing technologies, competition and a strong emphasis on intellectual property. We are aware of several companies focused on developing precision medicines in various indications that may compete with our products. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions with genetic medicine and other therapeutic approaches.

We consider our most direct competitors with respect to GEM103 for the treatment of AMD to be Apellis Pharmaceuticals, Inc. and IVERIC bio. Apellis Pharmaceuticals, Inc. has announced primary efficacy results from two ongoing Phase 3 studies of pegcetacoplan targeting complement at the level of C3. One study met its primary efficacy endpoint, while the other study did not. IVERIC bio is conducting a pivotal study in geographic atrophy for its C5 inhibitor. Other approaches are under investigation and in earlier stages of development such as programs from Gyroscope Therapeutics Limited and NGM Biopharmaceuticals.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we have been developing. We, along with our vendors, collaboration partners, contract research organizations ("CROs") and CMOs, would be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidate. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we have initially been focusing our product development, the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing

regulations. Biologics are also subject to other federal, state and local statutes and regulations. Our product candidates are early-stage and have not been approved by the FDA for marketing in the United States.

The process required by the FDA before our product candidates are approved for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practice ("GLP") requirements;
- submission to the FDA of an IND which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an Institutional Review Board ("IRB") or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practice ("GCP") requirements and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose;
- preparation and submission to the FDA of a Biologics License Application ("BLA") after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with current Good Manufacturing Practice requirements ("cGMPs") to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;
- potential FDA audit of the clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

Preclinical and clinical trials for biologics

Before testing any drug or biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and it must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Some long-term preclinical testing may continue after the IND is submitted. Accordingly, submission of an IND may or may not result in FDA authorization to begin a trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development of a product candidate, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the

objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the *www.clinicaltrials.gov* website.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. Generally, the FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

Clinical trials to evaluate therapeutic indications to support BLAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1* — Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2* — Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

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

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human participants exposed to the biologic and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the biological characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of

consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life and to identify appropriate storage conditions for the product candidate.

BLA Submission and Review by the FDA

To the extent we continue to develop our product candidates, we could seek data exclusivity or market exclusivity for our product candidates. Assuming successful completion of the required clinical testing, the relevant results of the pertinent preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. A BLA is a request for approval to market a new biologic for one or more specified indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new clinically active component, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA targets ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA filed for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each BLA must be accompanied by a user fee, and the sponsor of an approved BLA is also subject to an annual program fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA may refer an application for a biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") as a condition for approving the BLA to ensure that the benefits of the product outweigh its risks. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter will usually describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed, the FDA may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited development and review programs for biologics

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, priority review and Accelerated Approval.

A new biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the biologic, alone or in combination with or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including priority review and Accelerated Approval. A product is eligible for priority review if it is intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

A product intended to treat serious or life-threatening diseases or conditions may receive Accelerated Approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug or biologic approved under Accelerated Approval if, for example, the sponsor fails to conduct the confirmatory trials in a timely manner or the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for Accelerated Approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Fast Track designation, Breakthrough Therapy designation, priority review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

Post-approval requirements for biologics

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, product tracking and tracing, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by our employees but also by agents of ours or those speaking on our behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products carry reimbursement under federal health care programs. Promotional materials for approved biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of a BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug and biologics manufacturers and their subcontractors involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our CMOs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program fee for any marketed product.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation ("ODD") to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States of that drug or biologic. ODD must be requested before submitting a BLA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular clinically active component for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years from the approval of the BLA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Biosimilars and Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and regulatory interpretation of the BPCIA remain subject to significant uncertainty.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services ("HHS"), the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Recent Developments

2022 Restructuring and Process to Evaluate Strategic Alternatives

On February 28, 2022, we announced a restructuring plan to reduce our operations to preserve financial resources, resulting in a reduction of our workforce by up to 24 positions, or approximately 80%, by the end of the second quarter of 2022. As a result, we estimate that we will incur costs within the range of $1.6 million to $1.9 million, which are expected to consist of severance benefits for the affected employees, limited reimbursement of medical insurance premiums, outplacement services and other restructuring costs and expenses. Additionally, we have initiated a process to evaluate strategic alternatives in order to maximize shareholder value. There can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all.

Furthermore, effective as of February 28, 2022, Georges Gemayel, Ph.D., our current Executive Chair, was appointed as interim President and Chief Executive Officer to succeed Jason Meyenburg, who has transitioned from his roles as President, CEO and Director and will continue to serve as an advisor to the Company. Dr. Gemayel will continue to serve as the Chair of our Board.

Employees and Human Capital Resources

As of December 31, 2021, we had 33 employees, including four employees with M.D. degrees and six employees with Ph.D. degrees, and of whom 31 were full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider the relationship with our employees to be in good standing. We also engage consultants and contractors to supplement our permanent workforce.

We believe we offer competitive compensation (including base salary, incentive bonus, and long-term equity awards tied to the value of our stock price) and benefits packages designed to attract and reward talented individuals who possess the skills necessary to support our business objectives and assist in the achievement of our strategic goals.

We are committed to protecting our employees everywhere we operate. We have taken additional measures during the COVID-19 pandemic, including offering COVID-19 testing, as necessary. As of January 1, 2022, all of our employees are fully-remote workers as we are now a remote-first company that does not currently maintain a physical headquarters.

Facilities

Our facilities consisted of office space in Cambridge, Massachusetts. We terminated this lease on December 31, 2021 and no longer have any properties. We believe that our current remote working arrangement is sufficient for our current needs.

Legal Proceedings

We are not currently subject to any material legal proceedings.

Available Information

Additional information about Gemini is available on our corporate website at https://geminitherapeutics.com/, as well as Gemini's Investor Relations website at https://investors.geminitherapeutics.com/overview/. We use our website to distribute company information, including financial and other material information. We make available free of charge, on or through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, beneficial ownership reports on Forms 3 and 4, as well as other filings and any amendments to these documents, as soon as reasonably practicable following the time they are electronically filed with or furnished to the SEC. The SEC maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The SEC's Internet website is located at http://www.sec.gov. The content of any websites referred to in this Annual Report on Form 10-K is not incorporated by reference into this report or any other report filed with or furnished to the SEC.

Item 1A. Risk Factors.

RISK FACTORS

In evaluating our company and our business, you should carefully consider the risks and uncertainties described below, together with the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations". 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 or future prospects, in which case the market price of our common stock could decline, and you could lose part or all of your investment. Unless otherwise indicated, reference in this section and elsewhere in this Annual Report on Form 10-K to our business being adversely affected, negatively impacted or harmed will include an adverse effect on, or a negative impact or harm to, our business, reputation, financial condition, results of operations, revenue or our future prospects. The material and other risks and uncertainties summarized above in this Annual Report on Form 10-K and 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. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Cautionary Note Regarding Forward-Looking Statements".

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- We may not realize any additional value in a strategic transaction.
- If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.
- If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such a transaction.
- Our corporate restructurings and the associated headcount reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
- The impact and results of our ongoing strategic process are uncertain and may not be successful.
- We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.
- We have incurred significant losses since our inception and may incur losses for the foreseeable future.
- We may require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of GEM103 or any other product candidates.
- We may continue to be heavily dependent on the success of GEM103, our lead product candidate.
- GEM103 and any other product candidates would need to undergo rigorous clinical trials and regulatory approvals, and success in nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.
- We have been and may in the future be subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our products.
- We must retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.
- We may rely on third parties to conduct our clinical trials and for the manufacture of our clinical drug supply. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- Our business could be adversely affected by the effects of health epidemics, including the novel coronavirus ("COVID-19") pandemic, in regions where third parties for which we rely have significant research, development or manufacturing facilities, concentrations of clinical trial sites or other business operations, causing disruption in supplies and services.
- The future sales of shares by existing stockholders and future exercise of registration rights may adversely affect the market price of our common stock.
- If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

- If we fail to comply with our obligations in our current and future intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

Risks Related to Strategic Alternative Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.

In addition to our efforts, if any, to pursue clinical development of GEM103, GEM307 or any other product candidate, we also continue to evaluate all potential strategic options for the company, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

The market capitalization of our company is below the value of our cash and cash equivalents. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets given the limited data regarding our lead development program. Further, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;

- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In October 2021, and then again in February 2022, we undertook an organizational restructuring that significantly reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In October 2021, and then again in February 2022, we undertook an organizational restructuring that significantly reduced our workforce, including the departure of our chief executive officer. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

The impact and results of our ongoing strategic process are uncertain and may not be successful.

Over the past several years, we have focused our strategic efforts on maximizing stockholder value through strategic transactions, such as the Business Combination. In connection with the Business Combination, certain investors purchased an aggregate of $95.1 million of our Common Stock in a private placement of public equity (the "PIPE Financing"). Together with FSDC's cash resources and funding of the PIPE Financing, we received net proceeds from the Business Combination of approximately $195.9 million. We may continue to focus our efforts on creating value from GEM103, GEM307 or other product candidates for our stockholders through a sale or other transaction involving the program and pursuing potential strategic options for our company as a whole.

Our board of directors remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company's current strategic direction, or the board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value.

In addition, given the substantial restructuring of our operations over the past several years, it may be difficult to evaluate our current business and future prospects on the basis of historical operating performance.

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

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

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and may incur losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in March 2015.

For the years ended December 31, 2021 and 2020, we reported net losses of $71.9 million and $40.8 million, respectively. As of December 31, 2021, we had an accumulated deficit of $184.7 million. Depending on the outcome of our exploration of strategic alternatives, and although we revised our strategy, ceased our Phase 2 trials and announced a significant workforce restructuring, we may continue to incur significant losses for the foreseeable future, and we expect these losses would increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We anticipate that our expenses would increase substantially if, and as, we:

- conduct larger scale clinical trials for our lead product candidate, GEM103, and any other product candidates;
- discover and develop new product candidates, and conduct nonclinical studies, other investigational new drug ("IND") enabling studies and clinical trials;

- manufacture, or have manufactured, preclinical, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for our product candidates;
- commercialize GEM103 or any other product candidates, if approved;
- attempt to transition from a company with a clinical development focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- hire additional clinical, scientific, and management personnel;
- add operational, financial, and management information systems and personnel including costs related to funding our restructuring obligations;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- incur additional costs associated with operating as a public company.

Even if we continue to pursue product development and succeed in commercializing GEM103 or any other product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business for any reason, including as a result of the COVID-19 pandemic. 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 stockholders' equity and working capital.

We currently have a limited operating history, have not generated any revenue to date and may never become profitable.

We are a clinical-stage biotechnology company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and product candidates, and conducting clinical trials and preclinical studies of our product candidates. We have not yet demonstrated our ability to complete clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology product development is highly speculative because it entails substantial upfront expenditures in contract research organizations ("CROs"), and contract manufacturing organizations ("CMOs"), and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Even if we continue to pursue approval of GEM103, we would not expect to receive revenue from GEM103 for a number of years, if ever. To date, we have not generated any revenue, and we will not be able to generate product revenue unless and until GEM103, or any other product candidate, successfully completes clinical trials, receives regulatory approval and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third parties. Our ability to generate future product revenue from GEM103 or any other product candidates also depends on a number of additional factors, including our, or our current and future collaborators', ability to:

- successfully complete nonclinical studies and clinical trials for GEM103 and any other product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtains marketing approval, and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;

- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments for our product candidates;
- negotiate favorable terms in strategic alternatives including, but not limited to, any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we would achieve or maintain profitability if we continue to pursue product development. In addition, our expenses could increase beyond expectations if we decide, or are required by the U.S. Food and Drug Administration ("FDA") or applicable foreign regulatory authorities in other jurisdictions where we may pursue regulatory approval, or applicable foreign regulatory authorities, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

If we continue to pursue product development, we will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of GEM103 or any other product candidates.

As a clinical development company, our operations have consumed substantial amounts of cash since inception.

As of December 31, 2021, we had $136.6 million of cash and cash equivalents. Subject to the outcome of our exploration of strategic alternatives, we believe that our current cash resources will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months from the filing date of this Annual Report on Form 10-K. Our forecast of the period of time through which our financial reserves will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- the timing and outcome of our exploration of potential strategic alternatives;
- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for GEM103 or any other product candidates we may develop, including COVID-19-related delays or other effects on our development programs;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and applicable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;

- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent we continue to pursue product development, until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Risks Related to our Business

We may continue to be heavily dependent on the success of GEM103, our lead product candidate.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. If we continue to pursue regulatory approval of our product candidates, we expect that a substantial portion of our efforts and expenditures over the next several years would be devoted to our lead product candidate, GEM103. Accordingly, our business would depend heavily on the successful development, regulatory approval, and commercialization of GEM103. GEM103 was tested in a Phase 2a clinical trial in genetically defined patients with dry age-related macular degeneration ("AMD") and in a Phase 2a clinical trial as an add-on to anti-VEGF therapy for the treatment of wet AMD patients at risk for progressive vision loss due to macular atrophy. We announced that we were ending both of these studies in January 2022. We cannot be certain that we would successfully commence or complete any further clinical trials, receive regulatory approval or successfully commercialize GEM103 even if we were to receive regulatory approval. If we do not perform any future clinical development of GEM103 or if GEM103 does not receive regulatory approval or fails to achieve significant market acceptance, we would be substantially delayed in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of GEM103 is, and will remain, subject to comprehensive regulation by the FDA and applicable foreign regulatory authorities. Failure to obtain regulatory approval for GEM103 will prevent us from commercializing and marketing GEM103.

Further, any future clinical trials of GEM103 may not be able to replicate the results from our preclinical studies or past clinical trials of GEM103. To the extent any of the foregoing has not occurred, our expected development time and development costs for GEM103 may be increased.

Even if we are able to successfully obtain approval from the FDA or applicable foreign regulatory authorities for GEM103, any approval might contain significant limitations related to use, including limitations on the stage of disease GEM103 is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Furthermore, even if we obtain regulatory approval for GEM103, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs otherwise. If we, or any future collaborators, are unable to successfully commercialize GEM103, we may not be able to generate sufficient revenue to continue our business.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing GEM103 or other product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

If we continue to pursue regulatory approval of our product candidates, we would plan to devote a majority of our resources to the continued preclinical and clinical testing and potential approval of GEM103 for the treatment of patients with AMD. However, another key element of our strategy could be to discover, develop and commercialize a portfolio of products. We could seek to do so through our internal discovery programs, but our resources are limited. We may also explore strategic collaborations for the development or acquisition of new product candidates, but we may not be successful in entering into such relationships. GEM103 is our only product candidate in clinical stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets or make such entry economically impracticable.

If we continue to pursue product development and we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed, and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

GEM103 and any other product candidates would need to undergo rigorous clinical trials and regulatory approvals, and success in nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.

To the extent we continue to pursue product development, GEM103 and any other product candidates would be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and applicable foreign regulatory authorities. The approval process is typically lengthy and expensive, and approval is never certain. We have limited experience in conducting the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our planned clinical trials may be insufficient to demonstrate that our potential products will be active, safe or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether our results will support approval of a product, and flaws in the design of a

clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval. In addition, there is a high failure rate for drugs and biologics proceeding through clinical trials. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. For example, we provided updates from our Phase 2a studies in January 2022. Both studies were ended early, which may limit the ability of the data to support regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of development of our product candidates. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

We have published, and may from time to time in the future, publish interim "top-line" or preliminary data from our clinical trials. Preliminary or interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

Additionally, several of our previous clinical trials utilized an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved biologic, drug, 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.

We have been and may in the future be subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our products.

We have historically contracted with third party manufacturers to make new drug substance to support clinical trials and for commercial sale, if approved. Our CMOs may not be able to adopt, adapt or scale up the manufacturing process in a timely manner to support our future clinical trials. The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

- the manufacturing processes are susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our CMOs, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of GEM103 and other product candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of these products sometimes

encounter difficulties in production, especially during scale-up from the manufacturing process used for pre-clinical and early clinical trials to a validated process needed for pivotal clinical studies and commercial launch. These problems include failure to meet target production costs and yields, sub-par quality control testing, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of GEM103 or any other product candidates will not occur in the future.

We do not have and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or filled drug product for use in pre-clinical studies, clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials could delay the completion of pre-clinical studies or clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new pre-clinical studies or clinical trials at additional expense or terminate pre-clinical studies or clinical trials altogether.

We have no manufacturing facility. As a result, we have been dependent on third-party manufacturers, as well as on third parties for our supply chain, and if we experience problems with any third parties, or the actual demand for our future product candidates, if any, exceed our forecasts, the manufacture of adequate supplies of our future product candidates or products could be delayed.

We do not own or operate facilities for the manufacture of our future product candidates, if any. We currently have no plans to build our own manufacturing facilities for clinical or commercial operations. We have in the past relied on third party manufacturers for the chemical manufacture of active pharmaceutical ingredient and for the production of final product formulation and packaging for clinical trials, and expect to rely on such third party manufacturers for any future product candidate we are able to advance into clinical development. Although alternative third party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers should we commence clinical development of any future product candidate. We may encounter technical difficulties or delays in the transfer of manufacturing on a commercial scale to third party manufacturers. We may be unable to enter into agreements for commercial supply with third party manufacturers, or may be unable to do so on acceptable terms. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of any future product candidates, or market or distribute them.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates and could cause us to incur higher costs and prevent us from commercializing our product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of products, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for a clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our future product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. If our third party manufacturers cannot manufacture sufficient quantity to meet the demand for our product candidates after regulatory approval, there would be a shortage in supply which would negatively impact our revenue from the sale of our product candidates. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA.

Our business could continue to be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, including in regions where third parties on which we rely have significant research, development or manufacturing facilities, concentrations of clinical trial sites or other business operations, causing disruption in supplies and services.

Our business could be adversely affected by health epidemics in regions where third parties on which we rely, such as CROs or CMOs, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. The ongoing COVID-19 pandemic and the increased prevalence of variants of the virus, and government measures taken in response, have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The ongoing COVID-19 pandemic and related impacts have resulted in, and will likely continue to result in, significant disruptions to the global economy and capital markets around the world. We cannot predict the future progression or full impact of the outbreak and its effects on our business and operations.

We and our third-party CMOs, CROs and clinical sites have experienced, and may continue to experience, disruptions in supply of product candidates and/or procuring items that are essential for our research and development activities, including raw materials used in the manufacturing of our product candidates, medical and laboratory supplies used in our clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the pandemic.

Additionally, we enrolled patients in our clinical trials at sites located both in the United States and internationally. Our clinical trial sites were located in areas that were affected by COVID-19 and, as a result, our ability to enroll patients and complete our trials were impacted. We cannot predict how long these types of delays and impacts many continue, and whether they will similarly affect any future clinical trials. For example, even if sites are initiating and actively recruiting, we may face difficulties recruiting or retaining patients in our planned clinical trials if patients are affected by the virus or are unable to or are fearful of visiting or traveling to our clinical trial sites because of the pandemic, or if patients are unable or unwilling to be vaccinated or tested. Prolonged delays or closure to enrollment in our planned trials or patient discontinuations could have a material adverse impact on our clinical trial plans and timelines. In addition, our ability to collect and verify data requested of patients enrolled in our clinical trials during this pandemic was impacted to varying degrees by COVID-19, and COVID-19 could similarly impact future clinical trials. Although clinical trial data collection continued for each of our clinical trials, data was collected at a slower pace, and with challenges and interruptions in data collection, including, in some instances, disruption of collection of complete study data. This could have a material adverse impact on our data quality and analysis. In addition, clinical trial sites for any potential future clinical trials may be unable or unwilling to initiate a new trial if factors relevant to the pandemic render doing so impracticable. These COVID-19 related issues may prolong the time required to conduct any potential clinical trials and/or impact the quality of the data obtained from one or more of our completed or potential studies.

We have not incurred impairment losses in the carrying values of our assets as a result of the ongoing COVID-19 pandemic, and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our consolidated financial statements. Although the COVID-19 pandemic did not have a significant impact on our financial results in 2021, the full extent to which the ongoing COVID-19 pandemic may impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain, and the estimates of the impact on our business may change based on new information that may emerge concerning COVID-19, including the duration of the pandemic, any potential subsequent waves or strains of COVID-19 infection, the effectiveness, distribution and acceptance of COVID-19 vaccines and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

If we do not retain key employees, our ability to maintain our ongoing operations or execute a potential strategic option could be impaired.

As of February 28, 2022, we had 29 employees and we will rely heavily on the services of our existing employees to manage our ongoing operations and execute our strategic plans. On February 28, 2022, we announced a workforce reduction by up to 24 positions, or approximately 80% of our workforce. The loss of services from any of our existing or continuing employees could substantially disrupt our operations. To be successful and achieve our strategic objectives, we must retain qualified personnel. The continued review of our strategic options may create continued uncertainty for our employees and this uncertainty may adversely affect our ability to retain key employees and to hire new talent necessary to maintain our ongoing operations or to execute additional potential strategic options, which could have a material adverse effect on our business.

In addition, our current strategy and any changes to this strategy could place significant strain on our resources and our ability to maintain our ongoing operations. We may also be required to rely more heavily on temporary or part-time employees, third party contractors and consultants to assist with managing our operations. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We will have only limited control over the activities of these consultants and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our business could harm our business.

Accordingly, we may fail to maintain our ongoing operations or execute our strategic plan if we are unable to retain or hire qualified personnel or to manage our employees and consultants effectively.

We may encounter difficulties in managing any future growth, which could adversely affect our operations.

If we pursue further clinical development and the potential commercialization of our product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations were to expand, we would expect that we would need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively would depend, in part, on our ability to manage any future growth effectively. We have undertaken restructurings in October 2021 and February 2022 with a substantial reduction in headcount, which would adversely impact our ability to meet any potential growth needs.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act ("Section 404") or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

Commencing with the end of the fiscal year to which this Annual Report on Form 10-K relates, we are required to perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404. This has required that we incur substantial additional and recurring professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We will be required to disclose changes made in our internal controls and procedures on a quarterly basis. However, for as long as we are an emerging growth company ("EGC"), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

If we are not able to comply with the requirements of Section 404 in a timely manner or we are unable to maintain proper and effective internal controls over financial reporting we may not be able to produce timely and accurate financial statements. As a result, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

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

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Securities Exchange Act of 1934, as amended ("Exchange Act"), is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system

are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

As a result of our business combination with a special purpose acquisition company, regulatory obligations may impact us differently than other publicly traded companies.

We became a publicly traded company by completing a transaction with a special purpose acquisition company ("SPAC"). As a result of this transaction, regulatory obligations have, and may continue, to impact us differently than other publicly traded companies. For instance, the SEC and other regulatory agencies may issue additional guidance or apply further regulatory scrutiny to companies like us that have completed a business combination with a SPAC. Managing this regulatory environment, which has and may continue to evolve, could divert management's attention from the operation of our business, negatively impact our ability to raise additional capital when needed or have an adverse effect on the price of our common stock.

We must retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we faces significant competition for experienced personnel. If we do not succeed in retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. We are dependent on the members of our management team and our scientific advisors for our business success, the loss of whom could require us to identify and engage qualified replacements, and could cause our management and operations to suffer in the interim. For example, in February 2022, Jason Meyenburg transitioned from his role as our Chief Executive Officer. Also in February 2022, Georges Gemayel began serving as our Interim Chief Executive Officer. Even though we are confident in the interim leadership of Dr. Gemayel, any disruption resulting from Mr. Meyenburg's departure, or any further changes to our key management, commercial and scientific personnel, may be disruptive or cause uncertainty in our business and may adversely impact our results of operations and financial condition. We do not maintain "key person" insurance for any of our key personnel. An important element of our strategy is to take advantage of the research and development expertise of our current management. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

There is intense competition for qualified personnel, including management in the technical fields in which we operate and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of our product candidates. In particular, we have experienced a very competitive hiring environment in Cambridge, Massachusetts, where we are headquartered. Many of the other pharmaceutical 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 chances 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 with which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and applicable foreign regulatory authorities, fails to provide true, complete

and accurate information to the FDA and applicable foreign regulatory authorities, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government 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 result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. To the extent we continue to pursue product development, we may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites where patients are to be enrolled;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on us.

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. A number of pharmaceutical companies, as well as large and small biotechnology companies such as Apellis Pharmaceuticals, Inc. and IVERIC bio are pursuing the development or marketing of pharmaceuticals that target AMD. It is also probable that the number of companies seeking to develop products and therapies for the treatment of serious eye diseases, such as AMD, will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we do in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. In addition, to the extent we continue to pursue product development, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us is in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

Given our limited operating history, we are still in the process of implementing our internal security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. While we have not, to our knowledge, experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, 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 applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be hindered or delayed.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The rules dealing with United States federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the United States Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020, and, among other things, suspends the 80% limitation on the deduction for NOLs in taxable years beginning before January 1, 2021, permits a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

We might not be able to utilize a significant portion of our U.S. NOL carryforwards and U.S. research and development tax credit carryforwards.

As of December 31, 2021, we had federal net operating loss carryforwards of $7.6 million that are subject to expire at various dates through 2037, and net operating loss carryforwards of $156.5 million, which have no expiration date, can be carried forward indefinitely, and are limited to a deduction to 80% of annual taxable income. We have state tax net operating loss carryforwards of $143.1 million, which may be available to offset future income tax liabilities and expire at various dates through 2041, and net operating loss carryforwards of $1.0 million, which have no expiration date, can be carried forward indefinitely. We also have federal and state research and development tax credit carryforwards of $5.0 million and $1.2 million, respectively, which expire at various dates through 2041. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, unused losses generated in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 is permitted. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal NOLs is limited to 80% of our taxable income in any future taxable year. In addition, under Section 382 of the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50% over a three-year period. We may have experienced ownership changes in the past and we may experience ownership changes in the future as a result of the Business Combination and subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of U.S. federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. To the extent we continue to pursue product development, we may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and applicable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for GEM103 or any other product candidate would substantially harm our business.

The time required to obtain approval from the FDA and applicable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions.

To the extent we continue to pursue product development, GEM103 or our other product candidates could fail to receive regulatory approval from the FDA or an applicable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh our safety risks;

- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval.

The FDA or an applicable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product for fewer more limited indications than we request, may require labeling or a Risk Evaluation Mitigation Strategy ("REMS") that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Failures or delays in the commencement or completion of, or ambiguous or negative results from, our previous and potential clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether any of our potential clinical trials will be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or applicable foreign regulatory authorities may not authorize our or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold, and may request additional data to permit allowance of our investigational new drug ("IND");
- delays in filing or receiving allowance of additional IND applications that may be required;
- lack of adequate funding to continue our clinical trials, such as our previous Phase 2a studies, and nonclinical studies;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- the inability of CROs to perform under these agreements, including due to impacts from the COVID-19 pandemic on their workforce;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board ("IRB") approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- We may decide, or regulatory authorities may require us, to conduct additional nonclinical or clinical trials or abandon product development programs;

- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the FDA or applicable foreign regulatory authorities may disagree with our clinical study design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and
- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA or applicable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical study, a data and safety monitoring board ("DSMB") overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or clinical trials, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. For example, we announced in January 2022 that we were ending our Phase 2a studies of GEM103 early, and we currently do not have any ongoing clinical trials. In addition, if we make changes to a product candidate, such as changes to the formulation, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We have limited experience in conducting clinical trials and have never obtained approval for any product candidates and may be unable to do so successfully.

As a company, we have limited experience in designing, conducting or completing clinical trials and have never progressed a product candidate through to regulatory approval. In part because of this lack of experience, to the extent we continue to pursue product development, our potential clinical trials may require more time and incur greater costs than we anticipate, and we may not have sufficient resources to complete these trials. We cannot be certain that the planned clinical trials will begin or conclude on time, if at all. Large-scale trials will require significant additional financial and management resources. Any performance failure on the part of such third parties could delay the clinical development of our product candidates or delay or prevent us from obtaining regulatory approval or commercializing our product candidates, depriving us of potential product revenue and resulting in additional losses.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations,

statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), was enacted, which includes measures that has significantly changed the way health care is financed by both governmental and private insurers. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. Prior to the Supreme Court's decision, the current President of the United States issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how other healthcare reform measures of the current administrations or other efforts, if any, to challenge repeal or replace the Affordable Care Act, will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the Affordable Care Act was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the Affordable Care Act for plans sold through such marketplaces.
- 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 drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, the former President of the United States signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which 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 drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. At a federal level, the current President of the United States signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates would have been be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed, and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change these measures, both the current administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We expect that the healthcare reform measures that has been adopted and 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 and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

There has been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, 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 research, and if approved, markets, sells and distributes our products. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, prohibit individuals or entities from, among other things knowingly presenting, or causing to be presented, to the federal government or a government contractor, grantee, or other recipient of federal funds, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their implementing regulations, imposes obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates, which are individuals and entities that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal government price reporting laws, which require us 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 federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives); and

- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug prices; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our 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 may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act and California Consumer Privacy Act of 2018 ("CCPA")), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. The state of California, for example, recently adopted the CCPA, which will come into effect beginning in January 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation ("EU GDPR"). The CCPA 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 collection of consumer data from minors, 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. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

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

Clinical development is uncertain, and our clinical trials for GEM103 and any other product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all. To proceed with our development plans and ultimately commercialization, we may need to conduct and meet regulatory requirements for preclinical and clinical studies. For therapeutic applications, the FDA may require additional extensive preclinical and other studies. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical testing and studies will ultimately support the further development of our programs. As a result, there is no assurance that we will be able to submit INDs or similar applications on the timelines we expect, if at all, and we cannot be sure that submission of an IND or similar applications will result in the FDA or other regulatory authorities allowing a clinical trial design to begin.

Even if we are able to obtain regulatory approvals for our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may has significant variability. Even if we receive regulatory approval for GEM103 or any of our other product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be

identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns has been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our products, reformulate our product or make changes, create a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for GEM103 and any other product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our products if and when regulatory approvals for such products are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved products or substantially increase the costs and expenses of commercializing and marketing our products.

Even if our product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on our product candidates, including their indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Further, even if we obtain regulatory approval for a product candidate, we would be subject to ongoing requirements by the governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, tracking and tracing, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information.

The FDA and applicable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or applicable foreign regulatory authorities become aware of new safety information after approval of our product candidates, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice ("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 facility 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. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;

- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, applicable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug and biologic products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies has increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label product uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's 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 adopt 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidates, if approved, which could make it difficult for us to sell our product candidates profitably.

To the extent we continue to pursue product development, the success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which products and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

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. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also has their own methods and approval process apart from Medicare determinations. Even if we obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining applicable foreign regulatory authorities and compliance with applicable foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may has a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory

requirements in international markets and 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 and our business will be adversely affected. We may not obtain applicable foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidates by applicable foreign regulatory authorities, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or has actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, has had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of the Business Combination and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold due to the COVID-19 pandemic, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response

letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

GEM103 and other product candidates for which we may choose to seek approval as biologic products may face competition sooner than anticipated.

GEM103 and GEM307 are a biological product candidates. We believe that any of our product candidates approved in the United States as a biological product under a Biologics License Application ("BLA") should qualify for the 12-year period of regulatory exclusivity. The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") as part of the Affordable Care Act, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. 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 the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

However, there is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. The extent to which a biosimilar, once approved, will be substituted for any one of its 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. It is also possible that payers will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for GEM103 and other product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to GEM103 and other product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Risks Related to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for GEM103 and our other product candidates, proprietary patient screening technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. Finally, we maintain our non-patented, but proprietary technologies, as company trade secrets.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our licensors 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 issued will not be infringed, designed around or invalidated 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 rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We currently do not have any company-owned or in-licensed patents covering GEM103. Although we are pursuing pending patent applications on GEM103, these applications may not issue as patents and as a result we may not be able to prevent biosimilars to GEM103 from entering the market when the market exclusivity period has expired. We cannot be certain that the claims in U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the United States Patent and Trademark Office ("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 issued patent or our licensor's issued patents will not be found invalid or unenforceable if challenged.

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- Our competitors, many of whom have substantially greater resources than we 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 eliminate our ability to make, use and sell our potential 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 product candidates.

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 will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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 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.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize our product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the AMD field, and there are issued third-party patents and published third-party patent applications in these fields. Although no third party has asserted a claim of

patent infringement against us as of the date of this annual report, a third party may hold proprietary rights that could prevent our product candidates from being marketed. For example, we are aware of an issued European patent expiring in 2026 that claims an isolated CFH polypeptide which could be alleged to cover GEM103. While we believe that the expiration date of this patent will be prior to European launch of GEM103, there is a possibility that commercial manufacturing or product launch in Europe would predate the patent expiration. If commercial manufacturing or product launch in Europe predates the patent expiration, and in the event that this patent is successfully asserted against us, such litigation may negatively impact our ability to commercialize GEM103 in France, Germany, Ireland, Liechtenstein, the Netherlands, Switzerland or the United Kingdom. We may not be aware of all third-party intellectual property rights potentially relating to our product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of our product candidates, we may need to obtain a license under such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to in-licensed technologies.

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

If we fail to comply with our obligations under any license, collaboration or other agreements, including the license agreement with Sanquin Blood Supply Foundation related to anti-CFH agonistic antibodies, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We are dependent on patents, know-how and proprietary technology in-licensed from Sanquin Blood Supply Foundation and other licensors. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Sanquin Blood Supply Foundation and other licensors may have the right to terminate the license agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Sanquin Blood Supply Foundation or other licensors could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Sanquin Blood Supply Foundation, as well as any current or future potential licensors, regarding intellectual property subject to a license agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, the Research Collaboration and License Agreement under which we currently license intellectual property is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the Research Collaboration and License Agreement, either of which could has a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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 from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

Currently, we do not own or have in-licensed issued patents covering GEM103. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we and our licensor may not be able to prevent third parties from practicing our and our licensor’s inventions in all countries outside the United States, or from selling or importing products made using our and our licensor’s inventions in and into the United States or other jurisdictions. Competitors may use our and our licensor’s 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 and our licensor have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates our and our licensor’s 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 certain countries, particularly certain developing countries, do not favor the enforcement of

patents and other intellectual property protection, particularly those relating to biotechnology. This could make it difficult for us and our licensor to stop the infringement of our and our licensor's patents or the marketing of competing products in violation of our and our licensor's proprietary rights, generally. Proceedings to enforce our and our licensor's patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensor's efforts and attention from other aspects of our business, could put our and our licensor's patents at risk of being invalidated or interpreted narrowly, could place our and our licensor's patent applications at risk of not issuing and could provoke third parties to assert claims against our or our licensor. Our or our licensor may not prevail in any lawsuits that our or our licensor initiates and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, our and our licensor may have limited remedies if patents are infringed or if our or our licensor are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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. Accordingly, our and our licensor's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we owns or licenses.

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

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the USPTO and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensor fails to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe on our or our licensor's patents or misappropriate or otherwise violate our or our licensor's intellectual property rights. In the future, we or our licensor may initiate legal proceedings to enforce or defend our or our licensor's intellectual property rights, to protect our or our licensor's trade secrets or to determine the validity or scope of intellectual property rights we own or controls. Also, third parties may initiate legal proceedings against our or our licensor to challenge the validity or scope of intellectual property rights we own, controls or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our or our licensor's patents, requiring us or our licensor to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our or our licensor's efforts, we or our licensor may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, controls or has rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we or our licensor initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone

connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that we or our licensor's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensor's patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation reexamination, or *inter partes* review, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our licensor, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our or our licensor's patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us or our licensor to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us or our licensor a license on commercially reasonable terms, or at all. Even if we or our licensor obtains a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensor. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize product candidates. Even if we successfully defends such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and which may make defending or enforcing our or our licensor's patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our Common Stock.

Third parties may initiate legal proceedings against us alleging that we are infringing on their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our licensor alleging that we or our licensor is infringing on their intellectual property rights or we or our licensor may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can.

An unfavorable outcome in any such proceeding could require us or our licensor to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We perform searches of patent and scientific databases in order to identify documents that may be of potential relevance to the freedom-to-operate and/or patentability of our product candidates. In general, such searches are conducted based on keywords,

sequences, inventors/authors and assignees/entities to capture U.S. and European patents and patent applications, PCT publications and scientific journal articles.

The patent landscape around our GEM103 product candidate is complex, and we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and technologies. Although no third party has asserted a claim of patent infringement against us as of the date of this annual report, a third party may hold proprietary rights that could prevent our product candidates from being marketed. For example, we are aware of an issued European patent expiring in 2026 that claims an isolated CFH polypeptide which could be alleged to cover GEM103. While we believe that the expiration date of this patent will be prior to European launch of GEM103, there is a possibility that commercial manufacturing or product launch in Europe would predate the patent expiration. If commercial manufacturing or product launch in Europe predates the patent expiration, and in the event that this patent is successfully asserted against us, such litigation may negatively impact our ability to commercialize GEM103 in France, Germany, Ireland, Liechtenstein, the Netherlands, Switzerland or the United Kingdom. Moreover, it is possible that we may become aware of patents or pending patent applications that we think do not relate to our product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidates and to be valid and enforceable. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. If any third party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability and the ability of our licensor to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or our licensor or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we or our licensor and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. 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, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or we have misappropriated a third party's intellectual property, or claiming ownership of what we regards as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecutes or defends against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached,

and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CMOs, consultants, advisors and other third parties. We also enters into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information, and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including 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;
- the patents of others may harm our business; and
- 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 covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patents that ultimately issue that cover our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or our licensing partner initiate legal proceedings against a third party to enforce a patent, if obtained, covering our product candidates, the defendant could counterclaim that the patent covering our product candidates, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves technological and legal complexity, and obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. 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, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our and our licensor's 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 Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensor's ability to obtain new patents or to enforce existing patents and patents we and our licensor may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act ("Leahy-Smith Act"), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our and our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and may also affect patent prosecution and litigation, such as by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will has on the operation of our business. However, the Leahy-Smith Act and our implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents, all of which could has a material adverse effect on our business, financial condition and results of operations.

Risks Related to Reliance on Third Parties

We may rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We continue to depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We continue to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We continue to rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with good clinical practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and applicable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated 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.

The third parties who may conduct our future clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. 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 these third parties 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties 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 begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manages 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 CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) 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. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

We contract with third parties for the manufacture of our product candidates for nonclinical testing and expects to continue to do so for clinical trials and for commercialization, if approved. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expects to continue to rely, on third-party manufacturers for the manufacture of our product candidates for nonclinical and clinical testing and for commercial supply of any of these product candidates for which we obtain marketing approval. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. Any disruption in supply from any supplier or manufacturing location, including on account of the ongoing COVID-19 pandemic, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable

terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or applicable foreign regulatory requirements. Our failure, or the failure of 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 or medicines, 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.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current CMOs cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacturing of our product candidates is complex, and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fails to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our product candidates are complex, expensive, highly-regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other applicable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and applicable foreign regulatory authority requirements, including, for example, complying with cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and has an adverse effect on our business, financial condition, results of operations, and growth prospects.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may pursue collaborations in order to develop and commercialize GEM103 and other product candidates. We face significant competition in seeking appropriate collaborators. 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 or applicable 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 and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidates.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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 the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our 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.

Risks Related to Commercialization

Even if we commercialize our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs and biologics vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the product is approved by the FDA or applicable foreign regulatory

authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs and biologics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs and biologics from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establishes marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and they could expose our company to regulatory enforcement and legal risk in the execution of their sales and commercialization activities. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition, and prospects will be materially adversely affected.

Our product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product, or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions outside the United States where we may pursue regulatory approvals and market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies.

Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available products for the same disease, rather than allowing us to market our products at a premium as new

drugs. 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 of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidates.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop and insurance coverage may not be adequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;

- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks Related to Our Common Stock

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of common stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The price of our common stock has been and may continue to be volatile and the value of an investment in our common stock may decline.

Our stock price has been and is likely to continue to be highly volatile. From February 5, 2021, the date of our Business Combination, through February 28, 2022, the trading price of our common stock ranged between a low sales price of $1.36 and a high sales price of $19.08. The stock market in general and the market for biopharmaceutical companies in particular have experienced periods of extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, a holder may not be able to sell our common stock at or above the price at which such holder acquired shares of our common stock.

The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which our and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the ongoing COVID-19 pandemic on the markets and the broader global economy;
- 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, political and geopolitical conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism, such as the recent invasion by Russia of Ukraine.

These market and industry factors may materially reduce the market price of our common stock regardless of our operating performance.

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 or discontinue coverage and may publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price 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 share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

The future sales of shares by existing stockholders and future exercise of registration rights may adversely affect the market price of our Common Stock.

Sales of a substantial number of shares of our Common Stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our Common Stock in the public market, the market price of our Common Stock could decline.

Pursuant to the Registration Rights Agreement entered into in connection with the Business Combination, certain stockholders of FSDC and Old Gemini can each demand that we register their registrable securities under certain circumstances and each also have piggyback registration rights for these securities. The registration of these securities permit the public sale of such securities, subject to certain contractual restrictions imposed by the Registration Rights Agreement and the Merger Agreement. The presence of these additional shares of Common Stock trading in the public market may have an adverse effect on the market price of our securities.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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

We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our board of directors. Our board of directors may take into account general and economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders or by our subsidiary to us and such other factors as our board of directors may deem relevant. In addition, the terms of our existing financing arrangements restrict or limit our ability to pay cash dividends. Accordingly, we may not pay any dividends on our common stock in the foreseeable future.

Future offerings of debt or equity securities by us may adversely affect the market price of our common stock.

In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our common stock or offering debt or other equity securities, including commercial paper, medium-term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and/or cash from operations.

Issuing additional shares of our common stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our common stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued, and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our common stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our common stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings.

We may incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We may incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”), as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”), the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations are expected to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. For example, we have and will continue to devote significant resources for the continuing assessment and documentation of our internal control system and financial processes under Section 404, including an assessment of the design of our information systems associated with our internal controls.

We may identify control deficiencies and be unable to remediate them. Furthermore, if we fail to remediate any potential material weakness in our internal control over financial reporting or if material weaknesses are identified or arise in the future, we may not detect errors on a timely basis and our financial statements may be materially misstated. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we will be required to timely file accurate quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences. We will incur significant costs to remediate any potential material weaknesses that we may identify through these efforts. The increased costs would increase our net loss and may require us to reduce costs in other areas of our business. We also expect these rules and regulations to make it more expensive for us to maintain directors’ and officers’ liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of such costs.

New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act and rules adopted by the SEC and Nasdaq, would likely result in increased costs as we respond to their requirements, which may adversely affect our operating results and financial condition.

We may be at increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies, including us, have experienced significant stock price volatility in the past.

Anti-takeover provisions contained in our charter and our by-laws, as well as provisions of Delaware law, could impair a takeover attempt.

Our charter contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could discourage, delay, defer or prevent a merger, tender offer, proxy contest or other change of control transaction that a stockholder might consider in our best interest, including those attempts that might result in a premium over the market price for the shares of common stock held by our stockholders. These provisions provide for, among other things:

- a classified board with a three-year staggered term;
- limit the manner in which stockholders can remove directors from the board;
- the ability of our board of directors to issue one or more series of “blank check” preferred stock;
- certain limitations on convening special stockholder meetings;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at our annual meetings; and
- amendment of certain provisions of the organizational documents only by the affirmative vote of at least two-thirds of our then-outstanding shares of capital stock entitled to vote generally at an election of directors.

These anti-takeover provisions as well as certain provisions of Delaware law could make it more difficult for a third party to acquire us, even if the third party’s offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. If prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our Common Stock. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and to cause us to take other corporate actions that our stockholders desire.

Our by-laws provide that the Court of Chancery of the State of Delaware and the federal district courts of the District of Massachusetts will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our by-laws provide that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law (“DGCL”), our charter, or our by-laws;
- any action to interpret, apply, enforce or determine the validity of our charter or our by-laws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive-forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or the Securities Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our by-laws provides that the federal district courts of the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in the By-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our facilities consisted of office space in Cambridge, Massachusetts. We terminated this lease on December 31, 2021 and no longer have any properties. We believe that our current remote working arrangement is sufficient for our current needs.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on Nasdaq under the symbol "GMTX".

Holders

As of February 28, 2022, there were 37 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our board of directors. In addition, our board of directors is not currently contemplating and does not anticipate declaring stock dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Offerings

Except as previously disclosed in our Quarterly Reports on Form 10-Q during 2021, we did not sell any securities that were not registered under the Securities Act during the period covered by this Annual Report on Form 10-K.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage precision medicine company developing novel therapeutic compounds to treat genetically defined, age-related macular degeneration ("AMD"). Our lead product candidate, GEM103, is a recombinant form of the human complement factor H protein ("CFH") and is designed to address complement hyperactivity and overall dysregulation caused by loss of function mutations thus restoring retinal health in patients with AMD. Native CFH serves multiple functions in maintaining retinal health, including regulating lipid metabolism in the retina, protecting the retina against lipid and protein by-products of oxidative stress, and regulating the complement system, which is part of the innate immune system. This multifaceted regulation plays an integral role in engagement and maintenance of complement-mediated immune responses that are involved in pathogen defense and cellular debris clearance.

In January 2022, we announced that we discontinued both of our Phase 2a clinical trials of GEM103, the ReGAtta study and the GEM103 as an Add-On to Anti-VEGF Therapy for the Treatment of Wet-AMD study.

In February 2022, we announced a corporate restructuring and that we have initiated a process to evaluate strategic alternatives. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize shareholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

Since inception in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our product candidates. We do not have any products approved for sale, and we have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product.

To the extent we continue to pursue clinical development of GEM103 or any other product candidate, our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We have not yet successfully completed any pivotal clinical trials, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

We are also working to advance GEM307, that could be effective for treatment of systemic diseases, towards IND filing.

Recent developments

2022 Restructuring and Process to Evaluate Strategic Alternatives

On February 28, 2022, we announced a restructuring plan to reduce our operations to preserve financial resources, resulting in a reduction of our workforce by up to 24 positions, or approximately 80%, by the end of the second quarter of 2022. As a result, we estimate that we will incur costs within the range of $1.6 million to $1.9 million, which are expected to consist of severance benefits for the affected employees and other restructuring costs and expenses. The restructuring plan is expected to be completed by the end of the second quarter of 2022. Additionally, we have initiated a process to evaluate strategic alternatives in order to maximize shareholder value. There can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all.

In addition, effective as of February 28, 2022, Georges Gemayel, Ph.D., our current Executive Chair, was appointed as interim President and Chief Executive Officer to succeed Jason Meyenburg, who has transitioned from his roles as President, CEO and Director and will continue to serve as an advisor to the Company. Dr. Gemayel will continue to serve as the Chair of our Board.

2021 Restructuring

In October 2021, we announced a restructuring plan resulting in a reduction of our workforce by 11 positions, or approximately 26% of our then workforce. In connection with the October 2021 restructuring, we incurred costs of $1.4 million related to severance benefits for the affected employees. The restructuring plan was completed by the end of 2021.

Employment Agreement with Georges Gemayel

In November 2021, we entered into an employment agreement with Dr. Georges Gemayel to serve as Executive Chair of our board of directors.

COVID-19 pandemic

In March 2020, the World Health Organization declared the novel coronavirus ("COVID-19") outbreak a pandemic. The ongoing COVID-19 pandemic and the increased prevalence of variants of the virus, and government measures taken in response, have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The ongoing COVID-19 pandemic and related impacts have resulted in, and will likely continue to result in, significant disruptions to the global economy and capital markets around the world. We cannot predict the future progression or full impact of the outbreak and its effects on our business and operations.

We have not incurred impairment losses in the carrying values of our assets as a result of the ongoing COVID-19 pandemic, and we are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in our consolidated financial statements. Although the COVID-19 pandemic did not have a significant impact on our financial results in 2021, the full extent to which the ongoing COVID-19 pandemic may impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain, and the estimates of the impact on our business may change based on new information that may emerge concerning COVID-19, including the duration of the pandemic, any potential subsequent waves or strains of COVID-19 infection, the effectiveness, distribution and acceptance of COVID-19 vaccines and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

Business Combination

On February 5, 2021, FSDC consummated the previously announced Business Combination pursuant to the terms of the Agreement and Plan of Merger, dated as of October 15, 2020 (as amended, supplemented or otherwise modified from time to time, the "Merger Agreement"), by and among Old Gemini, Stockholders' Representative, and Merger Sub.

FSDC was incorporated in Delaware on June 25, 2020 and was formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

On the day prior to the Closing Date, Old Gemini changed its name to "Gemini Therapeutics Sub, Inc." Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC changed its name to "Gemini Therapeutics, Inc.", and (ii) Old Gemini merged with and into Merger Sub (the "Merger"), with Old Gemini as the surviving company in the Merger and, after giving effect to such Merger, Old Gemini becoming a wholly-owned subsidiary of Gemini. Upon the closing of the Business Combination, and pursuant to the terms of the Merger Agreement, the existing shareholders of Old Gemini exchanged their interests for shares of common stock of Gemini.

In connection with the Business Combination, certain investors purchased an aggregate of $95.1 million of our Common Stock in a private placement of public equity (the "PIPE Financing"). Together with FSDC's cash resources and funding of the PIPE Financing, we received net proceeds of approximately $195.9 million.

We accounted for the Business Combination as a reverse recapitalization, which is the equivalent of Old Gemini issuing stock for the net assets of FSDC, accompanied by a recapitalization, with FSDC treated as the acquired company for accounting purposes. The net assets of FSDC were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Gemini. The shares and

corresponding capital amounts and loss per share related to Old Gemini's outstanding convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the conversion ratio established in the Merger Agreement (1.00 Old Gemini share for 0.2180 shares of our company (the "Conversion Ratio")).

For additional information on the Business Combination, please read Note 2, *Business Combination*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Financial Operations Overview

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts were to continue and be successful and we were to commercialize any of our product candidates, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, as well as upfront, milestone and royalty payments from such collaboration or license agreements, or a combination thereof.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for research activities, including drug discovery efforts and the clinical development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our drug discovery efforts, preclinical studies, and clinical trials;
- CMOs that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to comply with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs as incurred. Any advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. We estimate and accrue for the value of goods and services received from CROs, CMOs and other third parties each reporting period based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs.

We do not track our research and development expenses on a program-by-program basis. Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development

activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities have been central to our business model to date. We anticipate that our research and development expenses will decrease in 2022 compared to 2021 due to our planned reduced clinical efforts in 2022 and recent restructurings announced in connection with our exploration of strategic alternatives. If we continue to pursue development efforts and we believe a regulatory approval of a product candidate appears likely, we would anticipate an increase in payroll and other expenses as a result of our preparation of regulatory filings and precommercial activities.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that would be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of any of our product candidates is highly uncertain. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, timing, outcome and costs of any continued preclinical development activities, clinical trials and other related development activities;
- delays, suspensions, or other setbacks or interruptions encountered, including as a result of the ongoing COVID-19 pandemic;
- establishing an appropriate safety and efficacy profile with any Investigational New Drug application (“IND”) enabling studies and obtaining clearance for future IND applications;
- successful patient enrollment in and the initiation and completion of any clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the U.S. Food and Drug Administration (“FDA”) and non-U.S. regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make and scale our products successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

A change in any of these variables with respect to any of our programs would significantly change the costs, timing and viability associated with that program.

General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries and related benefits, travel and stock-based compensation for personnel in executive, business development, finance, human resources, legal, information technology and administrative functions. General and administrative expenses also include direct and allocated

facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expense general and administrative costs as incurred.

We anticipate that our general and administrative expenses will decrease in 2022 as compared to 2021 due to recent restructurings announced in connection with our exploration of strategic alternatives. If, however, at any point in the future we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Other income (expense)

Interest expense

Interest expense consists of interest accrued on the Term Loan we entered into in February 2019 and the Notes, including the accretion of the beneficial conversion feature discount recognized on the issuance date of the Notes.

Interest income

Interest income consists of income earned on our cash, cash equivalents and restricted cash.

Loss on conversion of convertible notes

Immediately prior to the closing of the Business Combination, the outstanding principal and interest under the Notes converted into shares of Series B preferred stock, and we recorded other expense equal to the difference between the reacquisition price of the Notes and the net carrying amount of the Notes in the consolidated statements of operations and comprehensive loss.

Change in fair value of warrant liability

In February 2019, in conjunction with the Term Loan with SVB, we issued warrants to purchase 15,257 shares of Old Gemini's Series A preferred stock. We accounted for, and classified, these warrants as a liability on our balance sheet because the warrants were freestanding financial instruments. We remeasured this liability to fair value at each reporting date and recognized changes in the fair value of the warrant liability in our consolidated statements of operations and comprehensive loss. At the closing of the Business Combination, these warrants were automatically exercised for 15,257 shares of our common stock.

Provision for income taxes

We have not recorded any significant amounts related to income tax expense, we have not recognized any reserves related to uncertain tax positions, nor have we recorded any income tax benefits for the majority of our net losses we have incurred to date or for our research and development tax credits.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We continue to maintain a full valuation allowance against all of our net deferred tax assets based on our evaluation of all available evidence.

We file income tax returns in the United States ("U.S.") federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return period for U.S. federal income taxes for the tax years since 2018 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or positions is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and

refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our provision for income taxes. To date, no amounts are being presented as an uncertain tax position.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes as a result of subsequent shifts in our stock ownership.

Results of operations

Comparison of the years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (*in thousands*):

	Year Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	$ 48,717	$ 28,170	$ 20,547
General and administrative	20,285	5,870	14,415
Total operating expenses	69,002	34,040	34,962
Loss from operations	(69,002)	(34,040)	(34,962)
Other income (expense):			
Interest expense	(2,158)	(6,826)	4,668
Interest income	15	37	(22)
Loss on conversion of convertible notes	(711)	—	(711)
Change in fair value of warrant liability	—	(8)	8
Other expense	(13)	—	(13)
Net loss and comprehensive loss	$ (71,869)	$ (40,837)	$ (31,032)

Research and development expenses

Research and development expenses were $48.7 million for the year ended December 31, 2021, compared to $28.2 million for the year ended December 31, 2020. The increase of $20.5 million was primarily due to an increase in external research and development costs related to clinical trial activities of GEM103. In addition, research and development personnel costs were higher period over period, including stock-based compensation, due to an increase in headcount in our research and development function to support the advancement of our programs.

General and administrative expenses

General and administrative expenses were $20.3 million for the year ended December 31, 2021, compared to $5.9 million for the year ended December 31, 2020. The increase of $14.4 million was primarily due to higher personnel-related costs, including stock-based compensation, in support of organizational growth and higher legal, insurance and other professional fees incurred in connection with operating as a public company.

Interest expense

Interest expense was $2.2 million for the year ended December 31, 2021, compared to $6.8 million for the year ended December 31, 2020. The decrease of $4.6 million was due to the accretion of the beneficial conversion feature discount recognized at the issuance date of the Notes in 2020.

Loss on conversion of convertible notes

The loss on conversion of convertible notes was $0.7 million for the year ended December 31, 2021, compared to $0 for the year ended December 31, 2020. The increase reflects the difference between the reacquisition price of the Notes and the net carrying amount of the Notes at the time that the Notes converted into shares of Series B preferred stock immediately prior to the closing of the Business Combination.

Liquidity and capital resources

Sources of liquidity and capital

Since inception, we have not generated any revenue from any product sales or any other sources and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and do not expect to generate revenue from sales of any product candidates for several years, if at all. Our net loss was $71.9 million for the year ended December 31, 2021. As of December 31, 2021, we had an accumulated deficit of $184.7 million.

Prior to the Business Combination, we funded our operations to date primarily with proceeds from the sale of preferred stock, borrowings under convertible promissory notes and borrowings under loan agreements. In January 2020, we received gross proceeds of $20.1 million from the sale of our preferred stock. In August 2020, we received gross proceeds of $14.0 million from borrowings under convertible promissory notes. In February 2021, in connection with the Business Combination, we received net proceeds of $195.9 million.

As of December 31, 2021, we had cash and cash equivalents of $136.6 million. Continued cash generation is highly dependent on our ability to finance our operations through a combination of equity offerings, debt financings, collaboration arrangements and strategic transactions. However, our resource requirements could materially change to the extent we identify and enter into any strategic transaction.

Until required for use in our business, we typically invest our cash in investments that are highly liquid, readily convertible to cash with original maturities of 90 days or less at the date of purchase. We attempt to minimize the risks related to our cash and cash equivalents by maintaining balances in accounts only with accredited financial institutions and, consequently, we do not believe we are subject to unusual credit risk beyond the normal credit risk associated with ordinary commercial banking relationships.

Cash flows

The following table summarizes our cash flows for the year ended December 31, 2021 and 2020 (*in thousands*):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (59,700)	$ (32,708)
Net cash provided by (used in) investing activities	344	(22)
Net cash provided by financing activities	191,480	34,247
Net increase in cash, cash equivalents and restricted cash	$ 132,124	$ 1,517

Operating activities

We do not generate any cash inflows from our operating activities. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital requirements to support the business. We have historically experienced negative cash flows from operating activities as we invested in developing our platform, drug discovery efforts and related infrastructure.

During the year ended December 31, 2021, we used cash in operating activities of $59.7 million, reflecting a net loss of $71.9 million, partially offset by non-cash charges of $10.3 million and a net change of $1.9 million in our operating assets and liabilities. The non-cash charges consist primarily of $7.8 million of stock-based compensation expense, $1.6 million accretion of the discount on the Notes, and $0.7 million of expense related to the conversion of the Notes. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses and other current liabilities and a decrease in deferred offering costs, partially offset by an increase in prepaid expenses and other current assets.

During the year ended December 31, 2020, we used cash in operating activities of $32.7 million, reflecting a net loss of $40.8 million, offset by non-cash charges of $7.8 million and a net change of $0.3 million in our operating assets and liabilities. The non-cash charges primarily consist of $5.9 million accretion of the discount on the Notes, $1.0 million of stock-based compensation expense and $0.6 million of non-cash interest expense. The net change in our operating assets and liabilities was primarily due to a decrease in prepaid expenses and other current assets, partially offset by an increase in deferred offering costs.

Investing activities

During the year ended December 31, 2021, net cash provided by investing activities was $0.3 million, consisting primarily of proceeds from the sale of property and equipment, compared to net cash used in investing activities of less than $0.1 million during the year ended December 31, 2020, consisting of purchases of laboratory equipment.

Financing activities

During the year ended December 31, 2021, net cash provided by financing activities was $191.5 million, consisting primarily of $195.9 million of net proceeds received in connection with the Business Combination, partially offset by principal payments made on our term loan.

During the year ended December 31, 2020, net cash provided by financing activities was $34.2 million, consisting primarily of $20.1 million of net proceeds from the issuance of our Series B preferred stock and $14.0 million of net proceeds from the issuance of the convertible promissory notes.

Funding requirements

Our primary use of cash is to fund operating expenses, primarily related to our research and development activities. However, our resource requirements could materially change to the extent we identify and enter into any strategic transaction. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect our expenses to decrease in 2022 compared to 2021 due to our planned reduced clinical efforts in 2022 and the restructurings announced in October 2021 and February 2022 in connection with our exploration of strategic alternatives. To the extent we continue to pursue the development of our product candidates, the timing and amount of our operating expenditures will depend largely on our ability to:

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, including sourcing raw materials, our preclinical and clinical drug material and develop processes for late stage and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- 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 on our own;
- maintain and protect our intellectual property portfolio;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims;
- manage the costs of operating as a public company; and
- realize the anticipated benefits of our restructuring plans.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, would be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

As of December 31, 2021, we had cash and cash equivalents of $136.6 million. We believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months from the filing of this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. However, our resource requirements could materially change to the extent we identify and enter into any strategic transaction.

Until such time as we can generate substantial product revenue, if ever, and subject to our pursuit of a strategic transaction, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. 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 drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Working capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Subject to our pursuit of a strategic transaction, our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of raw materials and manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations and strategic alliances on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Contractual obligations and commitments

Term loan

In February 2019, we entered into a term loan facility of up to $10.0 million (the “Term Loan”) with SVB. The proceeds were used for general corporate and working capital purposes. Concurrent with the Term Loan, we issued SVB warrants to purchase 15,257 shares of Old Gemini’s Series A preferred stock at an exercise price of $5.46. At the closing of the Business Combination, these warrants were automatically exercised for 15,257 shares of our common stock. As of December 31, 2021 and 2020, we had $5.4 million and $10.0 million, respectively, in principal outstanding under the Term Loan.

The Term Loan is governed by a loan and security agreement, entered into in February 2019, between Gemini and SVB (the “SVB Loan Agreement”). The SVB Loan Agreement provided for two separate tranches under which we could borrow. In

April 2019, we borrowed $7.5 million under the first tranche, and in December 2019, we borrowed $2.5 million under the second tranche.

The Term Loan matures in January 2023 and accrues interest at a floating rate per annum equal to the greater of 3.75% or the prime rate minus 1.5% (1.75% as of September 30, 2021). The Term Loan provides for monthly interest-only payments until February 2021. Thereafter, payments are payable in equal monthly installments of principal, plus all accrued and unpaid interest. We may prepay the Term Loan in whole upon 5 days' prior written notice to SVB. Any such prepayment of the Term Loan is subject to a prepayment charge of 0.5% of the then outstanding principal balance. Amounts outstanding during an event of default are payable upon SVB's demand and will accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

In April 2020, we entered into a deferral agreement with SVB to defer scheduled principal repayments on its term loan by six months. The deferral agreement was offered in connection with SVB's venture debt relief initiative, which was started due to the COVID-19 pandemic. Our first principal payment under our credit facility occurred in February 2021. The required monthly interest-only payment was not impacted by the deferral. The Term Loan's new maturity date is January 2023.

At the end of the loan term (whether at maturity, by prepayment in full or otherwise), we are required to pay a final end of term charge to SVB in the amount of 4.0% of the aggregate original principal amount advanced by SVB.

Convertible promissory notes

In August 2020, we entered into a purchase agreement with existing investors to issue $14.0 million in convertible promissory notes, (the "Notes"). The Notes accrued simple interest at 8% per annum and matured in February 2021. The Notes served as a bridge loan prior to the PIPE Financing that was completed in connection with the closing of the Business Combination. The Notes were amended to allow for the principal and interest to convert to shares of Series B preferred stock prior to the closing of the Business Combination. Accordingly, immediately prior to the closing of the Business Combination, the outstanding principal and interest under the Notes converted into 2,341,316 shares of Series B preferred stock at a per share conversion price of $6.1986.

Contract research and manufacturing organizations

We enter into contracts in the normal course of business with CMOs, CROs and other third parties for the manufacture of our product candidates and to support clinical trials and preclinical research studies and testing. These contracts are generally cancelable at any time by us following a certain period of notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. We recorded accrued expenses of approximately $4.0 million in our consolidated balance sheet for expenditures incurred by CROs and CMOs as of December 31, 2021.

Tax-related obligations

To date, we have not recognized any reserves related to uncertain tax positions. As of December 31, 2021, we had no accrued interest or penalties related to uncertain tax positions.

Critical accounting policies and significant judgments and estimates

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

While our significant accounting policies are described in more detail in Note 3 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical studies and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, our estimated accruals have not differed materially from actual costs incurred.

Stock-based compensation

We measure all stock-based awards granted to employees, directors and non-employees based on the fair value on the date of grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. We grant stock options and restricted stock awards that are subject to either service or performance-based vesting conditions. For awards with service-based vesting conditions, we recognize equity-based compensation expense on a straight-line basis over the vesting period. Compensation expense related to awards to employees and non-employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. We estimate the probability that certain performance criteria will be met and do not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

Determination of Fair Value

Subsequent to the closing of the Business Combination, the fair value of each share of common stock underlying stock-based awards is determined based on the closing price of our common stock as reported by Nasdaq on the date of grant.

We estimate the fair value of stock options using the Black-Scholes option pricing model, which uses as inputs the fair value of our common stock, and certain management estimates, including the expected stock price volatility, the expected term of the award, the risk-free rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information is available. We select companies with comparable characteristics with historical share price information that approximates the expected term of the equity-based awards. We compute the historical volatility data using the daily closing prices for the selected companies’ shares during the equivalent period that approximates the calculated expected term of the stock options. We will continue to apply this method until a sufficient amount of historical information regarding the volatility of its stock price becomes available. The risk-free

interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. We use the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. We utilize this method due to lack of historical exercise data. The expected dividend yield is assumed to be zero as we have no current plans to pay any dividends on common stock.

Prior to the completion of the Business Combination, given there had been no public market for our common stock, the estimated fair value of our common stock was determined by the board of directors as of the date of each award grant, with input from management, considering our most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using an option pricing method ("OPM") or a hybrid method, both of which used market approaches to estimate enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a probability-weighted expected return method ("PWERM") where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of our common stock based upon an analysis of our future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which we sold shares of preferred securities, the superior rights and preferences of securities senior to the common securities at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Recently issued accounting pronouncements

Refer to Note 3, *Summary of Significant Accounting Policies*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information regarding recently issued accounting pronouncements.

Emerging growth company and smaller reporting company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised accounting standard. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceed $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and our principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

With respect to the year ended December 31, 2021, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2021 to provide reasonable assurance that the information required to be disclosed by us in this Annual Report was (a) reported within the time periods specified by SEC rules and regulations and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework* (2013 framework) (COSO). Based on its assessment, management believes that, as of December 31, 2021, our internal control over financial reporting is effective at the reasonable assurance level.

This Annual Report does not include an attestation report of our independent registered public accounting firm as allowed by the SEC's transition period for emerging growth companies.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal year ended December 31, 2021 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following sets forth certain information, as of the date of this report, concerning the directors and officers.

Name	Age	Position
Georges Gemayel, Ph.D.	61	Interim President and Chief Executive Officer, Executive Chairperson
Brian Piekos	47	Chief Financial Officer and Chief Business Officer
Samuel Barone, M.D.	48	Chief Medical Officer
Carl Gordon, Ph.D., CFA	57	Director
David Lubner	57	Director
Tuyen Ong, M.D., MRCOphth	47	Director
Jason Rhodes	52	Director
Jim Tananbaum, M.D.	58	Director

Georges Gemayel, Ph.D. Dr. Georges Gemayel has served as our Interim President and Chief Executive Officer since February 2022, Executive Chair of the Board since November 2021 and Chair of the Board since May 2021. Dr. Gemayel has over 30 years of experience in the pharmaceutical industry, including management and executive positions in the U.S., Europe and the Middle East. Dr. Gemayel currently serves on the board of directors of Supernus Pharmaceuticals, Inc., and is the chair of the boards of Dynacure, Enterome SA, and Orphazyme A/S. Previously, Dr. Gemayel served as Executive Chair of FoldRx Pharmaceuticals and of Syndexa Pharmaceuticals, as Chair of Oxthera AB, Dimension Therapeutics and Epitherapeutics and as Director of Prosensa, Raptor Pharmaceuticals, NPS Pharma, Momenta Pharmaceuticals and Adolor. From 2008 to 2009, Dr. Gemayel was President and Chief Executive Officer of Altus Pharmaceuticals Inc., a publicly traded pharmaceutical company. From 2003 to 2008, he was Executive Vice President at Genzyme Corporation where he was responsible for the company's global therapeutics, transplant, renal and biosurgery businesses. From 1998 to 2003, he held progressively senior roles at Hoffmann Ltd. and Roche Labs, most recently as Vice President, National Specialty Care, responsible for its U.S. business for dermatology, oncology, transplantation, hepatitis and HIV. Dr. Gemayel completed his doctorate in pharmacy at St. Joseph University in Beirut, Lebanon, and earned a Ph.D. in pharmacology at University in Paris, France. Our Board has concluded that Dr. Gemayel possesses the expertise and extensive professional experience and knowledge that qualifies him to serve as our Chair of the Board.

Brian Piekos has served as our Chief Financial Officer since February 2021 and has held the additional title of Chief Business Officer since October 2021. Mr. Piekos has more than 20 years of experience in industry and finance. Previously, Mr. Piekos was most recently Executive Vice President, Chief Financial Officer and Treasurer of AMAG Pharmaceuticals, Inc., from September 2015 to November 2020. Prior to joining AMAG, he held leadership roles in Corporate Finance, Tax and Treasury at Cubist Pharmaceuticals, Inc. from August 2010 to February 2015. Mr. Piekos began his career as a healthcare investment banker at Needham & Company and Leerink Partners, now SVB Leerink. Mr. Piekos earned his MBA from the Simon Business School at the University of Rochester. He obtained an M.S. in molecular biology from the University of Massachusetts Medical School and a B.A. in biochemistry from Ithaca College.

Samuel Barone, M.D. has served as our Chief Medical Officer since April 2021. Dr. Barone has more than 20 years of clinical and development experience. Previously, Dr. Barone was most recently co-Founder, Manager and Chief Medical Officer at Halodine, LLC, a company spun out of Veloce BioPharma. Prior to his role at Halodine, he held the role of Chief Medical Officer of Veloce BioPharma. Dr. Barone worked at Veloce BioPharma and subsequently Halodine from September 2017 to April 2021. Prior to joining Veloce BioPharma, he served as Senior Vice President at Adverum Biotechnologies (formerly Avalanche Biotechnologies) from May 2016 to September 2017. While at Avalanche Biotechnologies, Dr. Barone served as Chief Medical Officer from June 2014 to September 2016. Before joining Avalanche Biotechnologies, Dr. Barone served as a Medical Officer in the Office of Cellular, Tissue and Gene Therapies at the U.S. Food and Drug Administration (FDA) from October 2009 to June 2014. Dr. Barone received his B.S. in biology from Boston College and his M.D. from the Pennsylvania State University College of Medicine. After obtaining his medical degree, Dr. Barone served as a flight surgeon in the United States Air Force serving active duty at Andrews Air Force Base and at bases in Korea, Afghanistan, and Iraq for which he received several military honors. Following his military service, Dr. Barone completed a residency in ophthalmology at the New York Eye and Ear Infirmary, where he served as Chief Resident, as well as a medical and surgical retina fellowship at the University of California, San Diego.

Carl L. Gordon, Ph.D., CFA has served as a member of our Board since April 2016. Dr. Gordon is a founding member, Managing Partner, and Co-Head of Global Private Equity at OrbiMed Advisors LLC, an investment firm. Dr. Gordon currently serves on the boards of directors of Adicet Bio, Inc., Compass Therapeutics Inc., Keros Therapeutics Inc., Kinnate Biopharma, Inc., Terns Pharmaceuticals, Inc., and Thesus Pharmaceuticals, Inc., as well as several private companies. Dr. Gordon previously served on the boards of directors of several biopharmaceutical companies, including Alector Inc., ARMO Biosciences, Inc., Arsanis, Inc. (which merged with X4 Pharmaceuticals, Inc.), Intellia Therapeutics, Inc., ORIC Pharmaceuticals, Inc., Passage Bio Inc., Prevail Therapeutics Inc., Selecta Biosciences, Inc., SpringWorks Therapeutics Inc., and Turning Point Therapeutics, Inc. Dr. Gordon received a B.A. in chemistry from Harvard College, a Ph.D. in molecular biology from the Massachusetts Institute of Technology, and he was a Fellow at The Rockefeller University. Our Board believes that Dr. Gordon is qualified to serve on our Board due to his scientific expertise, extensive business experience, and experience in venture capital and the life science industry.

David C. Lubner has been a member of our Board since April 2020. Mr. Lubner is an experienced financial professional with tenure in the biotech and pharmaceutical industry. From January 2016, until its acquisition by UCB S.A. in April 2020, Mr. Lubner served as the Executive Vice President and Chief Financial Officer of Ra Pharmaceuticals, Inc., a publicly-traded biotechnology company. Before joining Ra Pharmaceuticals, Mr. Lubner served as Senior Vice President and Chief Financial Officer of Tetraphase Pharmaceuticals, Inc. from its inception in 2006 through 2015, as the Chief Financial Officer of PharMetrics Inc., a leading patient-based pharmacy and medical claims data informatics company, from 1999 until it was acquired by IMS Health in 2015 and as Vice President and Chief Financial Officer, from 1996 to 1999, of ProScript, Inc., a biotechnology company, where Velcade® (bortezomib), a therapy widely used for treatment of the blood cancer, multiple myeloma, was discovered. Mr. Lubner currently serves on the boards of directors of Dyne Therapeutics, Inc., Arcellx, Inc., Vor Biopharma, Inc., and Point Biopharma, Inc. and several other private companies. Mr. Lubner previously served on the board of directors of Nightstar Therapeutics plc, a company focused on the development of one-time retinal gene therapies for patients suffering from rare inherited retinal diseases, acquired by Biogen in June 2019 and Therapeutics Acquisition Corporation (d/b/a as Research Alliance Corp. I.), a blank check company focused on the healthcare industry. Mr. Lubner is a member of the American Institute of CPAs and a Certified Public Accountant in the Commonwealth of Massachusetts. Mr. Lubner received his B.S. in business administration from Northeastern University and M.S. in taxation from Bentley University. Our Board believes that Mr. Lubner is qualified to serve on our Board based on his extensive senior executive experience and his biotechnology company board experience, including serving as chair of the Audit Committee.

Tuyen Ong, M.D., MRCOphth., has served as a member of our Board since August 2020. Dr. Ong is a board- certified ophthalmologist and biotechnology/pharmaceutical industry management executive. He currently serves as Chief Executive Officer of Ring Therapeutics. Prior to joining Ring Therapeutics, Dr. Ong served as Senior Vice President and Head of Biogen Ophthalmology Franchise at Biogen. Dr. Ong served as Chief Development Officer at Nightstar Therapeutics up until its acquisition by Biogen in June 2019, during which time he was involved with the company's public listing on the Nasdaq, corporate and gene therapy strategy, investor and M&A activities. Dr. Ong brings over 20 years of clinical and drug development experience from both large pharma and biotech, working in the fields of ophthalmology, genetic and rare disease at PTC Therapeutics Inc., Bausch and Lomb Inc. (acquired by Valeant Pharmaceuticals International, Inc.), and Pfizer. Dr. Ong holds an M.D. from the University College London and an M.B.A. from New York University Stern School of Business. He is a member of the Royal College of Ophthalmologists and a Churchill Fellow. Our Board believes that Dr. Ong is qualified to serve on our Board based on his extensive leadership and medical experience.

Jason Rhodes has been a member of our Board since April 2016. Since 2014, Mr. Rhodes has been a partner at Atlas Ventures, a venture capital firm where he focuses on creating and building novel therapeutics companies. Mr. Rhodes currently serves as the chairman of the board of directors of Generation Bio Co., the chairman of the board of directors of Dyne Therapeutics, Inc., and Rectify Pharmaceuticals. He is also a member of the boards of directors of Replimune Group, Inc. and several private companies. Previously, Mr. Rhodes served as a director at Bicycle Therapeutics, Inc. from 2016 to 2020.Mr. Rhodes also served as the founding President and Chief Executive Officer of Dyne Therapeutics, Inc. from December 2017 to November 2018. From 2010 to 2014, Mr. Rhodes was at Epizyme, Inc., a biotechnology company, where he most recently served as President and Chief Financial Officer. Prior to that, he led business development at Alnylam Pharmaceuticals, Inc. from 2007 to 2010. Mr. Rhodes earned a B.A. in history from Yale University and an M.B.A. from the Wharton School of the University of Pennsylvania. Our Board believes that Mr. Rhodes is qualified to serve on our Board based on his extensive leadership experience, his biotechnology company board experience and his experience investing in life science companies.

Jim Tananbaum, M.D. has been a director since June 2020. Prior to the closing of the merger between FS Development Corp. ("FSDC") and Gemini Therapeutics Inc., Dr. Tananbaum also served as the President and Chief Executive Officer of FSDC since June 2020. Dr. Tananbaum currently serves as the chief executive officer of Foresite Capital, a U.S.-focused healthcare investment firm, which he founded in 2011. He is also a member of the boards of directors of Quantum-SI, Inc. Pardes

Biosciences, Inc., and Kinnate Biopharma Inc. Prior to founding Foresite Capital, Dr. Tananbaum served as Managing Director of Prospect Venture Partners L.P. II and III, healthcare venture partnerships, from 2000 to 2010. Dr. Tananbaum was also a Founder of GelTex, Inc. in 1991, an intestinal medicine pharmaceutical company acquired in 1999. Dr. Tananbaum was also the founding chief executive officer of Theravance, Inc., which has since split into two parts, Theravance Biopharma, Inc., a diversified biopharmaceutical company focused on organ-selective medicines, and Innoviva, Inc., a respiratory-focused healthcare asset management company partnered with Glaxo Group Limited. Dr. Tananbaum received a B.S. and a B.S.E.E. from Yale University in Applied Math and Computer Science, and an M.D. and an M.B.A. from Harvard University. Our Board believes that Dr. Tananbaum is qualified to serve on our Board based on his scientific, financial and strategic business development expertise gained as a physician, founder of two life science companies and venture capital investor focused on life science companies.

Number and Terms of Officers and Directors

Our Board consists of six members. In accordance with the filed Charter, the Board is divided into three classes. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following the election. The directors are divided among the three classes as follows:

- the Class I director is Dr. Carl Gordon, and his term will expire at the annual meeting of stockholders to be held in 2024;
- the Class II directors are David Lubner, Dr. Tuyen Ong, and Jason Rhodes, and their terms will expire at the annual meeting of stockholders to be held in 2022; and
- the Class III directors are Dr. Georges Gemayel and Dr. Jim Tananbaum, and their terms will expire at the annual meeting of stockholders to be held in 2023.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of the board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Committees of the Board of Directors

Our Board has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Members will serve on these committees until their resignation or until otherwise determined by our Board.

Audit Committee

Dr. Carl Gordon, David Lubner and Jason Rhodes serve on our Audit Committee, which is chaired by Mr. Lubner. The Board has determined that each member of the Audit Committee is independent under the listing standards of the Nasdaq Stock Market (“Listing Standards”), and Rule 10A-3(b)(1) of the Exchange Act. The Board has determined that Mr. Lubner is an “audit committee financial expert” within the meaning of SEC regulations. The Board has also determined that each member of the Audit Committee has the requisite financial expertise required under the applicable requirements of the Nasdaq Stock Market. In arriving at this determination, the Board has examined each Audit Committee member’s scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the Audit Committee is to discharge the responsibilities of the Board with respect to our accounting, financial, and other reporting and internal control practices and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing policies on risk assessment and risk management;

- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit service to be performed by the independent registered public accounting firm.

Compensation Committee

Dr. Tuyen Ong, Jason Rhodes and Dr. Jim Tananbaum serve on our Compensation Committee, which is chaired by Dr. Ong. The Board has determined each member is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The Board has determined that each member of the Compensation Committee, other than Dr. Tananbaum, is independent under the Listing Standards. The Listing Standards provide that, under limited and exceptional circumstances, a director who is not a current officer or employee (or a family member of an officer or employee) of the Company, but who does not otherwise meet the independence criteria, (i) may serve as a member of compensation committee if such membership is in the best interests of the Company and our shareholders and (ii) such member does not serve longer than two years. The Board has elected to rely on this limited exception in appointing Dr. Tananbaum as a member of the Compensation Committee. In making this election, the Board considered Dr. Tananbaum's extensive experience in the life sciences industry and the marketplace for life science executives. The primary purpose of the Compensation Committee is to discharge the responsibilities of the Board to oversee its compensation policies, plans and programs and to review and determine the compensation to be paid to its executive officers, directors and other senior management, as appropriate.

Specific responsibilities of the Compensation Committee include:

- reviewing and approving, or recommending that our Board approve, the compensation of our executive officers;
- reviewing and recommending to our Board the compensation of our directors;
- administering our stock and equity incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committee's compensation advisors;
- reviewing and approving, or recommending that our Board approve, incentive compensation and equity plans, severance agreements, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management, as appropriate;
- reviewing and establishing general policies relating to compensation and benefits of our employees; and
- reviewing our overall compensation philosophy.

Nominating and Corporate Governance Committee

David Lubner, Jason Rhodes and Dr. Jim Tananbaum serve on our Nominating and Corporate Governance Committee, which is chaired by Mr. Lubner. The Board has determined each member of the Nominating and Corporate Governance Committee, other than Dr. Tananbaum, is independent under the Listing Standards. The Listing Standards provide that, under limited and exceptional circumstances, a director who is not a current officer or employee (or a family member of an officer or employee) of the Company, but who does not otherwise meet the independence criteria, (i) may serve as a member of nominating and corporate governance committee if such membership is in the best interests of the Company and our shareholders and (ii) such member does not serve longer than two years. The Board has elected to rely on this limited exception in appointing Dr. Tananbaum as a member of the Nominating and Corporate Governance Committee. In making this election, the Board considered Dr. Tananbaum's extensive experience in the life sciences industry and in serving on the board of directors of numerous organizations.

Specific responsibilities of our Nominating and Corporate Governance Committee include:

- identifying, evaluating and selecting, or recommending that our Board approve, nominees for election to our Board;
- evaluating the performance of our Board and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;

- reviewing management succession plans; and
- developing and making recommendations to our Board regarding corporate governance guidelines and matters.

Director Nominations

Our Board will consider director candidates recommended for nomination by our shareholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of shareholders (or, if applicable, a special meeting of shareholders). Our shareholders that wish to nominate a director for election to our Board followed the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the Board will consider educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Compensation Committee Interlocks and Insider Participation

During 2021, Dr. Georges Gemayel, Dr. Tuyen Ong, Jason Rhodes and Dr. Jim Tananbaum served on the Compensation Committee. Other than Dr. Gemayel and Dr. Tananbaum, no member of the Compensation Committee has ever been an officer or employee of the Company or had any other relationship requiring disclosure herein. Prior to the closing of the Business Combination, Dr. Tananbaum served as the President and Chief Executive Officer of FSDC from June 2020 until such closing. Dr. Gemayel became an employee of the Company and transitioned to serve as Executive Chair of the Board in November 2021 and resigned from the Compensation Committee upon such transition. None of our current executive officers serves, or has served during the last fiscal year, as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any other entity that has one or more executive officers serving as one of our directors or on our Compensation Committee.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers, directors and persons who beneficially own more than ten percent of our ordinary shares to file reports of ownership and changes in ownership with the SEC. These reporting persons are also required to furnish us with copies of all Section 16(a) forms they file.

We are not aware of any late or delinquent filings required under Section 16(a) of the Exchange Act in respect of our equity securities other than the following reports filed late due to administrative error, as previously disclosed in our quarterly report on Form 10-Q for the period ended March 31, 2021 and our Proxy Statement dated August 17, 2021 filed with the SEC with respect to our 2021 Annual Meeting of Stockholders: a Form 3 which inadvertently omitted Foresite Capital Fund V, L.P and Foresite Capital Management V LLC as beneficial owners of 3,018,750 shares of Class B Common Stock of FSDC; a Form 3 for James Tananbaum, which inadvertently omitted 3,018,750 shares of Class B Common Stock of FSDC; and a Form 4 of the Sponsor, Foresite Capital Fund V, L.P, Foresite Capital Management V LLC and James Tananbaum which inadvertently omitted 441,500 shares of Class A Common Stock of FSDC.

Code of Ethics and Committee Charters

We have adopted a Code of Ethics that applies to all of our directors, executive officers and employees that complies with the rules and regulations of the Nasdaq. Copies of our code of ethics and our Board committee charters are available on our website (*https://geminitherapeutics.com*). You may review these documents by accessing our public filings at the SEC's web site at www.sec.gov. In addition, a copy of the Code of Ethics will be provided without charge upon request to us in writing at 297 Boston Post Road #248, Wayland, MA 01778 or by telephone at 617-401-4400. If we make any amendments to our Code of Ethics other than technical, administrative or other non-substantive amendments, or grant any waiver, including any implicit waiver, from a provision of the Code of Ethics applicable to our principal executive officer, principal financial officer principal accounting officer or controller or persons performing similar functions requiring disclosure under applicable SEC or Nasdaq rules, we will disclose the nature of such amendment or waiver on our website. The information included on our website, or any of the websites of entities that we are affiliated with, is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Limitations on Liability and Indemnification of Officers and Directors

The Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by the Delaware General Corporation Law ("DGCL"), and the Bylaws provide that we will indemnify them to the fullest extent permitted by such law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our Board. Under the terms of such indemnification agreements, we are required to indemnify each of our directors and officers, to the fullest extent permitted by the laws of the state of Delaware, if the basis of the indemnitee's involvement was by reason of the fact that the indemnitee is or was a director or officer of Gemini or any of its subsidiaries or was serving at our request in an official capacity for another entity. We must indemnify our officers and directors against all reasonable fees, expenses, charges and other costs of any type or nature whatsoever, including any and all expenses and obligations paid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal), or preparing to defend, be a witness or participate in any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative, or establishing or enforcing a right to indemnification under the indemnification agreement. The indemnification agreements also require us, if so requested, to advance within 10 days of such request all reasonable fees, expenses, charges and other costs that such director or officer incurred, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Item 11. Executive Compensation.

2021 Summary Compensation Table

Our named executive officers for the year ended December 31, 2021 are:

- Jason Meyenburg, our former President and Chief Executive Officer,
- Brian Piekos, our Chief Financial Officer and Chief Business Officer,
- Samuel Barone, M.D., our Chief Medical Officer, and
- Scott Lauder, Ph.D., our former Chief Technology Officer.

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for 2021.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(6)	Option Awards ($)(7)	Non-Equity Incentive Plan Compensation ($)(8)	All Other Compensation ($)	Total ($)
Jason Meyenburg (1), *Former Chief Executive Officer and President*	2021	515,000	—	—	9,647,917	193,125	7,832(9)	10,363,874
	2020	437,800	—	—	1,541,002	201,388	49,992(9)	2,230,182
Brian Piekos (2), *Chief Financial Officer and Chief Business Officer*	2021	367,875	—	—	3,621,871	146,910	5,519(10)	4,142,175
Dr. Samuel Barone (3), *Chief Medical Officer*	2021	305,897	150,000(5)	—	2,194,528	172,959	13,441(10)	2,836,825
Dr. Scott Lauder (4), *Former Chief Technology Officer*	2021	293,872	—	—	4,725,438	—	35,909(11)	5,055,219
	2020	355,000	—	—	136,517	141,645	7,500(10)	640,662

(1) Mr. Meyenburg's employment with us terminated on February 28, 2022.
(2) Mr. Piekos commenced employment with us on February 4, 2021. His annual base salary for 2021 was $405,000.
(3) Dr. Barone commenced employment with us on April 12, 2021. His annual base salary for 2021 was $425,000.
(4) Dr. Lauder resigned from the Company on September 17, 2021. His annual base salary for 2021 was $411,650.
(5) The amount reported represents a $100,000 signing bonus paid to Dr. Barone pursuant to the terms of his employment agreement and a $50,000 milestone bonus paid to Dr. Barone pursuant to the terms of his retention agreement.
(6) The amounts reported in the "Stock Awards" column reflect the aggregate grant date fair value of restricted stock units awarded to Mr. Piekos during 2021 based upon the probable outcome of performance conditions and computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718. The aggregate grant date fair value of such restricted stock unit award was $0 as achievement of the performance criteria was deemed not probable on the grant date. The value of this restricted stock unit award at the grant date assuming maximum achievement of the performance conditions is $322,056. See Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.
(7) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of stock options awarded during 2021 and 2020 computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718. See Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.
(8) The 2021 amounts reported represent cash incentive bonuses earned by the named executive officers for performance during the year ended December 31, 2021, which will be paid in March 2022.
(9) Consists of payment for a living expense allowance of $4,166 per month to facilitate Mr. Meyenburg's relocation to Cambridge, Massachusetts pursuant to the terms of his employment agreement with the Company as well as the Company's portion of the executive's health savings account contribution. The lease related to the living expense allowance was terminated in February 2021 and Mr. Meyenburg did not receive living expenses after February 2021.
(10) Represents our portion of the executive's 401(k) plan and health savings account contributions.
(11) Represents our portion of Dr. Lauder's 401(k) plan and health savings account contributions, as well as his vacation accrual payout of $26,409 upon terminating his employment with us on September 17, 2021.

Narrative to the Summary Compensation Table

Our Board and Compensation Committee review compensation annually for all employees, including our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, the Compensation Committee and the Board consider compensation for comparable positions in the market, the historical compensation levels of our executive officers, individual performance as compared to our expectations and objectives, internal equity, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to the Company. We target a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus and long-term incentives.

Our Compensation Committee is primarily responsible for determining the compensation for our executive officers. Our Compensation Committee typically reviews and discusses management's proposed compensation with our Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the Compensation Committee then sets the compensation for each executive officer other than the Chief Executive Officer and recommends the compensation for the Chief Executive Officer to our Board for approval. Our Board discusses the Compensation Committee's recommendation and ultimately approves the compensation of our Chief Executive officer without members of management present. Our Compensation Committee has the authority to engage the services of a consulting firm or other outside advisor to assist it in designing our executive compensation programs and in making compensation decisions. During 2021, the Compensation Committee retained the services of Arnosti Consulting, Inc. as its external compensation consultant to advise on executive compensation matters including our overall compensation program design and collection of market data to inform our compensation programs for our executive officers and members of our Board. Arnosti Consulting, Inc. reports directly to our Compensation Committee. Prior to engaging Arnosti Consulting, Inc., our Compensation Committee assessed its independence consistent with Nasdaq listing standards and concluded that the engagement of such consultant did not raise any conflict of interest.

Base salaries

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our Compensation Committee taking into account each individual's role, responsibilities, skills, and experience. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities,

performance and experience. For the year ended December 31, 2021, the annual base salary for each of Mr. Meyenburg, Mr. Piekos, Dr. Barone and Dr. Lauder was $515,000, $405,000, $425,000 and $411,650, respectively.

Non-equity incentive plan compensation

We pay cash bonuses to reward our executives for their performance over the fiscal year, based on goals established by our Board or Compensation Committee. Annual performance bonus awards are determined based on the achievement of certain predetermined annual corporate and individual performance milestones. For the year ended December 31, 2021, the target bonus for Mr. Meyenburg was equal to 50% percent of his base salary (100% based on achievement of annual corporate milestones) and the target bonus for each of Mr. Piekos, Dr. Barone and Dr. Lauder was equal to 40% of the executive officer's base salary (in each case, 80% based on achievement of annual corporate milestones and 20% based on achievement of individual performance milestones). For fiscal year 2021, 80% of our corporate milestones related to research and development targets and 20% related to organizational targets. Following review and determination of corporate and individual performance for 2021, the Board determined that Mr. Meyenburg's annual bonus was earned at 75% of his target bonus, Mr. Piekos' annual bonus was earned at 100% of his target bonus (pro-rated based on his start date) and Dr. Barone's annual bonus was earned at 100% of his target bonus (pro-rated based on his start date). Dr. Lauder was not eligible to, and did not, receive an annual bonus for 2021.

Equity compensation

We believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. During the year ended December 31, 2021, we granted options to purchase shares of our Common Stock and restricted stock units to Mr. Meyenburg, Mr. Piekos, Dr. Barone and Dr. Lauder, as described in more detail in the "Outstanding Equity Awards at 2021 Fiscal Year-End" table below.

Outstanding Equity Awards at 2021 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2021.

	Option awards					Stock awards	
Name and Principal Position	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($) (1)
Jason Meyenburg	9/23/2019(3)	329,890	256,582	2.16	11/12/2029	—	—
	3/11/2020(3)	56,815	73,047	2.53	3/11/2030	—	—
	10/16/2020(3)	74,904	181,909	7.62	10/16/2030	—	—
	2/5/2021(3)	—	1,124,832	12.66	2/4/2031	—	—
Brian Piekos	2/4/2021(3)	—	43,580	12.66	2/4/2031	—	—
	1/25/2021(3)	—	377,734	12.59	4/11/2031	—	—
	—	—	—	—	—	90,720(4)	263,995
Dr. Samuel Barone	4/12/2021(3)	—	255,212	12.59	4/11/2031	—	—
Dr. Scott Lauder(2)	—	—	—	—	—	—	—

(1) Based on the fair market value of our Common Stock as of December 31, 2021 of $2.91.
(2) Dr. Lauder resigned from the Company on September 17, 2021. He had no outstanding equity awards as of December 31, 2021.
(3) The shares underlying this stock option vest over four years with 25% of the shares vesting on the first anniversary of the vesting commencement date, and the remaining shares vesting in 36 equal monthly installments thereafter, subject to the executive's continued service.
(4) Represents a restricted stock unit award granted on October 18, 2021. Thirty-three percent (33%) of the restricted stock units shall vest upon the achievement of a clinical milestone, and the remaining sixty-seven percent (67%) of the restricted stock units shall vest on the one (1)-year anniversary of the achievement of this clinical milestone.

Employee Benefit Plans

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees, including our named executive officers, with an opportunity to save for retirement on a tax advantaged basis.

Employment Arrangements and Severance Agreements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers, the material terms of which are summarized below.

Jason Meyenburg Employment Agreement

We entered into an employment agreement with Mr. Meyenburg on January 21, 2021, which became effective as of February 5, 2021 (the "Meyenburg Employment Agreement") and replaced Mr. Meyenburg's earlier employment agreement. Pursuant to the Meyenburg Employment Agreement, we employed Mr. Meyenburg as our President and Chief Executive Officer. The Meyenburg Employment Agreement also provided for Mr. Meyenburg to serve as a member of our Board for as long as he was employed as our Chief Executive Officer. The employment of Mr. Meyenburg was "at will" and the Meyenburg Employment Agreement endures until terminated by either party.

Pursuant to the Meyenburg Employment Agreement, in the event Mr. Meyenburg's employment was terminated by us without Cause or he resigned for Good Reason (as each such term is defined in the Meyenburg Employment Agreement), subject to his execution and non-revocation of a separation agreement, including a general release of claims in our favor (and, in our sole discretion, a one-year post-employment noncompetition agreement) (a "Separation Agreement and Release"), Mr. Meyenburg was entitled to the following severance payments and benefits: (a) continuation of his then-current Base Salary (as such term is defined in the Meyenburg Employment Agreement) for 12 months; (b) a pro rata portion of his Target Bonus (as such term is defined in the Meyenburg Employment Agreement); and (c) if Mr. Meyenburg elected to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the 12-month anniversary of the date of termination, (ii) the date Mr. Meyenburg becomes eligible for health insurance through another employer, or (iii) the cessation of Mr. Meyenburg's continuation rights under COBRA.

In lieu of the payments and benefits described above, in the event Mr. Meyenburg's employment was terminated by us without Cause or he resigned for Good Reason, in either event within the 12-month period immediately following a Change in Control (as such term is defined in the Meyenburg Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Mr. Meyenburg was entitled to (a) a lump sum in cash equal to one and half times the sum of (i) Mr. Meyenburg's then current Base Salary (or his Base Salary in effect immediately prior to the Change in Control, if higher) plus (ii) Mr. Meyenburg's Target Bonus for the then-current year; (b) full accelerated vesting of any then-outstanding equity awards as of the later of (i) the date of termination or (ii) the effective date of the Separation Agreement and Release; and (c) if Mr. Meyenburg elected to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the 18-month anniversary of the date of termination, (ii) the date Mr. Meyenburg becomes eligible for health insurance through another employer, or (iii) the cessation of Mr. Meyenburg's continuation rights under COBRA.

In the event that Mr. Meyenburg was entitled to any payments pursuant to his Employee Confidentiality, Assignment and Noncompetition Agreement with us, cash severance amounts payable to him pursuant to the Meyenburg Employment Agreement would have been reduced by the amount that Mr. Meyenburg was paid in the same calendar year pursuant to the Employee Confidentiality, Assignment and Noncompetition Agreement. Severance payments under the Meyenburg Employment Agreement would have ceased in the event that Mr. Meyenburg breached his obligations under the Employee Confidentiality, Assignment and Noncompetition Agreement.

Mr. Meyenburg has also agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or customers during his employment and for 12 months following termination of his employment.

Meyenburg Separation Agreement

On February 28, 2022, we entered into a separation agreement with Mr. Meyenburg (the "Separation Agreement"). Pursuant to the Separation Agreement, Mr. Meyenburg is entitled to receive (i) an amount equal to 12 months of his base salary, (ii) a pro rata portion of his Target Bonus (as defined in the Meyenburg Employment Agreement) for 2022, and (iii) monthly COBRA premiums paid by the Company until the earlier of (a) 12 months from his separation date, (b) the date Mr. Meyenburg becomes eligible for health insurance through another employer, or (c) the cessation of Mr. Meyenburg's continuation coverage rights under COBRA. The Separation Agreement also contains a reaffirmation of Mr. Meyenburg's confidentiality and restrictive covenant obligations to the Company and a general release of claims by Mr. Meyenburg. Mr. Meyenburg will continue to contribute to the Company in an advisory role for a period of time following his separation date, during which time he will continue to vest in his existing equity awards. In addition, Mr. Meyenburg may exercise his vested stock options until 180 days after the termination of his advisory role, or the original expiration date of such stock options, if earlier.

Brian Piekos Employment Agreement

We entered into an employment agreement with Mr. Piekos on January 25, 2021, which became effective as of February 4, 2021 (the "Piekos Employment Agreement"). Pursuant to the Piekos Employment Agreement, Mr. Piekos serves as our Chief Financial Officer, principal accounting officer and principal financial officer. Mr. Piekos was also appointed as Chief Business Officer in October 2021. The employment of Mr. Piekos is "at will" and the agreement endures until terminated by either party.

Mr. Piekos's annual base salary for 2021 was $405,000, which is subject to periodic review and adjustment. Pursuant to the Piekos Employment Agreement, Mr. Piekos is eligible to receive an annual bonus targeted at 40% of his annual base salary. The actual amount of the bonus is determined by the Board or the Compensation Committee based on its assessment of the performance of Mr. Piekos and that of the Company against pre-established goals determined by our Board or Compensation Committee. Mr. Piekos is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

In the event Mr. Piekos's employment is terminated by us without Cause or he resigns for Good Reason (as each such term is defined in the Piekos Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Mr. Piekos is entitled to (a) continuation of his then-current Base Salary (as such term is defined in the Piekos Employment Agreement) for nine months, (b) a pro rata portion of the Target Bonus (as such term is defined in the Piekos Employment Agreement); and (c) if Mr. Piekos elects to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the nine-month anniversary of the date of termination, (ii) the date Mr. Piekos becomes eligible for health insurance through another employer, or (iii) the cessation of Mr. Piekos's continuation rights under COBRA. Such severance payments shall cease in the event that Mr. Piekos breaches his obligations post-employment obligations to the Company.

In lieu of the payments and benefits described above, in the event Mr. Piekos's employment is terminated by us without Cause or he resigns for Good Reason, in either event within the 12-month period immediately following a Change in Control (as such term is defined in the Piekos Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Mr. Piekos is entitled to (a) a lump sum in cash equal to one times the sum of (i) Mr. Piekos's then current Base Salary (or his Base Salary in effect immediately prior to the Change in Control, if higher) plus (ii) Mr. Piekos' Target Bonus for the then-current year; (b) full accelerated vesting of any then-outstanding equity awards as of the later of (i) the date of termination or (ii) the effective date of the Separation Agreement and Release; and (c) if Mr. Piekos elects to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the 12-month anniversary of the date of termination, (ii) the date Mr. Piekos becomes eligible for health insurance through another employer, or (iii) the cessation of Mr. Piekos's continuation rights under COBRA.

In the event that Mr. Piekos is entitled to Garden Leave Pay (as defined in the Piekos Employment Agreement), cash severance amounts payable to him pursuant to the Piekos Employment Agreement will be reduced by any Garden Leave Pay that Mr. Piekos is paid.

Mr. Piekos has also agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or customers during his employment and for one

year (or two years if Mr. Piekos breaches his fiduciary duty to us or if he has unlawfully taken, physically or electronically, property belonging to us) following termination of his employment.

Samuel Barone, M.D. Employment Agreement

We entered into an employment agreement with Dr. Barone on March 24, 2021, which became effective on April 12, 2021 (the "Barone Employment Agreement"). Pursuant to the Barone Employment Agreement, Dr. Barone serves as our Chief Medical Officer. The employment of Dr. Barone is "at will" and the agreement endures until terminated by either party.

Dr. Barone's annual base salary for 2021 was $425,000, which is subject to periodic review and adjustment. Pursuant to the Barone Employment Agreement, Dr. Barone is eligible to receive an annual bonus targeted at 40% of his annual base salary. The actual amount of the bonus is determined by the Board or the Compensation Committee based on its assessment of the performance of Dr. Barone and that of the Company against pre-established goals determined by our Board or Compensation Committee. Dr. Barone is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans. Pursuant to the terms of the Barone Employment Agreement, Dr. Barone also received a signing bonus of $100,000 on our first regular payroll date following March 24, 2021.

In the event Dr. Barone's employment is terminated by us without Cause or he resigns for Good Reason (as each such term is defined in the Barone Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Dr. Barone is entitled to (a) continuation of his then-current Base Salary (as such term is defined in the Barone Employment Agreement) for nine months, (b) a pro rata portion of the Target Bonus (as such term is defined in the Barone Employment Agreement); and (c) if Dr. Barone elects to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the nine-month anniversary of the date of termination, (ii) the date Dr. Barone becomes eligible for health insurance through another employer, or (iii) the cessation of Dr. Barone's continuation rights under COBRA. Such severance payments shall cease in the event that Dr. Barone breaches his obligations post-employment obligations to us.

In lieu of the payments and benefits described above, in the event Dr. Barone s employment is terminated by us without Cause or he resigns for Good Reason, in either event within the 12-month period immediately following a Change in Control (as such term is defined in the Barone Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Dr. Barone is entitled to (a) a lump sum in cash equal to one times the sum of (i) Dr. Barone's then current Base Salary (or his Base Salary in effect immediately prior to the Change in Control, if higher) plus (ii) Dr. Barone's Target Bonus for the then-current year; (b) full accelerated vesting of any then-outstanding equity awards as of the later of (i) the date of termination or (ii) the effective date of the Separation Agreement and Release; and (c) if Dr. Barone elects to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the 12-month anniversary of the date of termination, (ii) the date Dr. Barone becomes eligible for health insurance through another employer, or (iii) the cessation of Dr. Barone's continuation rights under COBRA.

Dr. Barone has agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from soliciting our employees or customers during his employment and for one year (or two years if Dr. Barone breaches his fiduciary duty to the Company or if he has unlawfully taken, physically or electronically, property belonging to the Company) following termination of his employment.

On October 4, 2021, we entered into a retention agreement (the "Barone Retention Agreement") with Dr. Barone, which terminated the Barone Employment Agreement (except for the surviving provisions as described in the Barone Retention Agreement) and to modify his role and responsibilities. Under the Retention Agreement, Dr. Barone will continue to receive his current salary and benefits and vest in his equity awards, and is also eligible to receive a cash incentive of up to $100,000, in two installments, upon achievement of certain milestones. The Retention Agreement also provides that Dr. Barone is eligible to receive a retention bonus equal to the sum of (i) nine months of his base salary and (ii) a pro rata portion of his target bonus for the calendar year in which the last day of his employment occurs, to be paid in calendar year 2022 on a date determined by the Company.

Samuel Barone, M.D. Retention Agreement

On October 4, 2021, we entered into an agreement with Dr. Barone (the "Retention Agreement") to modify his role and responsibilities. Pursuant to the Retention Agreement, Dr. Barone retained his title of Chief Medical Officer, however, he is no longer be primarily responsible for the Company's regulatory and medical affairs. Under the Retention Agreement, Dr. Barone continues to receive his current salary and benefits and vest in his equity awards, and was also eligible to receive payments in an aggregate amount of up to $100,000, in two installments, upon achievement of certain milestones specified in the Retention

Agreement. The Retention Agreement also provides that Dr. Barone is eligible to receive a retention bonus equal to the sum of (i) nine months of his base salary and (ii) a pro rata portion of his target bonus for the calendar year in which the last day of his employment occurs, to be paid in calendar year 2022 on a date determined by the Company.

Scott Lauder, Ph.D. Employment Agreement

We entered into an employment agreement with Dr. Lauder dated January 22, 2021, which became effective as of February 5, 2021 (the "Lauder Employment Agreement"). Pursuant to the Lauder Employment Agreement, Dr. Lauder served as our Chief Technology Officer.

Pursuant to the Lauder Employment Agreement, in the event Dr. Lauder's employment was terminated without Cause or he resigned for Good Reason (as each such term is defined in Lauder Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Dr. Lauder was entitled to the following: (a) continuation of his then-current Base Salary (as defined in the Lauder Employment Agreement) for nine months, (b) a pro rata portion of his Target Bonus (as such term is defined in the Lauder Employment Agreement); and (c) if Dr. Lauder elected to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earlier of: (i) the 12-month anniversary of the date of termination, (ii) the date Dr. Lauder became eligible for health insurance through another employer, or (iii) the cessation of Dr. Lauder's continuation rights under COBRA.

In lieu of the payments and benefits described above, in the event Dr. Lauder's employment was terminated without Cause or he resigned for Good Reason, in either event within the 12-month period immediately following a Change in Control (as such term is defined in the Lauder Employment Agreement), subject to his execution and non-revocation of a Separation Agreement and Release, Dr. Lauder was entitled to (a) a lump sum in cash equal to one times the sum of (i) Dr. Lauder's then-current Base Salary plus (ii) Dr. Lauder's Target Bonus for the then-current year; (b) full accelerated vesting of any then-outstanding equity awards as of the later of (i) the date of termination or (ii) the effective date of the Separation Agreement and Release; and (c) if Dr. Lauder elected to continue his health benefits through COBRA, monthly COBRA premiums paid by us until the earliest of: (i) the 12-month anniversary of the date of termination, (ii) the date Dr. Lauder became eligible for health insurance through another employer, or (iii) the cessation of Dr. Lauder's continuation rights under COBRA.

In the event that Dr. Lauder was entitled to any payments pursuant to his Employee Confidentiality, Assignment and Noncompetition Agreement with us, cash severance amounts payable to him pursuant to the Lauder Employment Agreement would have been reduced by the amount that Dr. Lauder was paid in the same calendar year pursuant to the Employee Confidentiality, Assignment and Noncompetition Agreement. Severance payments under the Lauder Employment Agreement would have ceased in the event that Dr. Lauder breached his obligations under the Employee Confidentiality, Assignment and Noncompetition Agreement.

Dr. Lauder has agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from competing with us or soliciting our employees or customers during his employment and for twelve months following termination of his employment.

Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our Board during 2021. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards to, or pay any other compensation to any of the non-employee members of our Board. Jason Meyenburg, our former President and Chief Executive Officer, did not receive any compensation for his service as a member of our Board during 2021. Mr. Meyenburg's compensation for service as an employee for fiscal year 2021 is presented in the "2021 Summary Compensation Table" above.

2021 Director Compensation Table

Name	Fees earned or paid in cash ($)	Option awards ($)(2)(3)	All other compensation ($)(4)	Total ($)
Dr. Georges Gemayel(1)	40,217	460,711	216,508	717,436
Dr. Carl Gordon	34,236	44,318	—	78,554
David Lubner	54,882	695,108	—	749,990
Dr. Tuyen Ong	43,785	706,212	—	749,997
Jason Rhodes	30,354	44,318	—	74,672
Dr. Jim Tananbaum	6,722	44,318	—	51,040

(1) In May 2021, Dr. Gemayel was appointed to serve as Chair of the Board. In November 2021, he entered into an employment agreement to serve as Executive Chair of the Board.
(2) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of stock options awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718. See Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards. For Dr. Gemayel, the amount reported includes $94,921 attributable to a stock option granted to him pursuant to the terms of his employment agreement with us.
(3) Non-employee directors who served on the board of directors during 2021 held the following unexercised stock options as of December 31, 2021: Dr. Gemayel – 86,225; Dr. Gordon – 17,245; Mr. Lubner – 126,731; Dr. Ong – 139,730; Mr. Rhodes – 17,245; and Dr. Tananbaum – 17,245.
(4) The amount reported for Dr. Gemayel represents (i) base salary paid from November 15, 2021 to December 31, 2021 for his role as Executive Chair ($38,333), (ii) a signing bonus paid to Dr. Gemayel pursuant to the terms of his employment agreement ($63,300), (iii) a cash incentive bonus earned for performance during the year ended December 31, 2021, which was paid in March 2022 ($112,500), and (iv) the Company's portion of the executive's 401(k) plan and health savings account contributions ($2,375). Dr. Gemayel's annual base salary as Executive Chair is $300,000 (which is inclusive of fees associated with Dr. Gemayel's services as both a director of the Company and in the capacity of Executive Chair).

Employment Agreement with Georges Gemayel, Ph.D.

We entered into an employment agreement with Dr. Gemayel, which became effective as of November 15, 2021 (the "Gemayel Employment Agreement"). Pursuant to the Gemayel Employment Agreement, we employ Dr. Gemayel as our Executive Chair of the Board. Effective as of February 28, 2022, Dr. Gemayel was appointed as Interim President and Chief Executive Officer. The employment of Dr. Gemayel is "at will" and the Gemayel Employment Agreement endures until terminated by either party.

Dr. Gemayel's current annual base salary is $300,000 (which is inclusive of fees associated with Dr. Gemayel's services as both a director of the Company and in the capacity of Executive Chair), which is subject to periodic review and adjustment. Dr. Gemayel's employment with the Company is part-time. Pursuant to the Gemayel Employment Agreement, Dr. Gemayel also received a signing bonus of $63,300. Further, pursuant to the Gemayel Employment Agreement, Dr. Gemayel is eligible to participate in any annual bonus programs as may be established from time to time by the Board. The actual amount of the bonus is determined by the Board. Dr. Gemayel is also eligible to participate in the employee benefit plans available to our employees, subject to the terms of those plans.

Pursuant to the Gemayel Employment Agreement, Dr. Gemayel is entitled to stock option grants as follows, in each case subject to approval of the Board, (i) a stock option to purchase 23,514 shares, which will vest in full on August 5, 2022; (ii) a stock option to purchase 17,245 shares, which will vest in full on the earlier of the one-year anniversary of the grant date and the Company's next annual meeting of stockholders, (iii) on January 3, 2022, a stock option to purchase 793,274 shares, which will vest 50% on August 5, 2022 and the remaining 50% on August 5, 2023, and (iv) an annual equity award of an option to purchase such number of shares equal to 0.16% of the then issued and outstanding shares of the Company, which shall vest on the earlier of the one-year anniversary of the grant date and the Company's next annual meeting of stockholders, subject in each case to Dr. Gemayel's continued service relationship with the Company on each such vesting date.

Dr. Gemayel has also agreed to refrain from disclosing our confidential information during or at any time following his employment with us and from soliciting our employees or customers during his employment and for 12 months following termination of his employment.

Non-Employee Director Compensation Policy

Our Board adopted a non-employee director compensation policy, which is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Employee directors do not receive additional compensation for their services as directors. Each director who is not an employee is paid cash compensation as set forth below for serving on the Board, with such compensation paid on a quarterly basis in arrears:

	Annual Retainer
Board of Directors	$ 35,000
Board of Directors Chair	$ 65,000
Audit Committee Chair	$ 15,000
Audit Committee Member	$ 7,500
Compensation Committee Chair	$ 10,000
Compensation Committee Member	$ 5,000
Nominating and Corporate Governance Committee Chair	$ 8,000
Nominating and Corporate Governance Committee Member	$ 4,000

In addition, each non-employee elected or appointed to the Board following the closing of the Business Combination is granted a stock option award to purchase a number of shares of Common Stock equal to 0.08% of the total shares outstanding on the date of such director's election or appointment to the Board, which vests in equal monthly installments over three years, subject to continued service through such vesting dates. On the date of each annual meeting of stockholders of the Company, each non-employee director will be granted an annual stock option award to purchase a number of shares of Common Stock equal to 0.04% of the total shares outstanding, which vests in full of the earlier to occur of the first anniversary of the date of grant or the next annual meeting, subject to continued service as a director through such vesting date.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily because its compensation programs are designed to create a greater focus on long-term value creation while balancing the need to meet shorter-term goals. The framework and goals of our annual performance-based incentive plan are consistent for all employees. Further all compensation decisions for our officers are approved by the Compensation Committee, while the Executive Chair and Chief Executive Officer's compensation requires further approval by the Board.

In addition, the Compensation Committee is responsible for reviewing and approving the design, goals and payouts under our annual bonus plan and equity incentive program for our named executive officers. The Compensation Committee directly engages an independent compensation consultant who advises on market competitive and best practices, as well as any potential risks related to its compensation programs. This includes pay mix, compensation vehicles, pay for performance alignment, performance measures and goals, payout maximums, vesting periods and Compensation Committee oversight and independence. Based on all the factors mentioned, we believe our compensation policies, programs and practices do not create risks that are reasonably likely to have a material adverse effect on us.

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2021. All outstanding option awards relate to our Common Stock.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)(3)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
2021 Stock Option and Incentive Plan(1)	4,034,537	$ 12.05	229,804
2021 Employee Stock Purchase Plan(2)	—	$ —	430,551
2017 Stock Option and Grant Plan	849,946	$ 10.32	—
Equity compensation plans not approved by security holders:			
2021 Inducement Plan	1,432,758	$ 4.11	766,949
Total	6,317,241		1,427,304

(1) The number of shares of common stock reserved for issuance under the 2021 Stock Option and Incentive Plan automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board. Subject to this provision, we added 1,728,326 shares to the 2021 Stock Option and Incentive Plan effective January 1, 2022.

(2) The number of shares of common stock reserved for issuance under the 2021 Employee Stock Purchase Plan automatically increases on January 1 of each calendar year, starting on January 1, 2023 and continuing through January 1, 2031, in an amount equal to the least of (a) 1% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, (b) 430,551 shares of common stock, or (c) such number of shares determined by the Board.

(3) The weighted-average exercise price is calculated based solely on outstanding stock options and does not include outstanding restricted stock units, which do not have an exercise price.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of the Common Stock as of February 28, 2022:

- each person, or group of affiliated persons, who is known by us to beneficially own greater than 5% of our outstanding Common Stock;
- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants (as applicable) that are currently exercisable or exercisable within 60 days of February 28, 2022 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person or entity. Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all Common Stock beneficially owned by them. Unless otherwise noted, the business address of each of the executive officers and directors of Gemini is 297 Boston Post Road #248, Wayland, MA 01778. The percentage of shares beneficially owned is based on 43,208,159 shares of Common Stock outstanding as of February 28, 2022.

Name and Address of Beneficial Owner	Number of Shares	%
Directors and Officers:		
Georges Gemayel(2)	11,367	*
Brian Piekos(1)	138,407	*
Samuel Barone(2)	63,803	*
Carl Gordon	—	
David Lubner(2)	52,676	*
Tuyen Ong(2)	45,981	*
Jason Rhodes	—	
Jim Tananbaum(3)	4,870,250	11.3
All Directors and Executive Officers as a group (8 individuals)	**5,182,484**	**12.0**
Five Percent Holders:		
FS Development Holdings, LLC(3)	4,870,250	11.3
Orbimed Private Investments VI, LP(4)	5,826,224	13.5
Entities affiliated with Atlas Ventures(5)	5,254,365	12.2
Entities affiliated with Lightstone Ventures(6)	4,836,106	11.2
Entities affiliated with Fidelity(7)	2,789,500	6.5
Franklin Resources, Inc.(8)	2,512,773	5.8
Suvretta Capital Management, LLC(9)	2,372,267	5.5

* Less than one percent.

(1) Represents shares currently held and shares of Common Stock that are currently exercisable or exercisable within 60 days of February 28, 2022.
(2) Represents shares of Common Stock that are currently exercisable or exercisable within 60 days of February 28, 2022.
(3) FS Development Holdings, LLC is the record holder of 4,870,250 shares reported herein. Foresite Capital Management V, LLC ("FCM V"), is the general partner of Foresite Capital Fund V LP ("FCM V LP") and Foresite Capital Opportunity Management V, LLC ("FCOM V") is the general partner of Foresite Capital Opportunity Fund V, L.P. ("FCOM LP"), with FCM LP and FCOM LP being the sole members of FS Development Holdings, LLC. FCM V and FCOM V, as general managers of the sole members, have voting and investment discretion with respect to the common stock held of record by FS Development Holdings, LLC. Dr. Tananbaum, in his capacity as managing member of FCM V and FCOM V, may be deemed to have voting and investment discretion over these shares. Each of FCM V LP, FCOM LP, FCM V, FCOM V and Dr. Tananbaum disclaim beneficial ownership of these shares except to the extent of any pecuniary interest therein.
(4) Represents 5,189,187 shares held by OrbiMed Private Investments VI, LP. OrbiMed Capital GP VI LLC, or GP VI, is the general partner of OrbiMed Private Investments VI, LP, or OPI VI. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VI. By virtue of such relationships, OrbiMed Advisors and GP VI may be deemed to have voting and investment power with respect to the shares held by OPI VI and as a result may be deemed to have beneficial ownership of these shares. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI.
(5) Represents 3,533,927 shares held by Atlas Venture Fund X, L.P. ("Atlas Fund X"), 641,926 shares held by Atlas Venture Opportunity Fund I, L.P. ("Atlas Fund I"), and 510,000 shares held by Atlas Venture Fund XII, L.P. ("Atlas Fund XII"). Atlas Venture Associates X, L.P. is the general partner of Atlas Fund X, and Atlas Venture Associates X, LLC is the general partner of Atlas Venture Associates X, L.P. Each of Atlas Fund X, Atlas Venture Associates X, L.P., and Atlas Venture Associates X, LLC may be deemed to beneficially own the shares held by Atlas Fund X. Each of Atlas Venture Associates X, L.P. and Atlas Venture Associates X, LLC disclaim Section 16 beneficial ownership of the securities owned by Atlas Fund X, except to the extent of its pecuniary interest therein, if any. Atlas Venture Associates Opportunity I, L.P. is the general partner of Atlas Fund I, and Atlas Venture Associates Opportunity I, LLC, or AVAO, LLC, is the general partner of Atlas Venture Associates Opportunity I, L.P. Each of Atlas Fund I, Atlas Venture Associates Opportunity I, L.P. and AVAO, LLC may be deemed to beneficially own the shares held by Atlas Fund I. Each of Atlas Venture Associates Opportunity I, L.P. and AVAO LLC disclaim Section 16 beneficial ownership of the securities owned by Atlas Fund I, except to the extent of its pecuniary interest therein, if any. The general partner of Atlas Fund XII is Atlas Venture Associates XII, L.P. ("AVA XII LP"). Atlas Venture Associates XII, LLC ("AVA XII LLC") is the general partner of AVA XII LP. Each of Atlas Fund XII, AVA XII LP, and AVA XII LLC may be deemed to beneficially own the shares held by Atlas Fund XII. Each of AVA XII LP and AVA XII LLC disclaim Section 16 beneficial ownership of the securities owned by Atlas Fund XII, except to the extent of its pecuniary interest therein, if any.
(6) The shares are owned as follows: (i) 2,422,995 by Lightstone Ventures, L.P. ("LV LP"), (ii) 336,099 by Lightstone Ventures (A), L.P. ("LV(A) LP"), and (iii) 1,501,438 by Lighstone Singapore, L.P. ("LV Singapore"). LSV Associates, LLC ("LSV Associates") is the General Partner of LV Singapore, LV LP and LV(A) LP. As the individual general partners of LSV Associates, Michael A. Carusi, Jean M. George and Henry A. Plain Jr. share voting and dispositive power with respect to the shares held of record by LV Singapore, LV LP and LV(A) LP.
(7) Fidelity Management & Research Company, or Fidelity, 82 Devonshire Street, Boston, Massachusetts 02109, a wholly owned subsidiary of FMR LLC and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of such shares of common stock as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees.
(8) Based on the information included in the Schedule 13G filed by Franklin Resources, Inc ("Franklin") on December 31, 2021, Charles B. Johnson ("Mr. Johnson"), Rupert H. Johnson, Jr. ("Mr. Johnson Jr."), and Franklin Advisors, Inc. ("Franklin Advisors"). The address of Franklin, Mr. Johnson, Mr. Johnson Jr., and Franklin Advisors is One Franklin Parkway, San Mateo, California 94403.

(9) Based on the information included in the Schedule 13G filed by Suvretta Capital Management, LLC ("Suvretta") on December 31, 2021, Averill Master Fund, Ltd. ("Averill") and Aaron Cowen. The address of the principal business office of Suvretta and Mr. Cowen is c/o Suvretta Capital Management, LLC, 540 Madison Avenue, 7th Floor, New York, New York 10022. The address of the principal business office of Averill is c/o Maples Corporate Services Limited, P.O. Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands.

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

Policies and Procedures Regarding Related Transactions

We have a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions. Our policy requires us to avoid, wherever possible, all Related Person Transactions (as defined below) that could result in actual or potential conflicts of interests, except under guidelines approved by the Board (or the Audit Committee).

A "Related Person Transaction" is a transaction, arrangement or relationship in which we or any of its subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest. A "Related Person" means:

- any person who is, or at any time during the applicable period was, one of our officers or directors;
- any person who is known by us to be the beneficial owner of more than five percent (5%) of its voting stock;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than five percent (5%) of its voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than five percent (5%) of its voting stock; and
- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a ten percent (10%) or greater beneficial ownership interest.

The Audit Committee of the Board has the responsibility for reviewing and approving any related person transactions. In reviewing any related person transaction, the Audit Committee will take into account, among other factors that it deems appropriate, whether the related person transaction is on terms no less favorable to us than terms generally available in a transaction with an unaffiliated third-party under the same or similar circumstances and the extent of the Related Person's interest in the related person transaction. We will not enter into any such transaction unless the Audit Committee and a majority of our disinterested " independent" directors determine that the terms of such transaction are no less favorable to us than those that would be available to us with respect to such a transaction from unaffiliated third parties. Additionally, we require each of our directors and officers to complete a directors' and officers' questionnaire that elicits information about related transactions.

These procedures are intended to determine whether any such related transaction impairs the independence of a director or presents a conflict of interest on the part of a director, employee or officer.

Certain Related Transactions

Below are our related transactions since January 1, 2019, to which we have been a party, other than compensation, termination, change in control and other arrangements, which are described in the sections titled "Executive Officer and Director Compensation."

Registration Rights Agreement

We are a party to a Registration Rights Agreement pursuant to which, among other things, certain holders of our capital stock, including certain investors of FSDC (the "FSDC Investors"), certain entities affiliated with Atlas Ventures, entities affiliated with Lightstone Ventures, OrbiMed Private Investments VI, LP, and Wu Capital Investment LLC (collectively, the "Major Gemini Investors" and together with the FSDC Investors, the "Investors") are granted certain registration rights with respect to Registrable Securities (as defined in the Registration Rights Agreement) held by them, subject to certain conditions and limitations.

In particular, the Registration Rights Agreement provides for the following registration rights:

- *Demand registration rights*. At any time after February 5, 2021, and following the expiration of any lock- up to which an Investor may have been subject, we are required, upon the written request of either (i) FSDC Investors holding a majority of the Registrable Securities held by all FSDC Investors or (ii) Major Gemini Investors holding a majority of the Registrable Securities held by all Major Gemini Investors, to file a registration statement under the Securities Act of 1933, as amended (the "Securities Act") on Form S- 1 or any similar long-form registration statement or, if then available, on Form S-3, and use reasonable best efforts to effect the registration of all or part of their registrable securities requested to be included in such registration by the Investors.

- *Shelf registration rights*. We were required to file a shelf registration statement pursuant to Rule 415 of Securities Act, which was filed on February 17, 2021 and became effective on April 28, 2021. At any time we have an effective shelf registration statement, if we shall receive a request from Investors holding registrable securities with an estimated market value of at least $5,000,000, to effect an underwritten shelf takedown, we shall use our reasonable best efforts to as expeditiously as possible to effect the underwritten shelf takedown.

- *Limits on demand registration rights and shelf registration rights.* We shall not be obligated to effect: (a) more than one (1) demand registration or underwritten shelf takedown during any six-month period; (b) any demand registration at any time there is an effective resale shelf registration statement on file with the SEC; (c) more than two underwritten demand registrations in respect of all registrable securities held by the FSDC Investors, including those made under a shelf registration statement, or (d) more than two underwritten demand registrations in respect of all registrable securities held by the Major Gemini Investors, including those made under a shelf registration statement.

- *Piggyback registration rights*. At any time after the first anniversary of the Closing Date, if Gemini proposes to file a registration statement to register any of its equity securities under the Securities Act or to conduct a public offering, either for its own account or for the account of any other person, subject to certain exceptions, the Investors are entitled to include their registrable securities in such registration statement, subject to customary cut-back rights.

- *Expenses and indemnification*. All fees, costs and expenses of underwritten registrations will be borne by us and underwriting discounts and selling commissions will be borne by the holders of the shares being registered. The Registration Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and holders of registrable securities are obligated to indemnify us for material misstatements or omissions attributable to them.

- *Registrable securities*. Securities of the Company shall cease to be registrable securities upon the earlier of (i) tenth anniversary of February 5, 2021 and (ii) the date as of which (1) a registration statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such registration statement, or (2) such securities shall have been transferred pursuant to Rule 144 of the Securities Act, or with respect to any Investor, securities of such Investor shall cease to be registrable securities, on the earlier of (x) the date such Investor ceases to hold at least 1% of the registrable securities or (y) if such Investor is an individual and such Investor is a director or an executive officer of the Company or FSDC as of immediately prior to the consummation of the Business Combination, the date when such Investor is permitted to sell the Registrable Securities under Rule 144 (or any similar provision) under the Securities Act without limitation on the amount of securities sold or the manner of sale.

- *Lockup*. Under the Registration Rights Agreement, each Investor was required to enter into a customary lockup agreement restricting such investor from transferring any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock for one hundred eighty (180) days following February 5, 2021, which restriction expired August 4, 2021. The foregoing notwithstanding, each of our executive officers and directors was permitted to establish a plan to acquire and sell shares of Common Stock pursuant to Rule 10b5-1 under the Exchange Act; provided, however, no sale of shares under any such plan shall be made prior to the expiration of the one hundred eighty (180) day lock-up period on August 4, 2021.

Voting Agreement

We are a party to the Voting Agreement, pursuant to which certain of our stockholders agree to vote all voting securities of the Company that it owns from time to time and that it may vote in accordance with the provisions of the Voting Agreement,

whether at a regular or special meeting of stockholders. Pursuant to the Voting Agreement, until the earlier of (i) the fifth (5th) anniversary of February 5, 2021 or (ii) the date on which FS owns less than 1,217,563 shares of Common Stock, at each of our annual or special meetings of stockholders, FS shall have the right to designate for election as a member of the Board, and the Board (including any committee thereof) shall nominate (and recommend for election and include such recommendation in a timely manner in any proxy statement or other applicable announcement to its stockholders), one individual to serve as a Class III Director. If FS ceases to be entitled to nominate any directors, then such directors shall be nominated by the Board and approved by the holders of the outstanding shares of Common Stock.

All directors elected pursuant to the terms of the Voting Agreement shall be removed from the Board only upon the vote or written consent of the voting party that is entitled to nominate, appoint or elect such director. Upon any decrease in the rights of any such voting party to nominate, appoint or elect any director, the applicable voting party shall promptly cause the removal or resignation of an applicable directors if requested by the Board. Upon any individual elected to serve as a director pursuant to the Voting Agreement ceasing to be a member of the Board, whether by death, resignation or removal or otherwise, only the voting party that was entitled to nominate, appoint or elect such individual shall have the right to fill any resulting vacancy in the Board; provided that such voting party still has the right to nominate, appoint or elect the applicable director.

Series B Preferred Stock Financing

On September 26, 2019, Merger Sub held the initial closing of its Series B Preferred Stock financing, pursuant to its Series B Preferred Stock Purchase Agreement (the "Series B Purchase Agreement"), at which time Merger Sub issued 9,916,375 shares of its Series B Preferred Stock for a per share price of $1.3513, for aggregate gross proceeds in the amount of $13.4 million. On January 21, 2020, Merger Sub held the second closing of its Series B Preferred Stock financing, pursuant to the Series B Purchase Agreement, at which time we issued 14,874,563 shares of its Series B Preferred Stock for a per share price of $1.3513, for aggregate gross proceeds in the amount of $20.1 million. The following holders of more than 5% of Merger Sub's capital stock participated in the initial closing and second closing of the Series B Preferred Stock financing. At the closing, the ancillary documents to the Series B Financing were terminated.

Name of 5% Gemini Stockholder	Number of Series B Preferred Stock Purchased – Initial Closing	Aggregate Purchase Price – Initial Closing	Number of Series B Preferred Stock Purchased – Second Closing	Aggregate Purchase Price – Second Closing
Entities affiliated with Lightstone Ventures(1)	1,924,073	$ 2,600,000.00	2,886,109	$ 3,899,999.09
OrbiMed Private Investments VI, LP	2,960,112	$ 3,999,999.35	4,440,168	$ 5,999,999.02
Atlas Venture Fund X, L.P.	2,072,078	$ 2,799,999.00	3,108,118	$ 4,199,999.85
Wu Capital Investment LLC(2)	2,960,112	$ 3,999,999.35	4,440,168	$ 5,999,999.02

(1) Includes Lightstone Ventures, L.P., which purchased 976,931 shares at the initial closing, Lightstone Ventures (A), L.P., which purchased 133,112 shares at the initial closing and Lightstone Singapore L.P., which purchased 814,030 shares at the initial closing and all of the shares at the second closing.
(2) Shares initially purchased by Wu Capital LLC and subsequently transferred to Wu Capital Investment LLC.

Certain Relationships and Related Transactions – FS Development Corp.

On June 30, 2020, FS purchased an aggregate of 2,875,000 shares (the "Founder Shares") of FSDC's Class B Common Stock, par value $0.0001 per share (the "Class B Shares") for a total purchase price of $25,000, or approximately $0.009 per share. In July 2020, FS transferred 30,000 Class B Shares to each of Robert Carey, Dan Dubin and Deepa Pakianathan. On August 11, 2020, FSDC effected a 1:1.05 stock split of FSDC Class B Common Stock, resulting in FS holding 2,928,750 Class B Shares and there being an aggregate of 3,018,750 Class B Shares outstanding. The number of Class B Shares outstanding was determined based on the expectation that the total size of the initial public offering of FSDC would be a maximum of 12,075,000 shares of FSDC's Class A Common Stock, par value $0.000 per share (the "Class A Shares"), if the underwriters' over-allotment option would be exercised in full, and therefore that such Class B Shares would represent 20% of the issued and outstanding shares of common stock (excluding the Private Placement Shares (as defined below)) after such offering.

FS purchased 441,500 Class A Shares (collectively, the "Private Placement Shares") at a price of $10.00 per share, or $4,415,000 in the aggregate, in a private placement that closed simultaneously with FSDC's initial public offering (the "FSDC IPO").

Until the Closing, FSDC utilized office space at 600 Montgomery Street, Suite 4500, San Francisco, California 94111 from FS. Following the closing of the FSDC IPO, FSDC paid FS $10,000 per month for office space, secretarial and administrative services provided to members of its management team pursuant to the terms of an administrative services agreement between FSDC and FS.

FS and FSDC's executive officers and directors were reimbursed for any out-of-pocket expenses incurred in connection with activities on FSDC's behalf, in connection with the completion of an initial business combination, such as identifying potential target businesses and performing due diligence on suitable business combinations. FSDC's audit committee reviewed on a quarterly basis all payments that were made to FS, officers, directors or its or their affiliates.

FS loaned FSDC $200,000 to be used for a portion of the expenses of the FSDC IPO. These loans were non-interest bearing, unsecured and were due at the earlier of December 31, 2020 or the closing of the FSDC IPO. These loans were fully repaid by FSDC on August 14, 2020.

In connection with the Business Combination, as part of the sale of 9,506,000 newly issued shares of Common Stock, an affiliate of FS had entered into a subscription agreement to purchase 1,500,000 shares of Common Stock at a purchase price of $10 per share in a private placement concurrent with the Business Combination. In connection with the closing of the Business Combination, the affiliate of FS assigned to FS its obligation to purchase its shares under the subscription agreement so that FS purchased such shares.

On August 11, 2020, FSDC entered into a registration rights agreement (the "prior registration rights agreement") with respect to the Founders Shares and Private Placement Shares. The holders of these securities were entitled to make up to three demands, excluding short form demands, that FSDC register such securities. In addition, the holders had certain "piggy-back" registration rights with respect to registration statements filed subsequent to the completion of FSDC's initial business combination. FSDC bears the expenses incurred in connection with the filing of any such registration statements. As part of the prior registration rights agreement, certain holders of registrable securities agreed to a lock-up period of one year from the closing of the Business Combination.

In connection with the closing of the Business Combination, the FSDC Investors and certain other stockholders entered into the Registration Rights Agreement with us that replaced the prior registration rights agreement.

In connection with the Merger Agreement related to the Business Combination, the FSDC Investors entered into support agreements with FSDC, Merger Sub and FS. Under such support agreements, each such stockholder agreed to vote, at any meeting of the stockholders of FSDC, and in any action by written consent of the stockholders of FSDC, all of such stockholder's Class B Common Stock of FSDC (i) in favor of (A) the Merger Agreement, (B) certain proposals requiring approval by our stockholders in connection with Business Combination, and (C) the transactions contemplated by the Merger Agreement and such support agreements, and (ii) in favor of any other matter reasonably necessary to the consummation of the transactions contemplated by the Merger Agreement and the approval of such stockholder proposals. In addition, such support agreements prohibit each such stockholder from, among other things, selling, assigning or transferring any Class B Common Stock of FSDC held by such stockholder or taking any action that would prevent or disable such stockholder from performing its obligations under the support agreement.

Convertible Note Financing

On August 21, 2020, Merger Sub issued convertible promissory notes for aggregate gross proceeds of $14,000,000 (the "Notes"), at a closing held pursuant to a convertible note purchase agreement among Merger Sub and certain investors. The following holders of more than 5% of Merger Sub's capital stock participated in the note financing. The Notes accrue simple interest at 8% per annum and matured on February 21, 2021. Prior to the closing of the Business Combination with FSDC, all principal and accrued interest under the Notes converted into shares of Merger Sub's Series B Preferred Stock.

Name of 5% Gemini Stockholder		Principal Amount of Note Purchased
Lightstone Singapore L.P.	$	3,000,000
OrbiMed Private Investments VI, LP	$	4,887,000
Atlas Venture Opportunity Fund I, L.P.	$	4,361,000
Wu Capital Investment LLC	$	1,752,000

Gemini Accounting Services

On April 17, 2020, Merger Sub engaged Danforth Advisors, an accounting and finance advisory company managed by Gregg Beloff, our former Interim Chief Financial Officer. For the year ended December 31, 2021, the costs incurred under this arrangement totaled $0.6 million.

Director Independence

Current Nasdaq listing guidelines require that a majority of our Board be independent. An "independent director" is defined generally as a person other than an executive officer or employee of the Company or any other individual having a relationship which, in the opinion of our Board, would interfere with the exercise of independent judgement in carrying out the responsibilities of a director. The Board has determined that each individual who serves on the Board, other than Dr. Gemayel and Dr. Tananbaum, qualifies as an independent director under the Listing Standards. In making such independence determination, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances that our Board deemed relevant in determining their independence.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Ernst & Young LLP, Boston, Massachusetts (PCAOB Auditor ID: 42).

Withum Smith+Brown, P.C. ("Withum") served as the independent registered public accounting firm for FSDC with respect to the audit of the 2020 Financial Statements. Withum was informed that it would be replaced by Ernst & Young as the Company's independent registered public accounting firm following completion of its audit of the Company's financial statements for the fiscal year ended December 31, 2020 and the consummation of the business combination between Merger Sub and FSDC on February 5, 2021 (the "Business Combination").

The following is a summary and description of fees paid by us to Ernst & Young for the fiscal year ended December 31, 2021 and to Withum for the period from June 25, 2020 (inception) through December 31, 2020.

Fee Category	2021	2020
Audit Fees(1)	$ 557,425	$ 122,365
Audit-Related Fees(2)	—	—
Tax Fees(3)	16,480	—
All Other Fees(4)	3,390	—
Total Fees	$ 577,295	$ 122,365

(1) Audit Fees include fees for professional services rendered for the audit of year-end financial statements, reviews of quarterly financial statements and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings.

(2) Audit-Related Fees include fees billed for assurance and related services that are reasonably related to performance of the audit or review of our year-end financial statements and are not reported under "Audit Fees." These services include attest services that are not required by statute or regulation and consultation concerning financial accounting and reporting standards.

(3) Tax Fees include fees consist of fees billed for professional services relating to tax compliance, tax planning and tax advice.

(4) All Other Fees consist of fees billed for all other services, including annual licensing fees for accounting database subscriptions.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The following Report and Consolidated Financial Statements of the Company are included in this Annual Report on Form 10-K:

- Report of Independent Registered Public Accounting Firm (PCAOB Auditor ID: 42)
- Consolidated Balance Sheets
- Consolidated Statements of Operations and Comprehensive Loss
- Consolidated Statements of Stockholders' Equity (Deficit)
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements

(2) Financial Statement Schedule

All financial statement schedules are omitted because they are not applicable, not required, or the required information is shown in the financial statements or the notes thereto.

(3) Exhibits

We hereby file as part of this report the exhibits listed in the attached Exhibit Index.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of Gemini Therapeutics, Inc. (incorporated by reference to Annex B to the Registrant's Proxy Statement/Prospectus on Form S-4/A (Registration No. 333-249785))
3.2	Amended and Restated By-laws of Gemini Therapeutics, Inc. (incorporated by reference to Annex C to the Registrant's Proxy Statement/Prospectus on Form S-4/A (Registration No. 333-249785))
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-4/A (Registration No. 333-249785))
4.2	Registration Rights Agreement, dated February 5, 2021, by and among Gemini Therapeutics, Inc. and the stockholder parties thereto (incorporated by reference to Exhibit 10.1 on Form 8-A12B/A filed on February 5, 2021)
4.3	Voting Agreement, dated February 5, 2021, by and among Gemini Therapeutics, Inc. and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on February 11, 2021)
4.4*	Description of Securities.
10.1#	Gemini Therapeutics, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Annex D to the Registrant's Proxy Statement/Prospectus on Form S-4/A (Registration No. 333-249785))
10.2#	Forms of Award Agreements under the Gemini Therapeutics, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.5 of Registrant's Current Report on Form 8-K filed on February 11, 2021)
10.3#	Gemini Therapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Annex 1 to Proxy Statement on Schedule 14A filed on August 17, 2021)
10.4#	Form of Indemnification Agreement for Directors of Gemini Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 of Registrant's Current Report on Form 8-K filed on February 11, 2021)
10.5#	Form of Indemnification Agreement for Officers of Gemini Therapeutics, Inc. (incorporated by reference to Exhibit 10.7 of Registrant's Current Report on Form 8-K filed on February 11, 2021)
10.6#	Employment Agreement, dated as of November 15, 2021, by and between Gemini Therapeutics, Inc. and Dr. Georges Gemayel (incorporated by reference to Exhibit 10.2 of Registrant's Quarterly Report on Form 10-Q filed on November 15, 2021)
10.7#	Retention Agreement, dated as of October 4, 2021, by and between Gemini Therapeutics, Inc. and Dr. Samuel Barone (incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q filed on November 15, 2021)
10.8#	Employment Agreement, dated as of February 4, 2021, by and between Gemini Therapeutics, Inc. and Brian Piekos (incorporated by reference to Exhibit 10.2 of Registrant's Quarterly Report on Form 10-Q filed on May 13, 2021)
10.9#	Employment Agreement, dated as of April 12, 2021, by and between Gemini Therapeutics, Inc. and Dr. Samuel Barone (incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q filed on August 12, 2021)
10.10#	Employment Agreement, dated as of February 5, 2021, by and between Gemini Therapeutics, Inc. and Jason Meyenburg (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed on February 11, 2021)
10.11#	Separation Agreement and Release, dated as of February 28, 2022, by and between Gemini Therapeutics, Inc. and Jason Meyenburg (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 28, 2022)

10.12#	Gemini Therapeutics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 99.3 of Registrant's Form S-8 filed on April 13, 2021 (Registration No. 333-255194))
10.13*	Second Amendment Agreement, dated March 7, 2022, by and between Sanquin Blood Supply Foundation and Gemini Therapeutics Sub, Inc.
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registrant's Current Report on Form 8-K filed on February 11, 2021)
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on signature page of this Annual Report)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed, or submitted electronically, herewith.

\# Indicates management contract or compensatory plan.

SIGNATURES

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

Company Name

Date: March 10, 2022

By: /s/ Georges Gemayel
Dr. Georges Gemayel
Interim President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Georges Gemayel, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the United States Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Georges Gemayel Dr. Georges Gemayel	Interim President and Chief Executive Officer and Executive Chair (Principal Executive Officer)	March 10, 2022
/s/ Brian Piekos Brian Piekos	Chief Financial Officer and Chief Business Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2022
/s/ Carl Gordon Dr. Carl Gordon	Director	March 10, 2022
/s/ David Lubner David Lubner	Director	March 10, 2022
/s/ Tuyen Ong Dr. Tuyen Ong	Director	March 10, 2022
/s/ Jason Rhodes Jason Rhodes	Director	March 10, 2022
/s/ Jim Tananbaum Dr. Jim Tananbaum	Director	March 10, 2022

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Gemini Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Gemini Therapeutics, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Boston, Massachusetts
March 10, 2022

Gemini Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 136,627	$ 4,503
Restricted cash, current	223	—
Prepaid expenses and other current assets	3,250	562
Total current assets	140,100	5,065
Property and equipment, net	—	294
Restricted cash, non-current	100	323
Deferred offering costs	—	2,637
Other assets	237	—
Total assets	$ 140,437	$ 8,319
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,950	$ 2,377
Accrued expenses and other current liabilities	6,884	5,810
Term loan, current portion	5,000	5,000
Convertible notes	—	11,689
Total current liabilities	14,834	24,876
Warrant liability	—	76
Other liabilities	358	277
Term loan, net of current portion and discount	404	4,951
Total liabilities	15,596	30,180
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 250,000,000 shares authorized; 43,208,159 and 15,565,380 shares issued and outstanding as of December 31, 2021 and 2020, respectively	4	2
Additional paid-in capital	309,527	90,958
Accumulated deficit	(184,690)	(112,821)
Total stockholders' equity (deficit)	124,841	(21,861)
Total liabilities and stockholders' equity (deficit)	$ 140,437	$ 8,319

The accompanying notes are an integral part of the consolidated financial statements.

Gemini Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 48,717	$ 28,170
General and administrative	20,285	5,870
Total operating expenses	69,002	34,040
Loss from operations	(69,002)	(34,040)
Other income (expense):		
Interest expense	(2,158)	(6,826)
Interest income	15	37
Loss on conversion of convertible notes	(711)	—
Change in fair value of warrant liability	—	(8)
Other expense	(13)	—
Net loss and comprehensive loss	$ (71,869)	$ (40,837)
Net loss per share, basic and diluted	$ (1.78)	$ (2.70)
Weighted average common shares outstanding, basic and diluted	40,362,303	15,115,129

The accompanying notes are an integral part of the consolidated financial statements.

Gemini Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Old Gemini Common Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019 (as previously reported)	39,722,088	$ 47,113	9,916,375	$ 13,252	5,313,766	$ 5	—	$ -	$ 1,182	$ (71,984)	$ (70,797)
Retroactive application of the recapitalization due to the Business Combination (Note 2)	(39,722,088)	(47,113)	(9,916,375)	(13,252)	(5,313,766)	(5)	11,979,586	1	60,369	—	60,365
Balance at December 31, 2019, effect of Business Combination (Note 2)	—	—	—	—	—	—	11,979,586	1	61,551	(71,984)	(10,432)
Issuance of Series B convertible preferred stock, net of issuance costs of $16	—	—	—	—	—	—	3,242,655	1	20,083	—	20,084
Beneficial conversion feature relating to discount on convertible promissory notes	—	—	—	—	—	—	—	—	8,177	—	8,177
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	285,260	—	164	—	164
Vesting of restricted common stock	—	—	—	—	—	—	57,879	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	983	—	983
Net loss	—	—	—	—	—	—	—	—	—	(40,837)	(40,837)
Balance at December 31, 2020, effect of Business Combination (Note 2)	—	$ —	—	$ —	—	$ —	15,565,380	$ 2	$ 90,958	$ (112,821)	$ (21,861)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Old Gemini Common Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	
Balance at December 31, 2020 (as previously reported)	39,722,088	$ 47,113	24,790,938	$ 33,336	6,900,493	$ 7	—	$ -	$ 10,504	$ (112,821)	$ (102,310)
Retroactive application of the recapitalization due to the Business Combination (Note 2)	(39,722,088)	(47,113)	(24,790,938)	(33,336)	(6,900,493)	(7)	15,565,380	2	80,454	—	80,449
Balance at December 31, 2020, effect of Business Combination (Note 2)	—	—	—	—	—	—	15,565,380	2	90,958	(112,821)	(21,861)
Issuance of common stock upon Business Combination, net of issuance costs (Note 2)	—	—	—	—	—	—	25,041,150	2	195,880	—	195,882
Conversion of promissory notes (Note 2)							2,341,316	—	14,515	—	14,515
Issuance of common stock upon exercise of warrants (Note 2)	—	—	—	—	—	—	15,257	—	76	—	76
Vesting of restricted common stock	—	—	—	—	—	—	35,561	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	209,495	—	311	—	311
Stock-based compensation expense	—	—	—	—	—	—	—	—	7,787	—	7,787
Net loss	—	—	—	—	—	—	—	—	—	(71,869)	(71,869)
Balance at December 31, 2021, effect of Business Combination (Note 2)	—	$ —	—	$ —	—	$ —	43,208,159	$ 4	$ 309,527	$ (184,690)	$ 124,841

The accompanying notes are an integral part of the consolidated financial statements.

Gemini Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (71,869)	$ (40,837)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	231	322
Gain on the sale of property and equipment	(303)	—
Stock-based compensation expense	7,787	983
Non-cash interest expense	283	613
Change in fair value of warrant liability	—	8
Loss on conversion of convertible notes	711	—
Accretion of discount on convertible notes	1,600	5,866
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,536)	1,677
Deferred offering costs	1,341	(1,341)
Other assets	(237)	2
Accounts payable	1,562	(2,408)
Accrued expenses and other current liabilities	1,730	2,407
Net cash used in operating activities	(59,700)	(32,708)
Cash flows from investing activities:		
Purchase of property and equipment	(71)	(22)
Proceeds from the sale of property and equipment	415	—
Net cash provided by (used in) investing activities	344	(22)
Cash flows from financing activities:		
Proceeds from Business Combination, net	195,882	—
Proceeds from sale of Series B convertible preferred stock, net	—	20,084
Proceeds from convertible notes	—	14,000
Proceeds from exercise of stock options	181	163
Principal payments on term loan	(4,583)	—
Net cash provided by financing activities	191,480	34,247
Increase in cash, cash equivalents and restricted cash	132,124	1,517
Cash, cash equivalents and restricted cash at beginning of year	4,826	3,309
Cash, cash equivalents and restricted cash at end of year	$ 136,950	$ 4,826
Supplemental disclosure		
Cash paid for interest	$ 307	$ 345
Noncash investing and financing activities		
Conversion of convertible notes to Series B preferred stock	$ 14,515	$ —
Exercise of warrants	$ 76	$ —
Proceeds from exercise of stock options included in other current assets	$ 131	$ —
Proceeds from the sale of property and equipment included in other current assets	$ 22	$ —
Discount on convertible notes	$ —	$ 8,177
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	$ —	$ 1,296

The accompanying notes are an integral part of the consolidated financial statements.

1. Nature of the business

Gemini Therapeutics Inc. (the “Company” or “Gemini”) is a clinical-stage precision medicine company developing novel therapeutic compounds to treat genetically defined, age-related macular degeneration. The Company was founded on March 3, 2015.

Unless the context otherwise requires, references in these notes to “Gemini”, “the Company”, “we”, “us” and “our” and any related terms are intended to mean Gemini Therapeutics, Inc. and its consolidated subsidiary following the Business Combination (as defined below).

Since its inception, the Company has devoted substantially all its efforts and financial resources to organizing and staffing the Company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for its product candidates. In January 2022, the Company discontinued both of its Phase 2a clinical trials for GEM103. The Company's other product candidate, GEM307, is in the preclinical stage of development.

On February 5, 2021 (the “Closing Date”), FS Development Corporation, a Delaware corporation (“FSDC”), consummated the previously announced business combination (the “Business Combination”) pursuant to the terms of the Agreement and Plan of Merger, dated as of October 15, 2020 (as amended, supplemented or otherwise modified from time to time, the “Merger Agreement”), by and among Gemini Therapeutics, Inc., a Delaware corporation (“Old Gemini”), Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the Company Securityholders (the “Stockholders’ Representative”), FSDC and FSG Merger Sub Inc., a Delaware corporation (“Merger Sub”).

FSDC was incorporated in Delaware on June 25, 2020 and was formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

On the day prior to the Closing Date, Old Gemini changed its name to “Gemini Therapeutics Sub, Inc.” Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC changed its name to “Gemini Therapeutics, Inc.” and (ii) Old Gemini merged with and into Merger Sub (the “Merger”), with Old Gemini as the surviving company in the Merger and, after giving effect to such Merger, Old Gemini becoming a wholly-owned subsidiary of Gemini. Upon the closing of the Business Combination, and pursuant to the terms of the Merger Agreement, the existing shareholders of Old Gemini exchanged their interests for shares of common stock of Gemini.

In connection with the Business Combination, certain investors purchased an aggregate of $95.1 million of the Company’s Common Stock in a private placement of public equity (the “PIPE Financing”). Together with FSDC’s cash resources and funding of the PIPE Financing, the Company received net proceeds of approximately $195.9 million.

For additional information on the Business Combination, please refer to Note 2, *Business Combination*, to these consolidated financial statements.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, compliance with government regulations and the impact of the novel coronavirus disease (“COVID-19”) pandemic. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

The Company’s product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company

operates in an environment of rapid change in technology and is dependent upon the services of its employees, consultants, third-party contract research organizations and other third-party organizations.

Prior to the Business Combination, the Company primarily financed its operations through the sale of convertible preferred stock, borrowings under convertible promissory notes and borrowings under loan agreements. The Company believes that its $136.6 million of cash and cash equivalents as of December 31, 2021 will enable it to fund its planned operations for at least twelve months from the issuance date of these consolidated financial statements, though the Company may raise additional capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Management's expectations with respect to its ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Its operating plan may change as a result of many factors currently unknown to management, and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by the Company, and it may need to seek additional funds sooner than anticipated. If adequate funds are not available to the Company on a timely basis, on acceptable terms or at all, management may be required to delay, limit, reduce or terminate certain of its research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to the Company, or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of its stockholders.

Impact of the COVID-19 Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The ongoing COVID-19 pandemic and the increased prevalence of variants of the virus, and government measures taken in response, have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The ongoing COVID-19 pandemic and related impacts have resulted in and will likely continue to result in significant disruptions to the global economy and capital markets around the world. The Company cannot predict the future progression or full impact of the outbreak and its effects on the Company's business and operations.

The Company has not incurred impairment losses in the carrying values of its assets as a result of the ongoing COVID-19 pandemic, and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these consolidated financial statements. Although the COVID-19 pandemic did not have a significant impact on the Company's financial results in 2021, the full extent to which the ongoing COVID-19 pandemic may impact the Company's business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain, and the estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19, including the duration of the pandemic, any potential subsequent waves or strains of COVID-19 infection, the effectiveness, distribution and acceptance of COVID-19 vaccines and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets.

2. Business Combination

On February 5, 2021, Old Gemini and FSDC completed the Business Combination pursuant to the Merger Agreement with Old Gemini surviving the merger as a wholly owned subsidiary of FSDC. Net proceeds from the Business Combination totaled approximately $195.9 million, which included funds held in FSDC's trust account and the completion of the concurrent PIPE Financing.

In accordance with the terms and subject to the conditions of the Merger Agreement, at the effective time of the Merger, (i) all shares of Old Gemini's Series B Preferred Stock (including shares of Series B Preferred Stock issued upon conversion of outstanding convertible promissory notes), Series A Preferred Stock and Common Stock (collectively, "Old Gemini Stock") issued and outstanding immediately prior to the effective time of the Merger, whether vested or unvested, were converted into the right to receive their pro rata portion of the 17,942,274 shares of FSDC Class A Common Stock (the "Common Stock") issued as Merger consideration (the "Merger Consideration"), provided that 2,150,000 shares of Common Stock are held in escrow for a period of 12 months from the Closing Date to satisfy any indemnification obligations of Old Gemini under the Merger Agreement; (ii) each option exercisable for Old Gemini Stock that was outstanding immediately prior to effective time of the Merger was assumed and continues in full force and effect on the same terms and conditions as were previously applicable to such options, subject to adjustments to exercise price and number of shares Common Stock issuable upon exercise based on the final conversion ratio calculated in accordance with the Merger Agreement, and (iii) 4,264,341 shares of Common Stock were reserved for issuance under the newly adopted 2021 Stock Option and Incentive Plan (the "2021 Plan").

The Company accounted for the Business Combination as a reverse recapitalization, which is the equivalent of Old Gemini issuing stock for the net assets of FSDC, accompanied by a recapitalization, with FSDC treated as the acquired company for accounting purposes. The determination of FSDC as the "acquired" company for accounting purposes was primarily based on the fact that subsequent to the Business Combination, shareholders of Old Gemini prior to the Business Combination have a majority of the voting power of the combined company, the operations of Old Gemini will comprise all of the ongoing operations of the combined entity, and Old Gemini's senior management will comprise all of the senior management of the combined company. The net assets of FSDC were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Gemini. The shares and corresponding capital amounts and loss per share related to Old Gemini's outstanding convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the conversion ratio established in the Merger Agreement (1.00 Old Gemini share for 0.2180 shares of the Company) (the "Conversion Ratio").
In connection with the Business Combination, the Company incurred equity issuance costs and other costs considered direct and incremental to the transaction totaling $21.0 million, consisting of legal, accounting, financial advisory and other professional fees. These amounts are reflected within additional paid-in capital in the consolidated balance sheet as of December 31, 2021.

PIPE Financing

Concurrent with the execution of the Business Combination, the Company entered into subscription agreements with certain investors (the "PIPE Investors") pursuant to which the PIPE Investors subscribed for and purchased an aggregate of 9,506,000 shares of Common Stock for an aggregate purchase price of $95.1 million.

Summary of Net Proceeds

The following table summarizes the elements of the net proceeds from the Business Combination (in thousands):

Cash - FSDC Trust Account and cash (net of redemptions)	$	121,782
Cash - PIPE Financing		95,060
Less: Equity issuance costs and other costs paid		(20,960)
Net proceeds from the Business Combination	$	195,882

Summary of Shares Issued

The following table summarizes the number of shares of Common Stock outstanding immediately following the consummation of the Business Combination:

FSDC shares outstanding prior to the Business Combination	15,535,150
Shares issued pursuant to the PIPE Financing	9,506,000
Business Combination and PIPE Financing shares	25,041,150
Conversion of Old Gemini Series A preferred stock for common stock	8,657,869
Conversion of Old Gemini Series B preferred stock for common stock	7,744,785
Conversion of Old Gemini common stock for common stock	1,539,603
Issuance of common stock upon exercise of warrants	15,257
Total shares of the Company's common stock outstanding immediately following the Business Combination	42,998,664

3. Summary of Significant Accounting Policies

Basis of presentation

The accompanying consolidated financial statements include those of the Company and its subsidiary, Gemini Therapeutics Sub, Inc., after elimination of all intercompany accounts and transactions. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

As a result of the Business Combination, the shares and corresponding capital amounts and loss per share related to Old Gemini's outstanding convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the Conversion Ratio established in the Merger Agreement. For additional information regarding the Business Combination, please refer to Note 2, *Business Combination*, to these consolidated financial statements.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates contained within these financial statements include, but are not limited to, the accruals of research and development expenses, share-based awards utilized for stock-based compensation purposes, and, prior to the Business Combination, the estimated fair value of the Company's common stock and warrant liability. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results may differ materially from those estimates or assumptions.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The objectives of the Company's cash management policy are to safeguard and preserve funds to maintain liquidity sufficient to meet the Company's cash flow requirements and to attain a market rate of return. The Company's cash equivalents consist of amounts invested in money market mutual funds as of December 31, 2021 and 2020.

Restricted cash

Restricted cash amounted to $0.3 million as of December 31, 2021 and 2020, which consists of $0.1 million to collateralize the Company's credit cards and $0.2 million to collateralize its irrevocable standby letter of credit for its facility lease arrangement. The letter of credit is in the name of the landlord and was required to fulfill lease requirements in the event the Company should default on its lease obligation. The facility lease arrangement was terminated on December 31, 2021.

A reconciliation of the cash and cash equivalents and restricted cash as presented in the Company's consolidated balance sheets to the Company's consolidated statements of cash flows is as follows (in thousands):

	December 31,	
	2021	2020
Cash and cash equivalents	$ 136,627	$ 4,503
Restricted cash	323	323
Total cash, cash equivalents and restricted cash	$ 136,950	$ 4,826

Concentration of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in accredited financial institutions in amounts that could exceed federally insured limits. Cash equivalents are invested in money market funds. The Company maintains each of its cash balances with high-quality and accredited financial institutions and accordingly, such funds are not exposed to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed on a straight-line basis over the estimated useful lives of the assets. The estimated useful lives are as follows:

Computer equipment	3 years
Furniture and fixtures	5 years
Laboratory equipment	3 years
Leasehold improvements	Shorter of the useful life of the asset or the life of the lease

Costs for capital assets not yet placed in service are capitalized and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for normal, recurring or periodic repairs and maintenance activities are charged to expense as incurred.

As of December 31, 2021, all fixed assets of the Company have been sold or disposed.

Impairment of long-lived assets

Long-lived assets, comprised of property and equipment, to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Offering costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company had no deferred offering costs as of December 31, 2021. As of December 31, 2020, the Company recorded deferred offering costs of $2.6 million related to the costs incurred in connection with the Business Combination.

Fair value measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 – Quoted prices in active markets that are identical assets or liabilities.

Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 – Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and preferred stock warrant liability (outstanding as of December 31, 2020) are carried at fair value, determined according to the fair value hierarchy described above (also see Note 4). The carrying values of the Company's prepaid expenses and other current assets and accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. In February 2019, the Company entered into a term loan facility of up to $10.0 million (the "Term Loan") with Silicon Valley Bank ("SVB"). The carrying value of the Company's Term Loan as of December 31, 2021 and 2020 (see Note 8) approximated fair value based on interest rates currently available to the Company.

Debt issuance costs

The carrying value of the Company's Term Loan was recorded net of issuance costs and discount relating to the issuance of warrants. The debt discounts are amortized over the term of the debt using the effective interest method and recognized as interest expense.

Warrants

In February 2019, concurrent with the Company's Term Loan agreement (see Note 8), the Company issued warrants to purchase shares of Old Gemini's Series A preferred stock. The Company accounted for the warrants to purchase Series A preferred stock as a liability as these warrants were freestanding financial instruments that may have required the Company to transfer assets upon exercise. The fair value of the warrants classified as liabilities is estimated using the Black-Scholes Option Pricing Model and adjusted to fair value at the end of each reporting period. Changes in the fair value of the warrants are recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The estimates in the Black-Scholes Option Pricing Model are based, in part, on subjective assumptions, including, stock price volatility, term of the warrants, risk free interest rate, dividend yield and the fair value of the preferred stock underlying the warrants. Such assumptions could differ materially in the future.

At the closing of the Business Combination, the warrants were automatically exercised for 15,257 shares of the Company's common stock.

Segment information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company's singular focus is the development of novel therapies for genetically defined, age-related macular degeneration. The Company has determined that it operates as a single operating segment and has one reportable segment. The Company's long-lived assets are located in the United States.

Research and development contract costs and accruals

Research and development expenses include employee payroll, consulting, contract research and manufacturing, depreciation, rent and other corporate costs attributable to research and development activities and are expensed as incurred.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development expenses in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent costs

The Company expenses all patent-related costs incurred in connection with filing and prosecuting patent applications. It records such costs within general and administrative expenses in its accompanying consolidated statements of operations and comprehensive loss.

Stock-based compensation

The Company measures all stock-based awards granted to employees, directors and non-employees based on the fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. The Company grants stock options and restricted stock awards that are subject to either service or performance-based vesting conditions. For awards with service-based vesting conditions, the Company recognizes equity-based compensation expense on a straight-line basis over the vesting period. Compensation expense related to awards to employees and non-employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. The Company estimates the probability that certain performance criteria will be met and does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Determination of Fair Value

Subsequent to the closing of the Business Combination, the fair value of each share of common stock underlying stock-based awards is determined based on the closing price of the Company's common stock as reported by Nasdaq on the date of grant.

The Company estimates the fair value of stock options using the Black-Scholes option pricing model, which uses as inputs the fair value of the Company's common stock, and certain management estimates, including the expected stock price volatility, the expected term of the award, the risk-free rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information is available. The Company selects companies with comparable characteristics with historical share price information that approximates the expected term of the equity-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period that approximates the calculated expected term of the stock options. The Company will continue to apply this method until a sufficient amount of historical information regarding the volatility of its stock price becomes available. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data. The expected dividend yield is assumed to be zero as the Company has no current plans to pay any dividends on common stock.

Prior to the completion of the Business Combination transaction, given that there had been no public market for the Company's common stock, the estimated fair value of its common stock was determined by the board of directors as of the date of each award grant, with input from management, considering the Company's most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The Company's common stock valuations were prepared using an option pricing method ("OPM") or a hybrid method, both of which used market approaches to estimate its enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a probability-weighted expected return method ("PWERM") where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of the Company's common stock based upon an analysis of its future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each

class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred securities, the superior rights and preferences of securities senior to the common securities at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by analyzing carryback capacity in periods with taxable income, reversal of existing taxable temporary differences and estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. To the extent an income tax provision is necessary, the provision for income taxes would include the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying consolidated financial statements.

Net loss per share

The Company calculates earnings per share in accordance with ASC Topic 260, *Earnings per Shar*e. The two-class method of computing earnings per share is required for entities that have participating securities. Under the two-class method, net income is allocated between ordinary shares and participating securities based on dividends declared (or accumulated) and participating rights in undistributed earnings as if all the earnings for the reporting period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common stock. For purpose of this calculation, outstanding options, unvested restricted common stock and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of net loss per share as their effect is anti-dilutive.

In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to be outstanding if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2021 and 2020.

Emerging growth company status

The Company qualifies as an "emerging growth company" ("EGC"), as defined in the Jumpstart Our Business Startups Act ("JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to avail itself of the extended transition period and, therefore, while the Company is an EGC it will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not EGCs, unless it chooses to early adopt a new or revised accounting standard. As a result of this election, the consolidated financial statements may not be comparable to companies that comply with public company FASB standards' effective dates.

Recently adopted accounting pronouncements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, ("ASU 2018-18"). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. This standard became effective for the Company on January 1, 2021 and did not have a material impact on its consolidated financial statements as the Company had no transactions applicable to this guidance; however, the standard may impact how the Company accounts for certain business transactions in the future.

Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (*Topic 842*), *Amendments to the FASB Accounting Standards Codification (*"ASU 2016-02"), which replaces the existing guidance for leases. ASU 2016-02 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a twelve-month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and a lease liability will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. The guidance is effective for annual reporting periods beginning after December 15, 2021 and interim periods beginning after December 15, 2022, and early adoption is permitted. The Company currently anticipates applying the modified retrospective approach effective January 1, 2022. The Company currently expects to elect the package of practical expedients which allows entities to not reassess (i) whether an arrangement is or contains a lease, (ii) the classification of its leases, and (iii) the accounting for initial direct costs. Further, the Company currently anticipates electing, by class of underlying asset, the short-term lease exception for leases with terms of twelve months or less. In doing so, the Company will not recognize a lease liability or right-of-use asset on its consolidated balance sheets for such short-term leases. Finally, the Company currently expects to elect, by class of underlying asset, the practical expedient to not separate lease and non-lease components. The Company does not expect that the adoption of ASU 2016-02 will have a material impact on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments*, which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2020-3 ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for the Company on January 1, 2023, with early adoption permitted. The Company is currently evaluating the potential impact that ASU 2016-13 may have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective for annual reporting periods beginning after December 15, 2021. The Company does not expect that the adoption of ASU 2018-18 will have a material impact on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"), which reduces the number of

accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company on January 1, 2024, with early adoption permitted. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

4. Fair value measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value (in thousands) on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

December 31, 2021	Level 1	Level 2	Level 3	Total
Assets				
Money market funds in cash and cash equivalents	$ 135,631	$ —	$ —	$ 135,631

December 31, 2020	Level 1	Level 2	Level 3	Total
Assets				
Money market funds in cash and cash equivalents	$ 4,015	$ —	$ —	$ 4,015
Liabilities				
Warrant liability	$ —	$ —	$ 76	$ 76

The values of cash equivalents are classified as Level 1 measurements under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. As of December 31, 2021 and 2020, cash equivalents were comprised of funds in money market accounts. There were no transfers or reclassifications between Level 1, Level 2 and Level 3 during the year ended December 31, 2021.

The value of the warrant liability was classified as a Level 3 measurement under the fair value hierarchy, as this liability was valued based on significant inputs not observable in the market.

Warrants to purchase Series A Preferred Stock

In February 2019, concurrent with the Company's Term Loan agreement, the Company issued warrants to purchase 15,257 shares of Old Gemini's Series A preferred stock. The warrants had an exercise price of $5.46 per share and expired in February 2029, representing a contractual term of ten years from issuance. At the closing of the Business Combination, the warrants were automatically exercised for 15,257 shares of the Company's common stock.

The fair value of the warrants was recorded as a liability on the date of issuance and was revalued at the end of each reporting period until being exercised upon the closing of the Business Combination.

The following table provides a roll-forward of the activity of the Company's Series A preferred stock warrant liability, which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

Balance at December 31, 2019	$ 68
Change in fair value	8
Balance at December 31, 2020	$ 76
Warrant exercise	(76)
Balance at December 31, 2021	$ —

The fair value of the warrants to purchase shares of the Company's Series A preferred stock at an exercise price of $5.46 per share, including subsequent remeasurements, was estimated using the Black-Scholes Option Pricing Model using the following assumptions:

	Year Ended December 31,	
	2021	2020
Fair value of the underlying instrument	$ —	$5.87 - $6.47
Risk-free interest rate	—%	0.57% - 0.75%
Expected term (in years)	—	8.1 - 8.9
Expected volatility	—%	73.8% - 79.2%
Expected dividend yield	—%	0.0%

The risk-free interest rate used is the rate for a U.S. Treasury zero coupon issue with a term consistent with the remaining contractual term of the warrant on the date of measurement. The Company has not paid, and does not expect to pay, any cash dividends in the foreseeable future. The Company based the expected term assumption on the actual remaining contractual term of the respective warrants as of the date of measurement. The expected volatility is based on historical volatilities from guideline companies since there is no active market for the Company's common stock. The fair value on the date of measurement of the Series A preferred stock, the underlying instrument, was estimated by management with the assistance of a third-party valuation specialist.

5. Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2021	2020
Laboratory equipment	$ —	$ 808
Computer equipment	—	29
Furniture and fixtures	—	53
Leasehold improvements	—	65
Total	—	955
Less accumulated depreciation	—	(661)
Property and equipment, net	$ —	$ 294

Depreciation expense for the years ended December 31, 2021 and 2020 was approximately $0.2 million and $0.3 million, respectively. The Company also recorded a gain on sale of property and equipment of $0.3 million for the year ended December 31, 2021, of which $0.2 million was recorded to research and development expense and $0.1 million was recorded to general and administrative expense in the accompanying consolidated statement of operations and comprehensive loss. As of December 31, 2021, all fixed assets of the Company have been sold or disposed.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued external research and development	$ 4,031	$ 3,136
Accrued payroll and benefits	2,603	1,500
Accrued professional fees	233	691
Accrued interest	17	437
Accrued other	—	46
	$ 6,884	$ 5,810

7. Corporate restructuring

In October 2021, the Company announced a restructuring plan that resulted in a reduction of the Company's workforce by 11 positions, or approximately 26% of the Company's then workforce. A majority of these employees' separation from the Company occurred in mid-October 2021, and the remaining affected employees transitioned by the end of 2021. As a result, the Company incurred costs of $1.4 million related to severance benefits for the affected employees, including severance payments, limited reimbursement of medical insurance premiums, outplacement services and other restructuring costs and expenses. Each affected employee's eligibility for the severance benefits was contingent upon such employee's execution (without revocation, as applicable) of a separation agreement, which includes a general release of claims against the Company. The restructuring plan was completed by the end of 2021.

Of the $1.4 million in costs recognized related to the restructuring plan, $0.9 million and $0.5 million have been charged to research and development and general and administrative expenses, respectively, in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2021. During the year ended December 31, 2021, the Company paid $0.5 million in severance benefits to separating employees related to the restructuring plan. At December 31, 2021, unpaid severance costs of $0.9 million are included in accrued expenses and other current liabilities in the accompanying consolidated balance sheet and are expected to be paid during the first quarter of 2022.

8. Term loan

In February 2019, the Company entered into a Term Loan facility of up to $10.0 million with SVB. The proceeds were used for general corporate and working capital purposes. Concurrent with the Term Loan, the Company issued SVB warrants to purchase 15,257 shares of the Company's Series A preferred stock at an exercise price of $5.46 (see Note 3). As of December 31, 2021 and 2020, the Company had $5.4 million and $10.0 million, respectively, in principal outstanding under the Term Loan.

The Term Loan is governed by a loan and security agreement, entered into in February 2019, between the Company and SVB (the "SVB Loan Agreement"). The SVB Loan Agreement provided for two separate tranches under which the Company could borrow. In April 2019, the Company borrowed $7.5 million under the first tranche, and in December 2019, the Company borrowed $2.5 million under the second tranche.

The Term Loan initially matured in July 2022 and accrues interest at a floating rate per annum equal to the greater of 3.75% or the prime rate minus 1.5% (1.75% as of December 31, 2021). The Term Loan initially provided for monthly interest-only payments until July 2020. Thereafter, payments are payable in equal monthly installments of principal, plus all accrued and unpaid interest. The Company may prepay the Term Loan in whole upon 5 days' prior written notice to SVB. Any such prepayment of the Term Loan is subject to a prepayment charge of 0.5% of the then outstanding principal balance. Amounts outstanding during an event of default are payable upon SVB's demand and will accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

In April 2020, the Company entered into a deferral agreement with SVB to defer scheduled principal repayments on its Term Loan by six months. The deferral agreement was offered to the Company in connection with SVB's venture debt relief initiative, which was started due to the COVID-19 pandemic. The Company's first principal payment under its credit facility occurred in February 2021. The required monthly interest-only payment was not impacted by the deferral. The Term Loan's new maturity date is in January 2023. After considering the debt guidance in ASC 470, the Company concluded that it did not meet the indicators of a troubled debt restructuring and accounted for the deferral of principal payment as a debt modification. Since there were no fees paid to SVB in connection with the deferral agreement, the Company did not record any adjustments to the Company's consolidated financial statements related to this deferral.

At the end of the loan term (whether at maturity, by prepayment in full or otherwise), the Company is required to pay a final end of term charge to SVB in the amount of 4.0% of the aggregate original principal amount advanced by SVB. The amount of the end of term charge is being accrued over the loan term as interest expense. As of December 31, 2021 and 2020, the Company had a liability related to the end of term charge of $0.4 million and $0.2 million, respectively, which has been classified within other long-term liabilities.

The SVB Loan Agreement includes a provision under which SVB may accelerate the scheduled maturities of the Term Loan under conditions that are not objectively determinable. The Company evaluated the likelihood of such acceleration and determined that it is not probable and classified the Term Loan on the consolidated balance sheet in accordance with the repayment schedule as of December 31, 2021.

As of December 31, 2021, scheduled principal payments for the Term Loan are as follows (in thousands):

Year Ending December 31,	
2022	$ 5,000
2023	417
Total principal	5,417
Unamortized discounts	(13)
Carrying amount	5,404
Less current portion	(5,000)
Long-term portion	$ 404

The Company recognized $0.5 million of interest expense related to the Term Loan during each of the years ended December 31, 2021 and 2020.

9. Convertible promissory notes

In August 2020, Old Gemini entered into a purchase agreement with various investors to issue $14.0 million in convertible promissory notes (the "Notes"). The Notes accrued simple interest at 8% per annum. The Company determined that a beneficial conversion feature ("BCF") existed and should be recognized on the issuance date. The Company recorded the Notes at the original issuance price, net of the BCF discount. The BCF discount was accreted to the face value of the Notes over the period from the issuance date until the maturity date, offset against interest expense.

The Notes served as a bridge loan prior to the PIPE Financing that was completed in connection with the closing of the Business Combination. The Notes were intended to automatically convert into shares of common stock issued in the PIPE Financing at a per share conversion price equal to the lowest per share price paid for such shares of common stock in the PIPE Financing. The Notes were amended to allow for the principal and interest to convert to shares of Series B preferred stock prior to the closing of the Business Combination. Accordingly, immediately prior to the closing of the Business Combination, the outstanding principal and interest under the Notes converted into 2,341,316 shares of Series B preferred stock at a per share conversion price of $6.1986, and the Notes liability was extinguished. The Company recorded a loss on conversion of convertible notes of $0.7 million for the difference between the reacquisition price of the Notes and the net carrying amount of the Notes in the consolidated statements of operations for the year ended December 31, 2021.

As of December 31, 2020, the carrying value of the Notes was as follows (in thousands):

Principal amount	$ 14,000
Unamortized discount (beneficial conversion feature)	(2,311)
Carrying amount	11,689
Less current portion	(11,689)
Long-term portion	$ —

The Company recognized $1.7 million and $6.3 million of interest expense related to the Notes during the years ended December 31, 2021 and 2020, respectively.

10. Stockholders' equity (deficit)

The consolidated statement of stockholders' equity (deficit) has been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as defined in Note 2, *Business Combination*.

Preferred Stock

Upon closing of the Business Combination and pursuant to the terms of the Amended and Restated Certificate of Incorporation entered into on February 5, 2021, the Company authorized 10,000,000 shares of preferred stock with a par value $0.0001 per share. The Company's board of directors has the authority, without further action by the stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of December 31, 2021.

In connection with the closing of the Business Combination, all previously issued and outstanding Series A convertible preferred stock and Series B convertible preferred stock were exchanged for common stock of the Company pursuant to the Conversion Ratio established in the Merger Agreement. All fractional shares were rounded down.

Common Stock

Pursuant to the term of the Amended and Restated Certificate of Incorporation, the Company authorized 250,000,000 shares of common stock with a par value of $0.0001 per share.

As discussed in Note 2, *Business Combination*, the Company has retroactively adjusted the shares issued and outstanding prior to February 5, 2021 to give effect to the Conversion Ratio established in the Merger Agreement to determine the number of shares of common stock into which they were converted.

Voting

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

Dividends

Common stockholders are entitled to receive dividends, as may be declared by the board of directors. No dividends have been declared to date.

11. Equity incentive plans

2017 Old Gemini Equity Incentive Plan

Old Gemini's 2017 Stock Option and Grant Plan, as amended (the "2017 Plan"), provided for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. The 2017 Plan was administered by the board of directors, or at the discretion of the board of directors, by a committee of the board of directors.

The exercise price for incentive options was determined at the discretion of the board of directors. All incentive options granted to any person possessing less than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date.

The option term for incentive awards may not be greater than ten years from the date of the grant. Incentive options granted to persons possessing more than 10% of the total combined voting power of all classes of stock may not have an option term of greater than five years from the date of the grant. The vesting period for equity-based awards under the 2017 Plan was determined at the discretion of the board of directors, which was generally four years. For awards granted to employees and non-employees with four-year vesting terms, 25% of the options vest on the first anniversary of the grant date and the remaining options vest equally each month for three years thereafter.

Upon completion of the Business Combination, the Company ceased granting awards under the 2017 Plan.

Conversion of Awards

Each Old Gemini option from the 2017 Plan and each option from Old Gemini's 2015 Stock Option and Grant Plan (the "2015 Plan") that was outstanding immediately prior to the Business Combination, whether vested or unvested, was converted into an option to purchase a number of shares of common stock (each such option, an "Exchanged Option") equal to the product (rounded down to the nearest whole number) of (i) the number of shares of Old Gemini common stock subject to such Old Gemini option immediately prior to the Business Combination and (ii) the Conversion Ratio, at an exercise price per share (rounded up to the nearest whole cent) equal to (A) the exercise price per share of such Old Gemini option immediately prior to the consummation of the Business Combination, divided by (B) the Conversion Ratio. Each Exchanged Option will continue to be governed by the same terms and conditions (including vesting and exercisability terms) as were applicable to the corresponding former Old Gemini option immediately prior to the consummation of the Business Combination. All stock option activity was retroactively restated to reflect the Exchanged Options.

As of the Closing Date, the 10,567,508 options and 163,157 restricted stock units ("RSUs") outstanding under the 2017 Plan and 2015 Plan were converted into 2,303,309 options and 35,561 RSUs, respectively, upon completion of the Business Combination after the effect of the Conversion Ratio. This effect of the Conversion Ratio has been retroactively adjusted throughout the Company's consolidated financial statements.

2021 Gemini Equity Incentive Plan

In February 2021, FSDC's stockholders approved the 2021 Stock Option and Incentive Plan (the "2021 Plan"), pursuant to which 4,264,341 shares of common stock were reserved for issuance. The 2021 Plan provides for the Company to grant incentive stock options or nonqualified stock options for the purchase of common stock, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards and dividend equivalent rights to employees, officers, directors and consultants of Gemini. Incentive stock options may only be granted to employees. The 2021 Plan is administered by the plan administrator, which is the compensation committee of Gemini's board of directors, provided therein, which has discretionary authority, subject only to the express provisions of the 2021 Plan, to interpret the 2021 Plan; determine eligibility for and grant awards; determine form of settlement of awards (whether in cash, shares of stock, other property or a combination of the foregoing), determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the 2021 Plan. As of December 31, 2021, 229,804 shares remained available for future issuance under the 2021 Plan. The number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors. Subject to this provision, the Company added 1,728,326 shares available for grant to the 2021 Plan effective January 1, 2022.

The exercise price of each stock option granted under the 2021 Plan will be 100% of the fair market value of the underlying stock subject to the award, determined as of the date of the grant, or such higher amount as the plan administrator may determine in connection with the grant, and the term of stock option may not be greater than ten years. The vesting and other restrictions are determined at the discretion of the plan administrator.

2021 Inducement Plan

In February 2021, the Company's board of directors approved the 2021 Inducement Plan. The 2021 Inducement Plan is a non-stockholder approved stock plan under which the Company grants equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Company to accept employment and provide them with a proprietary interest in the Company. The Company intends that the 2021 Inducement Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of the NASDAQ Stock Market, Inc. The 2021 Inducement Plan is administered by the board of directors or the compensation committee of the board, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. Awards granted under the 2021 Inducement Plan expire no later than ten years from the date of grant. As of December 31, 2021, 766,949 shares were available for issuance under the 2021 Inducement Plan.

2021 Employee Stock Purchase Plan

In July 2021, the Company's board of directors approved the 2021 Employee Stock Purchase Plan ("2021 ESPP"). The first offering period under the 2021 ESPP began on December 1, 2021. The Company has not yet issued any shares under the 2021 ESPP. The Company recorded $16 thousand of stock-based compensation expense related to the 2021 ESPP during the year ended December 31, 2021. As of December 31, 2021, 430,551 shares remained available for future issuance under the 2021 ESPP. The number of shares of common stock reserved for issuance under the 2021 ESPP automatically increases on January 1 of each calendar year, starting on January 1, 2023 and continuing through January 1, 2031, in an amount equal to the least of (a) 1% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, (b) 430,551 shares of common stock, or (c) such number of shares determined by the Company's board of directors.

Option valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and non-employees was as follows:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.6% - 1.4%	0.4% - 0.7%
Expected term	5.3 - 6.1 years	5.5 - 6.1 years
Expected volatility	79%	79%
Expected dividend yield	—%	—%

Options

Through December 31, 2021, all options granted by the Company are for the purchase of shares of common stock. The following table summarizes option activity since December 31, 2020:

	Number of stock options	Weighted average exercise price per share	Weighted average remaining contractual term	Aggregate intrinsic value
			(in years)	(in thousands)
Outstanding at December 31, 2020	2,316,899	$ 4.00		
Granted	5,057,146	$ 11.99		
Exercised	(208,890)	$ 1.48		
Forfeited and expired	(2,095,996)	$ 10.20		
Outstanding at December 31, 2021	5,069,159	$ 9.52	8.9	$ 734
Options vested and expected to vest at December 31, 2021	5,069,159	$ 9.52	8.9	$ 734
Options vested and exercisable at December 31, 2021	750,918	$ 3.88	7.7	$ 468

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

The intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was $0.9 million and $1.9 million, respectively.

The weighted average grant date fair value per share of options granted during the years ended December 31, 2021 and 2020 was $8.13 and $4.40, respectively.

The total fair value of options vested during the years ended December 31, 2021 and 2020 was $1.7 million and $0.6 million, respectively.

Restricted stock units

Under terms of the restricted stock units agreements covering the common stock, shares of common stock related to restricted stock units are subject to time-based and performance-based vesting. The restricted stock units will immediately be forfeited to the Company if the relationship between the recipient and the Company ceases.

The following table summarizes the Company's restricted stock activity since December 31, 2020:

	Number of shares	Weighted average grant date fair value
Unvested at December 31, 2020	35,568	$ 1.00
Granted	1,333,762	$ 3.56
Forfeited	(85,680)	$ 3.55
Vested	(35,568)	$ 1.00
Unvested at December 31, 2021	1,248,082	$ 3.56

The aggregate fair value of restricted stock units that vested during the years ended December 31, 2021 and 2020 was $31 thousand and $0.4 million, respectively.

The Company recorded stock-based compensation expense for restricted stock of $38 thousand and $30 thousand during the years ended December 31, 2021 and 2020, respectively.

Stock-based compensation expense

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	$ 2,575	$ 306
General and administrative	5,212	677
Total stock-based compensation expense	$ 7,787	$ 983

As of December 31, 2021, total unrecognized compensation cost related to the unvested stock-based awards was $24.7 million, which is expected to be recognized over a weighted average period of 3.0 years.

12. Income taxes

For the years ended December 31, 2021 and 2020, the Company recorded no income tax benefit for the net operating losses incurred in each year, due to the uncertainty of realizing a benefit from those items and recorded a full valuation allowance on its net deferred tax assets.

A reconciliation of income taxes computed using the statutory federal tax rate to the Company's effective income tax rate as of December 31, 2021 and 2020 are as follows:

	Year Ended December 31,	
	2021	2020
U.S. federal statutory income tax rate	21.0%	21.0%
State and local taxes, net of federal benefit	4.8%	5.4%
Research and development credits	2.9%	3.0%
Other	0.3%	0.3%
Change in valuation allowance	(29.0)%	(29.7)%
Effective income tax rate	0.0%	0.0%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 43,542	$ 27,469
Research and development credits	5,938	3,866
Other temporary differences	2,772	681
Gross deferred tax assets	52,252	32,016
Deferred tax liabilities:		
Depreciation	—	—
Stock-based compensation	—	—
Debt discount	—	(609)
Gross deferred tax liabilities	—	(609)
Net deferred tax assets	52,252	31,407
Valuation allowance	(52,252)	(31,407)
Net deferred tax assets	$ —	$ —

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that the Company's net deferred income tax assets will not be realized. As such, there is a full valuation allowance against the net deferred tax assets as of December 31, 2021 and 2020. The valuation allowance increased by $20.8 million during the year ended December 31, 2021 and $9.9 million during the year ended December 31, 2020 primarily as a result of net operating losses generated during the periods. The Company reevaluates the positive and negative evidence at each reporting period.

As of December 31, 2021, the Company had federal net operating loss carryforwards of $7.6 million that are subject to expire at various dates through 2037, and net operating loss carryforwards of $156.5 million, which have no expiration date, can be carried forward indefinitely, and are limited to a deduction to 80% of annual taxable income. The Company has state tax net operating loss carryforwards of $143.1 million, which may be available to offset future income tax liabilities and expire at various dates through 2041 and net operating loss carryforwards of $1.0 million, which have no expiration date, can be carried forward indefinitely. The Company also has federal and state research and development tax credit carryforwards of $5.0 million and $1.2 million, respectively, which expire at various dates through 2041.

Net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code of 1986, as amended (the "Code"), which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted a study to determine if any such changes have occurred that could limit its ability to use the net operating loss and tax credit carryforwards.

A study of research and development credit carryforwards, once undertaken by the Company, may result in an adjustment to its research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or consolidated statement of operations and comprehensive loss if an adjustment is required.

The Company has not recorded any liabilities for unrecognized tax benefits as of December 31, 2021 and 2020. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company is subject to U.S. federal income tax and Massachusetts state income tax. The statute of limitations for assessment by the IRS and state tax authorities is open for the tax years since 2018; currently, no federal or state income tax returns are under examination by the respective taxing authorities. However, the federal and state tax returns are subject to tax examination from the year of formation to the present. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was passed by the U.S. Congress and signed into law by the President of the United States. The CARES Act, among other things, includes certain provisions for individuals and corporations; however, these benefits do not impact the company's income tax provision.

13. Net loss per share

As a result of the Business Combination, the Company has retroactively restated the weighted average shares outstanding prior to February 5, 2021 to give effect to the Conversion Ratio.

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2021	2020
Net loss attributable to common stockholders	$ (71,869)	$ (40,837)
Weighted average common shares outstanding, basic and diluted	40,362,303	15,115,129
Net loss per share attributable to common stockholders, basic and diluted	$ (1.78)	$ (2.70)

The Company's unvested restricted common shares have been excluded from the computation of basic net loss per share attributable to common stockholders.

The Company's potentially dilutive securities, which include unvested restricted stock, common stock options outstanding and warrants to purchase shares of Series A preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2021	2020
Unvested restricted stock	1,248,082	35,568
Common stock options outstanding	5,069,159	2,316,899
Warrants to purchase shares of Series A preferred stock (as converted to common stock)	—	15,257
	6,317,241	2,367,724

14. Commitments and contingencies

Commitments

The Company's long-term contractual obligations include commitments entered into in the normal course of business. The Company's most significant contracts relate to agreements with clinical research organizations ("CROs") for clinical trials and preclinical studies and clinical manufacturing organizations ("CMOs"), which the Company enters into in the normal course of business. The contracts with CROs and CMOs are generally cancellable, with notice, at the Company's option. The Company also has commitments related to debt obligations, license agreements and other purchase obligations.

Lease agreements

The Company terminated its lease agreement on December 31, 2021 for its office and laboratory space. The lease required the Company to provide a security deposit in the amount of $0.2 million. The Company provided the landlord an irrevocable standby letter of credit in the name of the landlord for its security deposit and collateralized that letter of credit through its bank, which was included on the consolidated balance sheets as restricted cash as of December 31, 2021 and 2020. The Company was also required to pay certain operating costs. Rent expense for each of the years ended December 31, 2021 and 2020 was $1.0 million.

License agreements

In April 2017, the Company entered into a Research Collaboration and License Agreement with Sanquin Blood Supply Foundation ("Sanquin") (the "2017 License Agreement") to develop antibodies that bind and enhance the activity of CFH. As consideration for the license, the Company paid a one-time, non-refundable upfront payment of $0.1 million. The 2017 License Agreement includes additional consideration upon the achievement of certain development and commercial milestones (i.e., once net sales targets exceed certain thresholds) totaling up to an aggregate amount of $29.0 million. Finally, the Company is required to make royalty payments of between 1.25% and 2.50% of net product sales if commercialization is achieved. On March 7, 2022, the Company entered into an amendment to the 2017 License Agreement (the "2022 Amendment") to clarify that certain patent rights directed to CFH potentiating antibodies are jointly owned by the Company and Sanquin. Under the 2022 Amendment, Sanquin granted the Company an exclusive (even as to Sanquin) royalty-bearing license, with the right to sublicense through multiple tiers, to the portion of these patent rights owned by Sanquin. The consolidated financial statements as of December 31, 2021 and 2020 do not include liabilities with respect to this agreement as the Company has not yet generated revenue and the achievement of certain milestones is not deemed probable.

In June 2018, the Company entered into a Cell Line License Agreement with Life Technologies Corporation (the "2018 License Agreement") to obtain non-exclusive use of 293 H cells in support of GEM-103 manufacturing activities. As consideration for the license, the Company paid a one-time, non-refundable, non-creditable initial license fee of $0.1 million. In addition, an annual non-refundable, non-creditable development fee of $0.1 million is due on each anniversary date. The 2018 License Agreement includes additional consideration of $0.3 million contingent upon future commercialization of each licensed product. The consolidated financial statements as of December 31, 2021 and 2020 do not include a liability with respect to the additional consideration under this agreement as the Company has not yet generated revenue.

In March 2019, the Company entered into a second Cell Line License Agreement with Life Technologies Corporation (the "2019 License Agreement") to obtain non-exclusive use of a CTS Viral Production cell line for producing genetically engineered adeno-associated virus particles to be used in human therapeutics. In October 2021, the Company terminated the 2019 License Agreement. As consideration for the license, the Company paid a one-time, non-refundable, non-creditable initial license fee of $0.1 million. In addition, an annual non-refundable, non-creditable development fee of $0.1 million is due on each anniversary date, beginning on the second anniversary date. The 2019 License Agreement included additional consideration of $0.4 million contingent upon future commercialization of each licensed product. The consolidated financial statements as of December 31, 2021 and 2020 do not include a liability with respect to the additional consideration under this agreement as the Company has not yet generated revenue.

In October 2018, the Company entered into a Master License Agreement with Avitide, Inc. (the "2018 Master License Agreement") to license, on an exclusive basis, certain of Avitide's affinity chromatography resins comprised of proprietary ligands for affinity purification of biopharmaceuticals. As consideration for the license, the Company paid an upfront license fee of $0.2 million. In addition, an annual license fee of $0.1 million is due on each anniversary date. The 2018 Master License Agreement includes additional consideration upon the achievement of certain development, commercial and sales milestones totaling up to $0.7 million, $2.2 million and $7.0 million, respectively. Finally, the Company is required to make royalty payments of 1.25% of net product sales if commercialization is achieved. The consolidated financial statements as of December 31, 2021 and 2020 do not include liabilities with respect to additional consideration under this agreement as the Company has not yet generated revenue and the achievement of certain milestones is not deemed probable.

In June 2019, the Company entered into a GPEx-Derived Cell Line Sale Agreement with Catalent Pharma Solutions, LLC (the "2019 Sale Agreement") to purchase all right, title and interest in and to the GPEx Cell Line. As consideration for the GPEx Cell Line, the Company is required to make one-time milestone payments totaling up to $1.3 million in aggregate, as well as a contingent annual fee upon commercialization (1% of net sales, or $0.1 million, whichever is greater) and other fees after certain milestones are reached. Certain milestone payments may be waived if Catalent manufactures >50% of the total product required for the relevant clinical trial. The consolidated financial statements as of December 31, 2021 and 2020 do not include

liabilities with respect to this agreement as the Company has not yet generated revenue and the achievement of certain milestones is not deemed probable.

Contingencies

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2021 and 2020.

Legal proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. As of December 31, 2021 and 2020, the Company was not a party to any material legal matters or claims.

15. Benefit plans

The Company established a defined contribution savings plan under Section 401(k) of the Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Prior to 2019, matching contributions to the plan were made at the discretion of the Company's management. Beginning in 2019, the Company provides matching contributions equal to fifty percent (50%) up to six percent (6%) of each participant's salary. Employees are immediately and fully vested in the Company's contribution. During the years ended December 31, 2021 and 2020, the Company contributed $0.2 million and $0.1 million to the plan, respectively.

16. Related party transactions

The Company engaged a firm managed by an executive of the Company for professional services related to accounting, finance and other administrative functions. For the year ended December 31, 2021, the costs incurred under this arrangement totaled $0.6 million, of which $0.1 million was recorded in stockholders' equity (deficit) as a reduction to additional paid-in capital as a result of the Business Combination and $0.5 million was recorded as general and administrative expense in the consolidated statements of operations and comprehensive loss. For the year ended December 31, 2020, the costs incurred under this arrangement totaled $0.7 million, of which $0.7 million was capitalized as deferred offering costs associated with the business combination with FSDC and $44 thousand was recorded as general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2021 and 2020, amounts owed under this arrangement totaled $0 and $0.3 million, respectively, and is included in accounts payable in the accompanying consolidated balance sheet. The executive of the Company associated with this firm resigned from the Company in February 2021.

17. Subsequent events

The Company has evaluated subsequent events through the date of this Annual Report on Form 10-K to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2021, and events which occurred subsequently but were not recognized in the consolidated financial statements. The Company has concluded that no events or transactions have occurred that require disclosure in the accompanying consolidated financial statements, except as follows:

On February 28, 2022, the Company announced a restructuring plan to reduce the Company's operations to preserve financial resources, resulting in a reduction of the Company's workforce by up to 24 positions, or approximately 80%, by the end of the second quarter of 2022. As a result, the Company estimates that in total it will incur costs within the range of $1.6 million to $1.9 million, which are expected to consist of severance benefits for the affected employees, limited reimbursement of medical insurance premiums, outplacement services and other restructuring costs and expenses. Each affected employee's eligibility

for the severance benefits is contingent upon such employee’s execution (without revocation, as applicable) of a separation agreement, which includes a general release of claims against the Company. The restructuring plan is expected to be completed by the end of the second quarter of 2022.

Additionally, the Company has initiated a process to evaluate strategic alternatives in order to maximize shareholder value. There can be no assurance that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all.

Furthermore, effective as of February 28, 2022, Georges Gemayel, Ph.D., the Company's current Executive Chair, was appointed as interim President and Chief Executive Officer to succeed Jason Meyenburg, who has transitioned from his roles as President, CEO and Director and will continue to serve as an advisor to the Company. Dr. Gemayel will continue to serve as the Chair of the Board.

Exhibit 4.4

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The common stock, par value $0.0001 per share (the "Common Stock"), of Gemini Therapeutics, Inc. ("Gemini", "we", or "our") is registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Articles of Incorporation (the "Charter"), our Amended and Restated Bylaws (the "Bylaws") and the provisions of applicable law. The Charter and the Bylaws are incorporated by reference as an Exhibit 3.1 and 3.2, respectively, to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part.

Authorized and Outstanding Stock

The Charter authorizes the issuance of 260,000,000 shares, consisting of 250,000,000 shares of Common Stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value.

Common Stock

The Charter provides the following with respect to the rights, powers, preferences and privileges of the Common Stock.

Voting Power

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of Common Stock possess all voting power for the election of Gemini's directors and all other matters requiring stockholder action. Holders of Common Stock are entitled to one vote per share on matters to be voted on by stockholders.

Dividends

Holders of Common Stock will be entitled to receive such dividends, if any, as may be declared from time to time by the Board in its discretion out of funds legally available therefor. In no event will any stock dividends or stock splits or combinations of stock be declared or made on Common Stock unless the shares of Common Stock at the time outstanding are treated equally and identically.

Liquidation, Dissolution and Winding Up

In the event of Gemini's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the Common Stock will be entitled to receive an equal amount per share of all of Gemini's assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied.

Preemptive or Other Rights

There are no sinking fund provisions applicable to the Common Stock.

Preferred Stock

The Board has the authority to issue shares of preferred stock from time to time on terms it may determine, to divide shares of preferred stock into one or more series and to fix the designations, preferences, privileges, and restrictions of preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms, and the number of shares constituting any series or the designation of any series to the fullest extent permitted by the General Corporation Law of Delaware (the "DGCL"). The issuance of preferred stock could have the effect of decreasing the trading price of Common Stock, restricting dividends on the capital stock of Gemini, diluting the voting power of the Common Stock, impairing the liquidation rights of the capital stock of Gemini, or delaying or preventing a change in control of Gemini.

Election of Directors and Vacancies

Subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances and the terms and conditions of the Voting Agreement, dated February 5, 2021, by and among us and the other parties thereto (the "Voting Agreement"), the number of directors of the Board shall be fixed solely and exclusively by resolution duly adopted from time to time by the Board.

Under the Bylaws, at all meetings of stockholders called for the election of directors, a plurality of the votes properly cast is sufficient to elect such directors to the Board.

Except as the DGCL or the Voting Agreement may otherwise require and subject to the rights, if any, of the holders of any series of preferred stock, in the interim between annual meetings of stockholders or special meetings of stockholders called for the election of directors and/or the removal of one or more directors and the filling of any vacancy in that connection, newly created directorships and any vacancies on the Board, including unfilled vacancies resulting from the removal of directors, may be filled only by the affirmative vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director. All directors will hold office until the expiration of their respective terms of office and until their successors will have been elected and qualified. A director elected or appointed to fill a vacancy resulting from the death, resignation or removal of a director or a newly created directorship will serve for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until his or her successor will have been elected and qualified.
Subject to the rights, if any, of any series of preferred stock, any director may be removed from office only with cause and only by the affirmative vote of the holders of not less than two-thirds of the outstanding voting stock (as defined below) of Gemini then entitled to vote at an election of directors. Any such director proposed to be removed from office is entitled to advance written notice as described in the Charter. Subject to the terms and conditions of the Voting Agreement, in case the Board or any one or more directors should be so removed, new directors may be elected at the same time for the unexpired portion of the full term of the director or directors so removed.

In addition to the powers and authorities hereinbefore or by statute expressly conferred upon them, the directors are empowered to exercise all such powers and do all such acts and things as may be exercised or done by Gemini, subject, nevertheless, to the provisions of the DGCL, the Charter and to any Bylaws adopted and in effect from time to time; provided, however, that no Bylaw so adopted will invalidate any prior act of the directors which would have been valid if such Bylaw had not been adopted.

Notwithstanding the foregoing provisions, any director elected pursuant to the right, if any, of the holders of preferred stock to elect additional directors under specified circumstances will serve for such term or terms and pursuant to such other provisions as specified in the relevant certificate of designations related to the preferred stock.

Quorum

The holders of a majority of the voting power of the capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, will constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise required by law or provided by the Charter. If, however, such quorum will not be present or represented at any meeting of the stockholders, the holders of a majority of the voting power present in person or represented by proxy, will have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum will be present or represented. At such adjourned meeting at which a quorum will be present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting will be given to each stockholder entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Registration Rights

Pursuant to the terms of our Registration Rights Agreement, dated February 5, 2021, with certain of our stockholders (the "Registration Rights Agreement"), certain of our stockholders are entitled to rights with respect to the registration of their shares (which we refer to herein a "Registrable Securities") under the Securities Act of 1933, as amended (the "Securities Act"), including demand registration rights, shelf-registration rights and piggyback registration rights.

- *Demand registration rights*. At any time after February 5, 2021, and following the expiration of any lock- up to which a holder of Registrable Securities may have been subject, we are required, upon the written request of either (i) FS Development Holdings, LLC, Robert Carey, Daniel Dubin and Deepka Pakianathan (collectively, the "FSDC Investors") holding a majority of the Registrable Securities held by all FSDC Investors or (ii) Atlas Venture Fund X, L.P., Atlas Venture Opportunity Fund I, L.P., Lightstone Singapore L.P., Lightstone Ventures (A), L.P., Lightstone Ventures, L.P., OrbiMed Private Investments VI, LP and Wu Capital Investment LLC (collectively, "Major Gemini Investors" and together with the FSDC Investors, the "Investors") holding a majority of the Registrable Securities held by all Major Gemini Investors, to file a registration statement under the Securities Act on Form S- 1 or any similar long-form registration statement or, if then available, on Form S-3, and use reasonable best efforts to effect the registration of all or part of their registrable securities requested to be included in such registration by the Investors.

- *Shelf registration rights*. We were required to file a shelf registration statement pursuant to Rule 415 of Securities Act, which was filed on February 17, 2021 and became effective on April 28, 2021. At any time we have an effective shelf registration statement, if we shall receive a request from Investors holding registrable securities with an estimated market value of at least $5,000,000, to effect an underwritten shelf takedown, we shall use our reasonable best efforts to as expeditiously as possible to effect the underwritten shelf takedown.

- *Limits on demand registration rights and shelf registration rights.* We shall not be obligated to effect: (a) more than one (1) demand registration or underwritten shelf takedown during any six-month period; (b) any demand registration at any time there is an effective resale shelf registration statement on file with the United States Securities and Exchange Commission; (c) more than two underwritten demand registrations in respect of all registrable securities held by the FSDC Investors, including those made under a shelf registration statement, or (d) more than two underwritten demand registrations in respect of all registrable securities held by the Major Gemini Investors, including those made under a shelf registration statement.

- *Piggyback registration rights*. At any time after February 5, 2022, if Gemini proposes to file a registration statement to register any of its equity securities under the Securities Act or to conduct a public offering, either for its own account or for the account of any other person, subject to certain exceptions, the Investors are entitled to include their registrable securities in such registration statement, subject to customary cut-back rights.

- *Expenses and indemnification.* All fees, costs and expenses of underwritten registrations will be borne by us and underwriting discounts and selling commissions will be borne by the holders of the shares being registered. The Registration Rights Agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and holders of registrable securities are obligated to indemnify us for material misstatements or omissions attributable to them.

- *Registrable securities*. Securities of the Company shall cease to be registrable securities upon the earlier of (i) tenth anniversary of February 5, 2021 and (ii) the date as of which (1) a registration statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such registration statement, or (2) such securities shall have been transferred pursuant to Rule 144 of the Securities Act, or with respect to any Investor, securities of such Investor shall cease to be registrable securities, on the earlier of (x) the date such Investor ceases to hold at least 1% of the registrable securities or (y) if such Investor is an individual and such Investor is a director or an executive officer of the Company or FS Development Corp. as of immediately prior to the consummation of the business combination pursuant to the Merger Agreement, dated October 15, 2020, by and among us and the parties named therein, the date when such Investor is permitted to sell the Registrable Securities under Rule 144 (or any similar provision) under the Securities Act without limitation on the amount of securities sold or the manner of sale.

Anti-Takeover Provisions

Charter and Bylaws

Among other things, the Charter and Bylaws:

- permit the Board to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change of control;

- provide that the authorized number of directors may be changed only by resolution of the Board;

- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed only with cause by the holders of at least $66^{2/3}$% of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;

- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- provide that Special Meetings of Gemini's stockholders may be called by the Board pursuant to a resolution adopted by a majority of the total number of authorized directors;

- provide that the Board is divided into three classes of directors, with the classes to be as nearly equal as possible, and with the directors serving three-year terms, therefore making it more difficult for stockholders to change the composition of our Board; and

- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The combination of these provisions will make it more difficult for the existing stockholders to replace the Board as well as for another party to obtain control of Gemini by replacing the Board. Because the Board has the power to retain and discharge its officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce Gemini's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for Gemini's shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock.

Delaware Anti-Takeover Law

We have opted out of Section 203 of the DGCL. Section 203 of the DGCL prohibits a Delaware corporation from engaging in a "business combination" with an "interested stockholder" (i.e. a stockholder owning 15% or more of company's voting stock) for three years following the time that the "interested stockholder" becomes such, subject to certain exceptions.

Limitations on Liability and Indemnification of Officers and Directors

The Certificate of Incorporation limits the liability of the directors of Gemini to the fullest extent permitted by the DGCL, and the Bylaws provide that we will indemnify them to the fullest extent permitted by such law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our Board. Under the terms of such indemnification agreements, we are required to indemnify each of our directors and officers, to the fullest extent permitted by the laws of the state of Delaware, if the basis of the indemnitee's involvement was by reason of the fact that the indemnitee is or was a director or officer of Gemini or any of its subsidiaries or was serving at Gemini's request in an official capacity for another entity. We must indemnify our officers and directors against all reasonable fees, expenses, charges and other costs of any type or nature whatsoever, including any and all expenses and obligations paid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal), or preparing to defend, be a witness or participate in any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative, or establishing or enforcing a right to indemnification under the indemnification agreement. The indemnification agreements also require us, if so requested, to advance within 10 days of such request all reasonable fees, expenses, charges and other costs that such director or officer incurred, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Exclusive Jurisdiction of Certain Actions

The Bylaws require, to the fullest extent permitted by law, unless Gemini consents in writing to the selection of an alternative forum, that derivative actions brought in the name of Gemini, actions against directors, officers and employees for breach of fiduciary duty, actions asserting a claim arising pursuant to any provision of the DGCL or the Certificate of Incorporation or the Bylaws, actions to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Bylaws and actions asserting a claim against Gemini governed by the internal affairs doctrine may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel. Although we believe this provision benefits Gemini by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

In addition, the Bylaws require that, unless Gemini consents in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. Gemini has chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action.

Transfer Agent

The transfer agent for our common stock is Continental Stock Transfer & Trust Company.

THIS SECOND AMENDMENT AGREEMENT (the "**Amendment**") is made on March 7, 2022 (the "**Amendment Date**")

BETWEEN

(1) **Sanquin Blood Supply Foundation**, a non-profit organization, with offices located at Plesmanlaan 125, 1066 CX Amsterdam, the Netherlands ("**Sanquin**"); and

(2) **Gemini Therapeutics Sub, Inc.**, formerly Gemini Therapeutics Inc., a corporation organized under the laws of Delaware, having a place of business at One Kendall Square, Building 300, Floor 3,. Cambridge MA 02139 ("**Gemini**")

Sanquin and Gemini are hereinafter jointly also referred to as the "**Parties**" and individually as a "**Party**".

RECITALS

(A) The Parties entered into a Research Collaboration and License Agreement dated 1 April 2017 as subsequently amended on April 29, 2018 (the "**Original Agreement**").

(B) The Parties wish to amend and supplement certain provisions of the Original Agreement as set out in this Amendment.

AGREED TERMS

1. Definitions and Interpretation

1.1 In this Amendment, including the Recitals, terms defined in the Original Agreement will have the same meaning when used in this Amendment. In addition, in this Amendment:

(a) "**Second Patent Application**" shall mean International Application No. PCT/NL2019/050018 filed on January 15, 2019, together with (i) all patents which may be granted pursuant to the foregoing, (ii) all reissues, extensions (including patent term adjustments and supplementary protection certificates (or the equivalent thereof)), renewals, substitutions, confirmations, registrations, re-registrations, restorations, re-examinations, continuations, continuations-in-part, divisions, and patents of addition, with respect to the foregoing; and (iii) all patent applications and patents which claim priority from or common priority with the foregoing; and

(b) "**Third Patent Application**" shall mean International Application No. PCT/US2020/042627 filed on July 17, 2020, together with (i) all patents which may be granted pursuant to the foregoing, (ii) all reissues, extensions (including patent term adjustments and supplementary protection certificates (or the equivalent thereof)), renewals, substitutions, confirmations, registrations, re-registrations, restorations, re-examinations, continuations, continuations-in-part, divisions, and

patents of addition, with respect to the foregoing; and (iii) all patent applications and patents which claim priority from or common priority with the foregoing.

1.2 Except as otherwise provided in this Amendment, the terms of the Original Agreement shall remain in full force and effect provided that in the event of a conflict or ambiguity between the terms of the Original Agreement and the terms of this Amendment, the terms of this Amendment shall prevail.

2. Supplement to Original Agreement

2.1 The Parties hereby acknowledge and agree, notwithstanding any provision of the Original Agreement:

(a) The Third Patent Application shall be jointly owned by the Parties;

(b) Gemini shall have the exclusive right to prepare and file the Third Patent Application at Gemini's discretion and expense (and Sanquin shall not take any action in connection with the same);

(c) Gemini will have the first right (but not the obligation) to prosecute and maintain the Third Patent Application and shall use counsel reasonably acceptable to Sanquin for such activities. Gemini will provide to Sanquin all patent office papers promptly upon receipt, and drafts of responses to office actions from and other substantive filings with any patent office regarding the Third Patent Application sufficiently in advance before their submission to enable review and comment by Sanquin, and Gemini will consider in good faith all comments made by Sanquin. If Gemini chooses not to continue with the prosecution and maintenance of any patent right within the Third Patent Application, Gemini will notify Sanquin of such decision at least ninety (90) days before any such patent right would become forfeited or abandoned, and Sanquin will have the right (but not the obligation) to prosecute and maintain the relevant patent right(s) within the Third Patent Application provided that Sanquin will provide to Gemini all patent office papers promptly upon receipt, and drafts of responses to office actions from and other substantive filings with any patent office regarding the relevant patent right(s) sufficiently in advance before their submission to enable review and comment by Gemini, and Sanquin will consider in good faith all comments made by Gemini;

(d) The provisions of clauses 7.2 and 7.3 of the Original Agreement shall apply equally to the Third Patent Application (including following termination of the Original Agreement).

(e) Subject to clause 2.1(f) of this Amendment, Sanquin hereby grants to Gemini and its Affiliates an exclusive (even as to Sanquin however with the exception under clause 2.1(f)) worldwide license, with the right to sublicense through multiple tiers, under the Third Patent Application for all purposes in all fields, provided that such sub-licences will honour and follow provisions in this Amendment.

(f) Gemini hereby grants to Sanquin a non-exclusive, fully paid-up, non-transferable:

(i) non-sublicensable, licence under the Third Patent Application solely for the purpose of performing its obligations under the Research Plan;

(ii) license to use and permit other non-profit research institutions to use the Third Patent Application for educational and non-clinical research purposes provided that such third parties are not granted any rights to sell or commercialize products or services within the scope of the Third Patent Application.

(g) In the event of termination of the Original Agreement prior to expiry of the Third Patent Application:

(i) the provisions of clauses 2.1(a) to 2.1(d)of this Amendment shall continue to apply until expiry of the Third Patent Application (unless otherwise mutually agreed by the Parties in writing);

(ii) the provisions of clauses 2.1(e) and 2.1(f) of this Amendment shall terminate and each Party shall have (and to the extent necessary hereby grants and agrees to grant to the other) a fully paid-up, non-exclusive, worldwide, perpetual, irrevocable, transferable license, with the right to sublicense through multiple tiers, under the Third Patent Application for all purposes in all fields; in all cases without any obligation to account to the other Party.

(h) The Third Patent Application shall be deemed to be included within “Research Program Patent Right” and “Research Program Intellectual Property” for the purposes of the following clauses of the Original Agreement: 3, 4.4(c), 4.5 and 8.3 and in addition:

(i) 1.16 (definition of “Licensed Product”) and all instances in which such defined term is used in the Original Agreement;

(ii) 1.19 (definition of “Non-Royalty Sublicense Income”) and all instances in which such defined term is used in the Original Agreement;

(iii) 1.32 (definition of “Sanquin Intellectual Property”) and all instances in which such defined term is used in the Original Agreement; and

(iv) 1.36 (definition of “Valid Claim”) and all instances in which such defined term is used in the Original Agreement; and

(i) The Third Patent Application shall be deemed not to be included within “Research Program Patent Right” or “Research Program Intellectual Property” for the purposes of the following clauses of the Original Agreement: 2.1(b), 4.3(b), 7.1, 8.1, 8.4, and 10.3.

2.2 With effect from 1 April 2017 clause 10.4 of the Original Agreement shall be deemed to be deleted and replaced with the following:

"*Termination or expiration of this Agreement will not affect the rights and obligations of the Parties accrued prior to termination hereof. The provisions of Section 4.9 Section 10.2 and this Section 10.4, Article 1, entitled Definitions; Article 3, entitled Term of Agreement; Article 7, entitled Intellectual Property; Article 8.2(b) entitled Sublicensing Terms and Article 8.5, entitled No Implied Rights; Article 9, entitled Confidentiality, Publication, Use of Name; Article 11, entitled Warranties, Indemnification; Article 12, entitled Dispute Resolution; and Article 13, entitled Additional Provisions will survive any such termination or expiration.*"

2.3 With effect from April 29, 2018, the definition of "Research Program Patent Rights" shall be deemed to include, without limitation, the Second Patent Application.

2.4 The Parties acknowledge and agree that, at all times prior to the Amendment Date, Gemini has complied with all of its obligations under clause 6.1 of the Original Agreement and Sanquin does not have any right to terminate the Original Agreement for any breach of clause 6.1 of the Original Agreement prior to the Amendment Date.

3. General

3.1 The provisions of clause 12 of the Original Agreement shall apply equally to disputes of any nature arising under, relating to, or in connection with this Amendment.

3.2 The provisions of clause 13 of the Original Agreement shall apply equally to this Amendment (and references to 'hereunder' or 'this Agreement' or similar shall include a reference to this Amendment and its provisions).

3.3 Each Party agrees to execute, acknowledge, and deliver all such further instruments, and do all such further similar acts, as may be necessary or appropriate to carry out the purpose and intent of this Amendment.

Agreed by the Parties through their authorized signatories:

Sanquin Blood Supply Foundation	**Gemini Therapeutics Sub, Inc.**
Signature: /s/ Gerald de Haan	Signature: /s/ Brian Piekos
Name: Gerald de Haan	Name: Brian Piekos
Title: Director Research	Title: Chief Financial Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-255194) pertaining to the 2021 Stock Option and Incentive Plan and the 2021 Inducement Plan of Gemini Therapeutics, Inc., and

(2) Registration Statement (Form S-8 No. 333-260243) pertaining to the 2021 Employee Stock Purchase Plan of Gemini Therapeutics, Inc.;

of our report dated March 10, 2022, with respect to the consolidated financial statements of Gemini Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Georges Gemayel, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Gemini Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: /s/ Georges Gemayel
Dr. Georges Gemayel
Interim President and Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Piekos, certify that:

1. I have reviewed this Annual Report on Form 10-K of Gemini Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Gemini Therapeutics, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2022

By: /s/ Georges Gemayel
Dr. Georges Gemayel
Interim President and Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Gemini Therapeutics, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 10, 2022

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer
(Principal Financial Officer)