2022
ANNUAL REPORT

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, 2022

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 1-41403

COMERA LIFE SCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**87-4706968** **(I.R.S. Employer Identification No.)**
12 Gill Street **Suite 4650** **Woburn, MA** **(Address of principal executive offices)**	**01801** **(Zip Code)**

(617) 871-2101
Registrant's Telephone number, including area code

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock	**CMRA**	**The Nasdaq Stock Market LLC**
Warrants	**CMRAW**	**The Nasdaq Stock Market LLC**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐No ☒
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
The aggregate market value of the voting common shares held by non-affiliates of the registrant was approximately $22,610,072, computed by reference to the closing sale price of the Common Stock on the Nasdaq Capital Market on June 30, 2022, the last trading day of the registrant’s most recently completed second fiscal quarter.

The number of shares of the registrant’s Common Stock outstanding as of March 15, 2023 was 22,302,693.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Auditor Firm Id: 23 Name of Auditor: Baker-Tilly US LLP Auditor Location: Tewksbury, MA

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, references to "Holdco" "the Company," "our company," "we," "us" and "our" refer to Comera Life Sciences Holdings, Inc. and, as the context requires, its direct and indirect subsidiaries.

This Annual Report on Form 10-K (this "Report") contains forward-looking statements. All statements other than statements of historical fact contained herein, including statements regarding our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies are forward-looking statements. Words such as "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "forecasts," "guides," "intends," "is confident that," "may," "plans," "seeks," "projects," "targets," and "would," and their opposites and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the risk that we will need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at all; our ability to maintain the listing of our securities on the Nasdaq Capital Market ("Nasdaq");
- the price of our securities may be volatile due to a variety of factors, including volatility in the capital markets generally, the low trading volume for our Common Stock, changes in the competitive and highly regulated industries in which we plan to operate, variations in performance across competitors, changes in laws and regulations affecting our business and changes in our capital structure;
- the ability to implement business plans, forecasts, and identify and realize additional opportunities;
- the risk of economic downturns and the possibility of rapid change in the highly competitive industry in which we operate;
- the risk that we and our current and future collaborators are unable to successfully develop and commercialize our products or services, or experience significant delays in doing so;
- the risk that we may never achieve or sustain profitability;
- the risk that we experience difficulties in managing our growth and expanding operations;
- the risk that third-party suppliers and manufacturers are not able to fully and timely meet their obligations;
- the risk that we are unable to secure or protect our intellectual property;
- the effect of COVID-19 or other pandemics or epidemics on our business;
- general economic conditions; and
- other risks and uncertainties described in this Report, including those under the section entitled "Risk Factors."

Should one or more of these risks or uncertainties materialize or should any of the assumptions made by the management of the Company prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

Except to the extent required by applicable law or regulation, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

TRADEMARKS

This document contains references to trademarks, trade names and service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this Report may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable owner will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

MARKET AND INDUSTRY DATA

This Report contains estimates, projections, and other information concerning our industry and business, as well as data regarding market research, estimates, and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "*Risk Factors*." Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from sources which we paid for, sponsored, or conducted, unless otherwise expressly stated or the context otherwise requires. While we have compiled, extracted, and reproduced industry data from these sources, we have not independently verified the data. Forecasts and other forward-looking information with respect to industry, business, market, and other data are subject to the same qualifications and additional uncertainties regarding the other forward-looking statements in this document. See "*Cautionary Note Regarding Forward-Looking Statements"* above.

PART I

ITEM 1. Business.

Overview

We are a preclinical stage biotechnology company dedicated to promoting a compassionate new era in medicine. We apply a deep knowledge of formulation science and proprietary technology to optimize biologic medicines. Our internal portfolio of proprietary techniques known as our SQore™ platform, is designed to potentially:

- transform essential biologic medicines from intravenous ("IV") to subcutaneous ("SQ") forms;
- optimize current versions of subcutaneous biologics; and
- produce biosimilar versions of existing subcutaneous products.

We aim to develop these potentialities in order to transform administration from IV to SQ and thereby provide patients using biological products through intravenous infusion, and their families, with the freedom of self-injectable care which, we believe, would allow them to enjoy both the potential benefits of biologic treatments and the potential of their own lives while simultaneously lowering healthcare costs and increasing patient compliance.

The SQore™ platform, which is the foundation of our work, is supported by an extensive patent portfolio and encompasses years of knowledge and development from our team of scientists, including industry-leading experts in polymer engineering and interfacial dynamics (the way that different molecules interact) who are inventors on dozens of patents and have published widely-cited research in their fields. We believe that our combined polymer and small molecule capability will allow us to leverage a mechanistic understanding of protein-protein and protein-solvent interactions to identify suitable excipients for specific formulations, that allows the active, therapeutic ingredient to enter the body and arrive with sufficient potency.

We aim to achieve our mission by developing our own portfolio of therapeutic product candidates and by collaborating with pharmaceutical and biotechnology companies to transform their biologic medicines into enhanced SQ formulations.

Since our founding in 2014, we have primarily engaged in early-stage, preclinical studies, commissioned on a fee-for-services basis by larger pharmaceutical companies and have not yet developed any products approved for marketing. Our studies for larger companies were generally early-stage investigations, often amounting to proof-of-concept work, aimed at moving existing formulations from IV infusion to SQ delivery via injection.

In 2021, we brought on a new leadership team and carried out a transition of our business model. We shifted away from simple “fee for services” formulation work and focused our efforts on engaging with higher-value-add partners in integrated, collaborative projects to develop formulations for their key products. We are currently working with multiple companies under research and development service agreements. These agreements typically have a term of less than 12 months and provide for an initial payment by the company of a fee to us for the evaluation by us of our proprietary technology for viscosity reduction with the other company’s proprietary biotherapeutic agent. The agreements set forth the detailed research plans and the related timeline for completion of the research. The agreements provide that each party retains ownership of its technology throughout the process. Upon completion of the project, the parties may negotiate in good faith the terms of a license agreement. If the parties do not successfully negotiate a license, each party retains ownership of its technology and neither party may use the joint invention. Because these research and development service agreements may result in the future negotiation and execution of licensing agreements, we believe these projects provide far greater opportunities for generating revenue. When we meet our partners’ defined project criteria for the formulations, we will seek a license agreement to receive license fees, milestone payments, and longer-term and more stable royalty revenue on commercial assets that are vital to our partners.

On January 7, 2022, we changed the name of our operating subsidiary from ReForm Biologics, Inc. to Comera Life Sciences, Inc. This change marks our development into a revenue-generating, commercially-focused business with the potential to derive future revenue from multiple existing and future partnering opportunities.

On May 19, 2022, we consummated a business combination, contemplated by the Business Combination Agreement, dated January 31, 2022 (as amended, the “Business Combination Agreement”), by and among Holdco, OTR Acquisition Corp. (“OTR”), CLS Sub Merger 1 Corp., CLS Sub Merger 2 Corp. and Comera Life Sciences, Inc. (“ Legacy Comera”). Pursuant to the Business Combination Agreement, CLS Sub Merger 1 Corp. merged with and into Legacy Comera and CLS Merger 2 Corp. merged with and into OTR resulting in Legacy Comera and OTR becoming wholly owned subsidiaries of Holdco. Collectively, we refer herein to these transactions as the “Transaction.”

We continued to grow our leadership team in 2022, with a focus on expanding the scope of work over research collaborations and developing our internal pipeline. In July 2022, we announced favorable topline results from our SEQURUS-1 study, which provides supportive evidence of the safety of our lead caffeine-based SQore excipient when administered as a SQ biologic drug product formulation with a monoclonal antibody (mAb). In October 2022, we announced favorable safety and pharmacokinetic results from our SEQURUS-2 study. Also in October 2022, we announced our lead pipeline candidate CLS-001 as an SQ formulation of vedolizumab, a currently marketed product for the treatment of IBD including Crohn’s disease and ulcerative colitis.

In August 2022, we announced entry into a purchase agreement (the “Arena Purchase Agreement”) with Arena Business Solutions Global SPC II, Ltd. (“Arena”) providing for the purchase of up to $15 million of the Company’s common stock over a 36-month period, subject to certain limitations,, with an option to increase to $30 million. The equity line of credit will be used to invest in our pipeline and proprietary SQore platform.

The Market

According to Visiongrain Reports Ltd., the global market for biologics, including therapeutic drugs produced from living organisms (“biotherapeutics”), was valued at approximately $383 billion in 2022, and is estimated to grow at an 8.8% CAGR through 2032. Global market growth is attributed to the ongoing rising prevalence of chronic and acute diseases as well as general aging of the population. Therapeutic proteins, including monoclonal antibodies, accounted for 66% of the overall biologic market and is anticipated to grow at the highest rate. North America held the highest market share in 2020, at 34.8%, and is expected to grow at an 5.6% CAGR over the next 5 years, with the Asia-Pacific region anticipated to grow at the highest rate over the next 5 years, with a CAGR of 10.3%.

The rapid expansion of biotherapeutics is largely driven by monoclonal antibodies (“mAbs”). The high target specificity of mAbs, their overall low toxicity and immunogenicity, or ability to “prime” the immune system to respond, compared to conventional pharmacotherapies make mAbs helpful in treating life threatening cancers as well as inflammatory, cardiovascular, respiratory, ophthalmic and infectious diseases. mAbs have a low potency when compared to more traditional therapeutic drugs and, as a result, are typically administrated in high doses, up to several hundred milligrams, via slow intravenous infusion, generally by inserting a needle into the patient’s vein in the arm and adding the mAbs to a saline solution that slowly feeds through the needle and into the patient’s blood stream. This time-consuming “IV drip” process typically requires medical supervision that increases the burden on the health care system and negatively impacts the patient’s quality of life, especially those with limited mobility and with conditions needing long-term treatment. Our technology is designed to enable many IV mAbs to move to SQ injection through the use of excipients (specialized formulation ingredients) that reduce the high viscosity associated with SQ injections.

Industry Challenges

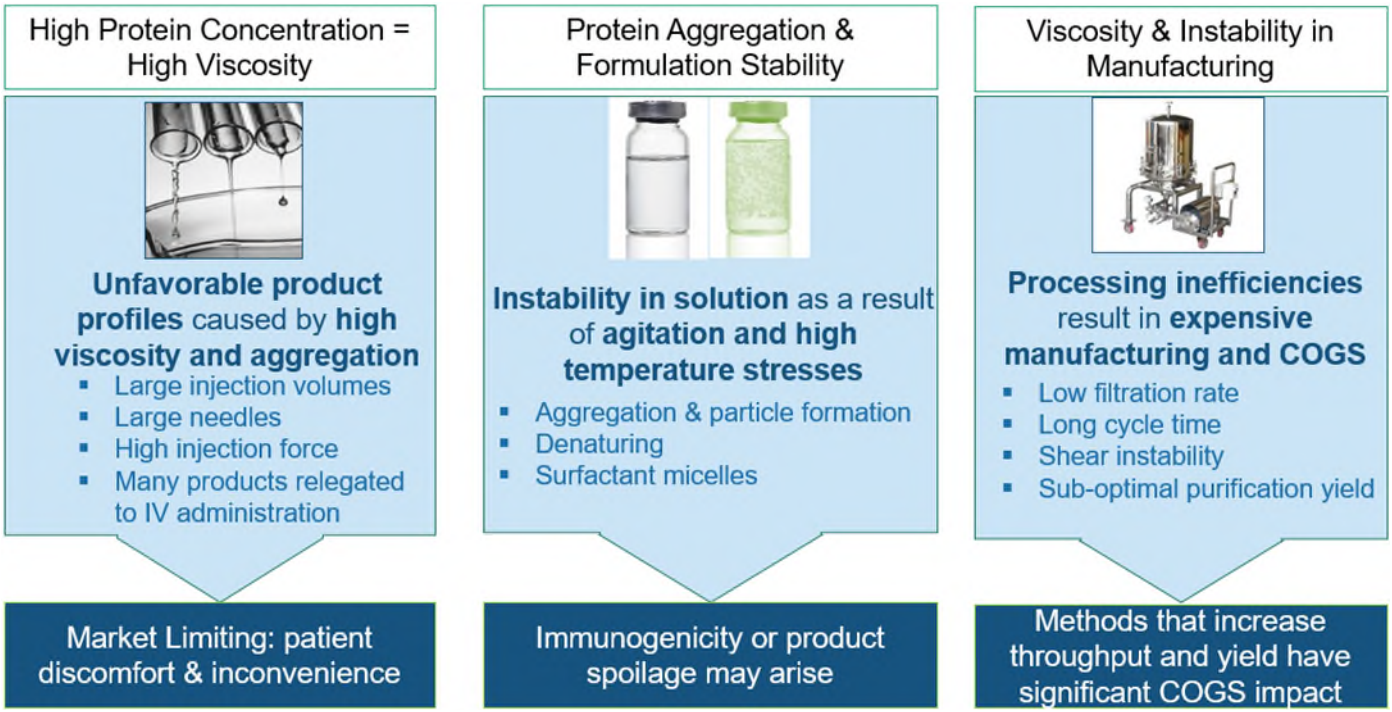
There has been little technology advancement for therapeutic protein product formulation in the industry over the past decade. Currently there are three major problems that our technologies and formulations are designed to address:

Problem 1: High concentrations and high formulation viscosity. Conventional IV delivery of biologics is accomplished by administering a dilute solution of the drug, typically in 100-1000 mL of saline solution. By contrast, the SQ delivery route requires a much lower injection volume such as 1-2 mL, so the same amount of drug must be highly concentrated in a small volume of liquid to be delivered by SQ injection. Highly concentrated solutions of protein biologics become viscous, meaning that products tend to be thick and therefore cannot be delivered by a syringe except with large volumes administered with large bore needles at high force. This becomes very uncomfortable or even painful for patients. Certain excipients can be added to modify the drug formulation to enable high concentration while maintaining viscosity low enough for SQ administration. IV infusion can take over several hours, while SQ injection by syringe can be completed in seconds and can be self-administered in a home setting, thereby making it more desirable to patients. SQ administration of biologics can improve patient compliance, thereby improving disease control, and saving on healthcare costs.

Problem 2: Protein aggregation and formulation instability. Biotherapeutic proteins have limited stability in solution and especially in highly concentrated solutions, and this can cause aggregation, forming soluble and insoluble clumps, or aggregates, that can exist as visible or subvisible particles. Protein aggregation can be caused by thermal stress, mechanical agitation, freeze/thaw cycles, or other stress factors. These aggregates can cause immunological and other adverse reactions in patients receiving the biotherapeutic agent. A surfactant, a substance that reduces interfacial tension, can be added to reduce the tendency for the proteins to form aggregates. However, the most common surfactants used consist of polysorbates which contain a labile ester bond that can either thermally or enzymatically break down in solution. Ester bond cleavage yields byproducts of a water-soluble sorbitol derivative and a water-insoluble fatty acid salt. The fatty acid salts can aggregate into particles and adsorb to proteins and surfaces. In short, polysorbates are known to break down, aggregate, attach to proteins and surfaces, and cause the product to degrade during storage. Replacing polysorbates with a more stable surfactant would reduce aggregation, thus improving to patient care. We have developed patented surfactant replacement compounds that we believe can be used as an alternative to polysorbates, offering a new approach that avoids the problems associated with these materials. In our laboratory testing, the new surfactant replacement compounds have shown the ability to prevent antibody aggregation upon exposure to shear stress; moreover, the surfactant replacement has been shown to avoid oxidation and aggregation of the therapeutic antibodies upon storage of formulations at 4, 25, or 40°C temperatures. This oxidation and aggregation is evident when polysorbates are used. This work has been presented at an industry conference and validated at the internal research and development group of one of the largest multinational chemical companies. In addition to the surfactants, we have developed new thermal stabilizers that we believe can be used to protect protein formulations from thermal degradation in storage conditions, and this can reduce the dependency on cold-chain storage and handling requirements of the finished drug products. In our laboratory testing, the new thermal stabilizers have been shown to reduce formation of antibody aggregates upon storage of antibodies at accelerated stress conditions of 40°C.

Problem 3: Viscosity and instability in manufacturing. After fermentation, biotherapeutic proteins are purified and isolated during a series of steps termed downstream processing. The final protein product can then be isolated. Adverse conditions during downstream processing, such as mechanical shear, pH swings, high concentration, and temperature, can cause protein denaturing, aggregation, and particle formation as they are being purified and isolated. This results in a reduced amount of purified protein passing the filtration process, increasing shear instability and required time and costs while decreasing purification yield. Our SQore™ platform technology is expected to benefit manufacturing and purification steps by reducing viscosity, enabling higher product recovery, reducing aggregation, and improving filtration efficiency.

The following diagram illustrates these three major problems:



Our new surfactant replacements and thermal stabilizers have not yet been used in clinically-approved products, but, we believe, validate our technology platform and well-position us to develop viable product candidates.

Our Technology Platform

We have developed, and continue to work on, an internal portfolio of proprietary techniques that we call the SQore™ platform. Our SQore™ platform, supported by an extensive patent portfolio and encompassing years of development and experience, is designed to enable the conversion of IV biologics to SQ formulations. The SQore™ platform includes proprietary structural calculations combined with analytical measurements to guide the selection of excipients for a given protein. We have customized, high-throughput analytical screening methods for the selection and optimization of excipients in a formulation. We have developed a library of over 200 excipients that are well established chemical structures, most with known toxicology profiles so that data to support regulatory requirements may be more readily assembled. The library is based on structure-mechanism of action and includes a number of proprietary assays, including an assay for excipient-protein unfolding inhibition. Currently we are developing a proprietary database to mine the data from our excipient library to select the best excipient for each specific biologic protein.

Our library of over 200 excipients has been created and validated by our proprietary testing methods, and we have filed patent applications disclosing or claiming the excipients or their use. Our patent portfolio includes seven issued United States ("U.S.") patents, plus patents in Canada, Japan, China, and Korea with over 35 other pending applications. We believe our technology will meet one of the current needs of the biotherapeutics industry: a wider range of excipient options to make medications with lower viscosity and greater stability that can be produced more efficiently and without conventional surfactants. This will allow for a greater range of product performance through different concentrations and dosing regimens.

Wider excipient options: Excipients are functional ingredients that are added to pharmaceutical formulations to improve their physical properties, stability, or safety. Our team of experienced scientists includes industry-leading experts in colloid science, polymer engineering, and interfacial dynamics, who are inventors on dozens of patents and have published widely-cited research in their fields. We believe that our technology, our team, our solid grounding in traditional protein chemistry and the resulting polymer and small molecule capability allows us to run structural calculations to identify a suitable excipient to deliver each specific biologic formulation subcutaneously. We believe our excipient capability will address the market need for a wider range of options as formulators have been using the same short list of excipients for decades while the number of therapeutics has expanded dramatically in that period. Moreover, extant excipients were originally selected for traditional small-molecule therapeutics. Today's biologics are comprised of larger molecules that result in higher solution viscosity. Our technology is optimized for these larger molecules and the high concentrations needed for SQ injections. Our excipients are not new chemical entities. Instead, we select compounds that have a known safety profile. Our team focuses on deploying the latest formulation methods and has experience working on the formulations of dozens of protein therapeutics.

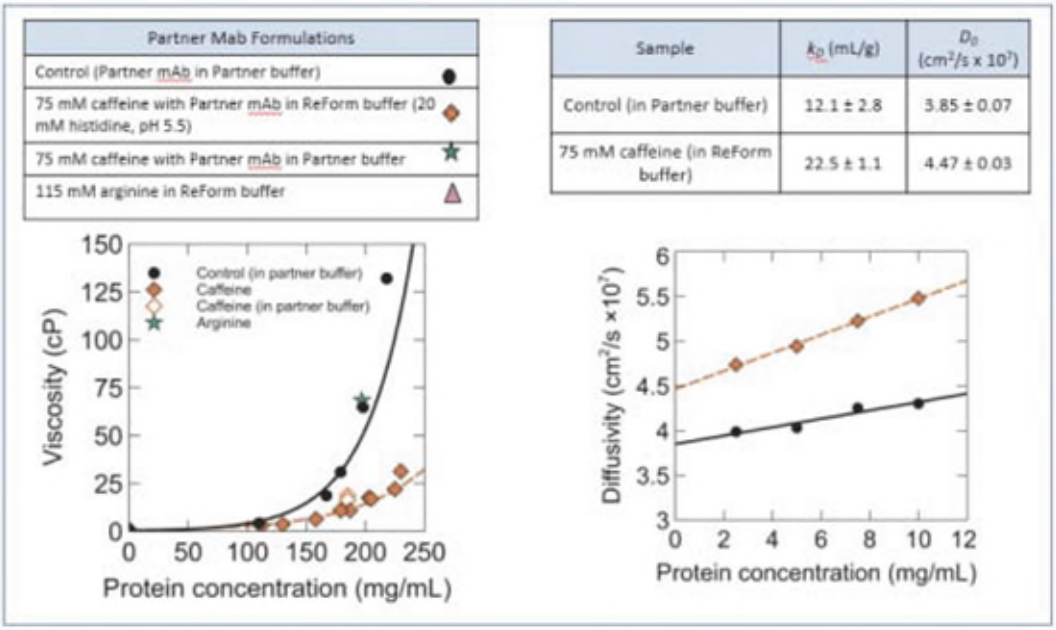
In contrast, some competitor approaches use combinations of amino acids as excipients, and we believe these are generally less effective at managing viscosity, limiting protein aggregation, and holding manufacturing costs down. Some competitor patents describe the use of new chemical entities that would require new GMP manufacturing plus extensive regulatory and safety studies. By comparison, we believe our excipient library offers numerous options that have not previously been considered. We believe that we have industry-leading expertise in biolayer interferometry which can be used to assess protein-excipient interactions in small sample volumes. The SQore™ excipient data are protected by our intellectual property portfolio and can only be accessed through licenses we grant.

Lower Viscosity: Our viscosity reduction technologies are being developed to significantly lower the viscosity of highly concentrated drug products. Highly viscous products tend to be thick and therefore cannot be delivered by a syringe. Instead, they must often be administered by intravenous infusion. By lowering the viscosity, we hope to open up potential new dosing protocols for these biologics, including a shift from intravenous infusion to SQ injection by syringe, and improvements on existing subcutaneous biologics. Our viscosity-reducing excipients have been tested on a wide range of antibodies including most of the top selling mAb drugs. We have partnered with over ten large pharmaceutical companies on high concentration formulations of mAbs. The viscosity reductions were confirmed by each of these pharmaceutical partners by testing validation samples. Between partnerships and internal studies, we have utilized the SQore™ platform to investigate improved formulations of biologics from 15 of the top 20 pharmaceutical companies, based on publicly disclosed 2020 revenues. We have state-of-the-art analytical equipment that can characterize the protein formulations of excipient candidates and scientists who are experts in biophysical characterization.

Caffeine is the first excipient that we have employed extensively for viscosity reduction of therapeutic antibodies. Protected by U.S. Patent Nos. 10,478,498, 9,605,051, and 9,867,881 along with issued patents in Canada, Japan, and China, plus a portfolio of other patent applications filed worldwide, our method of using caffeine in this way has significantly reduced viscosity for highly concentrated formulations. We have performed over 20 viscosity reduction projects internally and with our partners, and have achieved a greater than 92% success rate at reducing viscosity of protein formulations at concentrations ranging from 125-275 mg/mL. In comparison, excipients such as arginine and sodium chloride ("NaCl"), which are typically used for viscosity reduction, had marginal or no impact on reducing viscosity of some of the mAbs tested. In addition, we have identified the mechanism of action as to how caffeine and other excipients reduce viscosity.

The following chart shows the viscosity and diffusivity, respectively, of a partner's mAb formulation at increasing levels of concentration. In the concentration versus viscosity chart, the mAb formulation can be made at high concentrations (200 – 240 mg/mL) while maintaining a relatively low viscosity using caffeine as an excipient. Without the caffeine excipient, the viscosity is much higher at the 200 – 240 mg/mL concentration range. A comparison of arginine (green star symbol) shows that caffeine produces lower viscosity than arginine in this formulation. In the protein concentration versus diffusivity chart, the slope of the line is defined as kD, a protein interaction parameter. In general, changing a kD value from negative (attractive) to positive (repulsive), or from a low positive value to a higher positive value, can indicate less tendency to form viscous solutions. The formulation without caffeine has a kD value of 12.1 mL/g which indicates repulsive protein-protein interactions. With caffeine, the formulation has a kD value of 22.5 mL/g, indicating stronger repulsive protein-protein interaction forces.

Viscosity Reduction of Pharma Partner Antibody with Caffeine



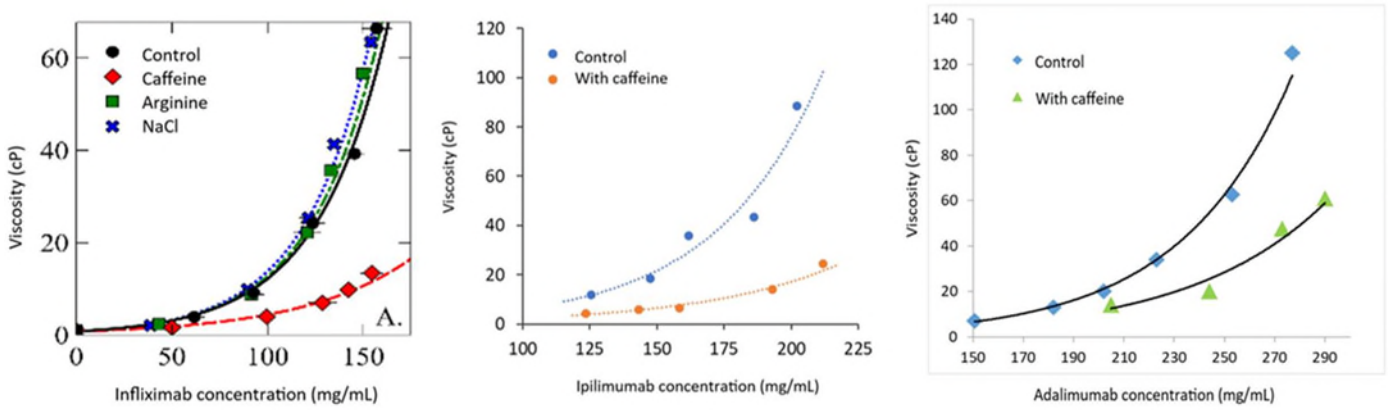
For viscosity reduction, we believe based on our research described below, that use of caffeine is safe in humans at use levels of approximately 15-30 mg caffeine for a 1-2 mL subcutaneous dose. This amount of caffeine is lower than the amount in a typical cup of coffee or tea. Caffeine currently is used in U.S. Food and Drug Administration ("FDA") approved products administered parenterally, as well as orally, with a well-established, known safety and usage profile. We filed a Type IV Drug Master File ("DMF") for caffeine use as an excipient with the FDA in January 2017. The FDA does not review or "approve" a DMF filing, but the information in the filing is available to the FDA on a confidential basis to support any future drug application submitted by third parties to whom we have given a right of reference to the DMF without disclosing the contents of the DMF to them.

Our advances in caffeine use prompted our research and development team to publish a peer-reviewed article in the November 2021 edition of the Journal of Pharmaceutical Sciences (volume 110, pages 3594-3604), a peer-reviewed journal for breakthrough drug formulation research. It documents the potential benefits of new excipients like caffeine in reducing the viscosity of concentrated formulations of two marketed antibodies: ipilimumab, marketed as Yervoy® by Bristol Myers Squibb, and infliximab, marketed as Remicade® by Janssen Pharmaceuticals. While the conventional excipients, NaCl and arginine, did not reduce infliximab viscosity, caffeine reduced viscosity by 77%. Likewise, caffeine reduced ipilimumab viscosity by 45%, 57%, and 78% in three different buffers, all while maintaining industry standard stability requirements. All four of these reductions are sufficient to potentially allow SQ delivery. The paper reported that the in vitro biological activity of both therapeutics using the caffeine excipient was confirmed, showing by biolayer interferometry- (BLI-) based ELISA method against CTLA-4, no loss of activity for ipilimumab in the presence of caffeine, and showing by a cell-based bioassay at a third-party laboratory that infliximab did not lose anti-tumor necrosis factor (TNF) activity in the presence of caffeine. Moreover, the attractive protein-protein interactions were shown to have a relationship with viscosity, and the caffeine excipient is shown to reduce these potentially harmful interactions.

We have also evaluated our approach to low viscosity excipients through animal testing to assess the viability of our SQore™ platform to deliver by SQ injection vs. IV infusion. The first test series showed no negative effects of the caffeine excipient on Sprague Dawley® rats, upon administration by IV and SQ. A second test series on Sprague Dawley® rats commissioned from WuXi AppTec, conducted in New Jersey, began in December 2021 and was completed in February 2022. The goals of this second test series were to compare IV to SQ administration, compare caffeine as an excipient to a control excipient, measure absorption and serum concentrations of the mAb to generate a pharmacokinetics (PK) profile, and evaluate bioavailability over different routes of administration, such as injection in the arm or leg, and observe the rats for any signs of positive or negative health effects. The second test series confirmed the findings of the first test series, with no evidence of local or systemic toxicity demonstrated, no interference with mAb absorption, and no significant differences in area under the curve (AUC) between groups administered a caffeine-containing formulation versus the control formulation. Based on the results of the February study, a follow-on study has been commissioned with WuXi AppTec, which includes a larger sample size to reinforce the statistical robustness of our conclusions as well as to provide additional quantitative data to support our SQore platform and internal pipeline activities.

The following charts compare the viscosities of infliximab, ipilimumab and adalimumab, using various excipients and at increasing concentrations:

Viscosity Reduction of Therapeutic Antibodies with Caffeine



Enhanced stability: Protected by U.S. Patents No. 10,016,513, 10,279,048, and 10,610,600, we have developed two types of surfactant replacements that are structurally different and displace protein from interfaces to mitigate particle formation. Importantly, unlike polysorbates, none of these surfactant replacements contain unstable ester bonds. The result is a more robust, aqueous, homogeneous protein formulations that are resistant to a variety of stress conditions. These new excipients have added benefits in that they do not form micelles in the same way that conventional polysorbates do, and as a result these new excipients can be added before filtration steps without becoming artificially over-concentrated during processing. This offers new potential to stabilize therapeutic proteins during processing steps, where the conventional polysorbates are incompatible due to their tendency to form micelles and become concentrated during processing. In our laboratory testing, the new surfactant replacement compounds have shown the ability to prevent antibody aggregation upon exposure to shear stress; moreover, the surfactant replacement has been shown to avoid oxidation and aggregation of the therapeutic antibodies upon storage of formulations at 4, 25, or 40°C temperatures. This oxidation and aggregation is evident when polysorbates are used. This work has been presented at an industry conference and validated at the internal research and development group of one of the largest multinational chemical companies.

Improved manufacturing: We have utilized caffeine and other excipients in bench lab scale studies to reduce viscosity. Our surfactant replacement technologies can potentially improve the throughput efficiency and overall yield of downstream processing which may reduce the cost of goods for the drug product.

Our Strategy

Our business model has a two-pronged approach. First, we plan to develop therapeutic formulations by collaborating with biopharmaceutical companies to optimize their products and offer licenses specific to the formulations that we create for them. We believe this combines a lower-risk licensing driven platform technology with a multi-billion dollar biopharmaceutical upside. Second, we plan to develop our own proprietary formulations for legacy molecules. We plan to exclusively license these formulations to biopharmaceutical companies and biosimilar companies. Both of these business approaches — the collaborations and the internal pipeline — will potentially benefit from our SQore™ platform technology to make formulations with optimized viscosity, concentrations and stability.

The key elements of our strategy include:

Drive future revenue from multiple existing and future partnering opportunities

In order to maintain near-term revenue and drive ongoing revenue growth, we intend to continue partnering with biopharmaceutical companies to develop SQ formulations of their products utilizing our SQore™ platform, with a focus on later-stage commercially licensed or late-stage assets. Possible clinical milestone payments will be used to provide near-term revenue while exclusive licensing agreements with royalties based on the sales of the biopharmaceuticals formulated with our preclinical stage technology will provide future revenue growth. We have entered into collaborations ranging from proof-of-concept research projects to full-fledged formulations and believe that our collaboration partners are satisfied with the results we deliver.

Advance our own pipeline programs

We are developing our own proprietary biologics that leverage our technology to improve existing, approved biologics. To do this we will examine an existing, patented biologic that we license from the patent holder and attempt to create a patentable biologic of our own that keeps the therapeutic elements of the pre-existing biologic but makes it better by, for example, adding additional therapeutic qualities or eliminating elements that cause negative side effects. We will file investigational new drug ("IND") applications and conduct clinical trials in order to obtain our own approvals of these products. We believe that our SQore™ platform may help us develop our products faster and at lower risk and cost than would be expected for standard new biological product development, because, for example, we will have a precedent for the types of clinical studies that FDA is likely to agree to in support of a Biologics License Application ("BLA") for our products. Although our focus will be on developing SQ products, we will not limit our efforts to this area and will consider pursuing product candidates that may deliver other benefits such as shortened infusion times.

We will explore options to license these formulations to leading biopharmaceutical companies or continue to bring these important advancements to market ourselves. We believe this strategy has a significantly higher value potential than our partnering agreements since we will be targeting large existing markets that we identify based upon where the SQore™ platform is likely to give us the greatest boost.

We will carefully evaluate potential in-licensed product candidates based on the following criteria: area of significant unmet medical need; strong scientific rationale and established clinical and regulatory pathways; defined competitive landscape and potential future commercial opportunity; and license exclusivity.

Product Pipeline

In addition to the revenue opportunities provided by using our SQore™ platform to partner with third-party patent-holders, we have several therapeutic product candidates in our product pipeline that could represent future revenue opportunities either through out-licensing at value-creating development milestones or through commercialization after approval.

We are currently advancing our main product program, CLS-001, a preclinical stage biobetter for Crohn's and Ulcerative Colitis disease.

CLS–001. CLS-001 is a subcutaneous formulation of a marketed, IV administered monoclonal antibody therapeutic for Crohn's disease and ulcerative colitis. We have initiated development work on CLS-001 and we currently anticipate that we will initiate manufacturing process development work with our development and manufacturing partner in 2023. We anticipate filing our IND for CLS-001 and initiating first in human studies in 2025. Based on our analysis, we estimate the peak sales opportunity for CLS-001 to be in excess of $1 billion, with upside potential significantly greater, depending on future competitive landscape assumptions.

Manufacturing

Regarding our internal pipeline development and eventual commercialization of our products, the development and manufacturing of biologic drugs is a highly capital-intensive and technologically complex process. As such, we intend to partner with industry-leading contract development and manufacturing organizations for key aspects of our development and commercialization plans, including production of mAb proteins and final drug product formulation for our preclinical, clinical study programs and eventually commercial manufacturing, quality release testing, and fill/finish.

Customers

The key customers for our partnering activities include pharmaceutical and biotechnology companies who are either developing or commercializing innovative and/or biosimilar mAb drug formulations, most commonly IV formulations for which the partner seeks to develop an SQ formulation. Other potential customers include pharmaceutical and biotechnology companies who have existing SQ mAb drugs and are seeking to optimize delivery using next-generation transdermal delivery technology (e.g., needleless systems, microneedle delivery). With regard to our internal pipeline, our customers would be the same as traditionally defined for approved drugs. The ultimate users of our commercialized drug products would be patients. However, as is typically defined in the U.S. healthcare market, third party payers, pharmacy benefit managers and/or healthcare institutions are the entities that would pay for our products and with whom we, or a commercial partner on our behalf, would contract to establish rates of reimbursement.

At this time, it is too early in our pipeline product lifecycle to determine the optimal commercialization pathway (e.g., license or sell rights to another pharmaceutical company, partner with third-parties to execute commercialization functions, or commercialize ourselves) and as we approach key milestones in development, we will retain all options and determine what is in the best interest of the company and stockholders to maximize value of our programs.

Our development agreements with pharmaceutical and biotechnology companies include research collaboration agreements, where an evaluation fee is paid to us by our partner to research and evaluate the applicability of our SQore™ platform technology to the partner's drug. If our technology is successful in the research evaluation phase and the partner desires to incorporate our SQore™ technology in their drug program, licensing terms including any combination of upfront licensing fees, milestone payments, royalty payments would be contemplated.

Competition

We face competition in the area of new formulation and delivery strategies for biologics, including some established companies and some earlier stage biotechnology companies. Excelse Bio, Arecor, and Eagle Biologics use excipient-based approaches to optimize protein formulations, using either amino acids or new compounds. Lindy Biosciences uses a microglassification approach to make a suspension of protein particles in a nonaqueous carrier fluid. Halozyme and Alteogen are companies that market hyaluronidase technology to allow subcutaneous injection of larger volumes than traditional SQ approaches. Rani Therapeutics offers an oral capsule drug delivery system that is pH-activated to inject a formulation into the walls of the intestine. We believe that our SQore™ platform is well-positioned versus other approaches, representing a scientifically-validated, well-characterized excipient technology, including ingredients previously used in humans, allowing for low-volume, easy-to-administer SQ formulations across multiple different mAbs.

Intellectual Property

We have developed a strong and differentiated intellectual property position that protects our formulation technology and its potential uses. Currently, we have seven issued U.S. patents shown below as well as six international patents. The issued patents and pending applications, if granted, will expire between 2035 and 2044. A summary of our active intellectual property portfolio is shown below.

Title	Country	Application Number	Patent Number	Granted Claim Type
Viscosity-Reducing Excipient Compounds for Protein Formulations [Foreign counterparts: issued JP6674901B2 and JP6983266B2, issued CA 2951716, issued CN ZL2015800398346; pending in EP, IN, and KR (PCT/US2015/036724)]	U.S.	14/966,549	9,605,051	formulation
	U.S.	15/434,379	9,867,881	formulation
	U.S.	16/284,583	pending	pending
	Canada	2951716	2951716	formulation
	Japan	2016-574175	6674910	formulation
	Japan	2020-039681	6983266	formulation
	China	201580039834.6	ZL 2015 8 0039834.6	formulation
	Korea	10-2017-7001786	102463682	formulation
Excipient Compounds for Biopolymer Formulations	U.S.	15/331,197	10478498	formulation
	U.S.	16/659,046	pending	pending
Excipient Compounds for Biopolymer Formulations	U.S.	63/280,080	pending provisional	pending
Excipient Compounds for Protein Processing	U.S.	15/896,374	11,357,857	formulation
Excipient Compounds for Protein Formulations	U.S.	17/011,014	pending	pending
	U.S.	17/332,521	pending	pending
	U.S.	17/175,162	pending	pending
	U.S.	17/471,518	pending	pending
Stabilizing Excipients for Therapeutic Protein Formulations [Foreign counterparts: issued CA 3030422; pending in KR, EP (PCT/US2017/041691)]	U.S.	15/647,669	10,279,048	formulation
	U.S.	16/354,557	10,610,600	formulation
	U.S.	15/676,168	10,016,513	formulation
	Canada	3030422	3030422	formulation

U.S. Biopharmaceuticals 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, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics. We, along with our vendors, contract research organizations, or CROs, clinical investigators, and contract manufacturing organizations, or CMOs, will be required to comply with 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 candidates. The process of obtaining regulatory approvals of drugs and biologics 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 U.S., the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and biologics under the FD&C Act and the Public Health Service Act, as amended, or the PHSA, and their implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to accept applications, the suspension of review of pending applications, the denial of approval of applications, issuance of clinical holds on proposed or ongoing clinical studies, revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Our product candidates must be approved for therapeutic indications by the FDA before they may be marketed in the U.S. For drug product candidates regulated under the FD&C Act, the FDA must approve a New Drug Application, or NDA. For biological product candidates regulated under the FD&C Act and PHSA, the FDA must approve a BLA. The process for obtaining approval for each type of product candidate is similar and generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- completion of the manufacture, under current Good Manufacturing Practice, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND, which must become effective, typically via the issuance of a Study May Proceed Letter by the FDA or the expiration of a 30 day time period without comment from the FDA, before clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an institutional review board, or 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 applicable IND regulations, good clinical practice, or GCP, requirements, including human subject protection requirements, and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA, as applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval or pre-license inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biological product's identity, strength, quality and purity;
- satisfactory completion of an FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical studies and clinical trials for drugs and biologics

Before testing any drug or biologic in humans, a product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product 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 regulation and requirements, including GLP requirements for safety/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 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 the 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. Some long-term preclinical testing may continue after the IND is submitted. The IND becomes effective typically when FDA issues a Study May Proceed Letter but may also become effective, by operation of law, 30 days after receipt by the FDA without such a letter, unless the FDA, within the 30-day time period, issues a clinical hold order. A clinical hold may be issued for a variety of reasons in accordance with regulations set forth at 21 C.F.R. 312.42, including concerns that human research subjects would be exposed to unreasonable health risks or that the study is not adequately designed and well-controlled. FDA may also impose a clinical hold at any time after a trial begins, thereby suspending enrollment and further administration of the investigational drug (unless it would not be safe to do so). FDA must notify the sponsor of the grounds for the hold, and any identified deficiencies must be resolved before the FDA will lift the clinical hold and permit the clinical trial to begin or resume.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are 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 compared 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. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

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. If a foreign clinical trial is not conducted under an IND, FDA may nevertheless accept the results of the study in support of an NDA or BLA if the study was well-designed and well-conducted in accordance with GCP requirements, including that the clinical trial was performed by a qualified investigator(s); the data are applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, and that the trials were conducted in compliance with all applicable U.S. laws and regulations, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs and 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 in a limited population of 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, excretion 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 drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

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 and physician labeling. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of an NDA or BLA.

In August 2018, the FDA released a draft guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by the FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce development costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, 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 NDA or BLA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. 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 volunteers 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 chemistry and physical 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.

U.S. marketing approval for drugs and biologics

Assuming successful completion of the required clinical testing, the results of the 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 an NDA or BLA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and effectiveness for the requested indications. A BLA is a request for approval to market a new biologic for one or more specified indications and must contain proof of the biologic's safety, purity and potency for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to demonstrate the safety and effectiveness of a product or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug, or the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. The FDA must approve an NDA or BLA, as applicable, before a new drug or biologic may be marketed in the United States.

The FDA reviews all submitted NDAs and BLAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or 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 NDA or BLA. The FDA reviews an NDA or BLA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, as amended, or PDUFA, the FDA targets ten months from the filing date in which to complete its initial review of a new molecular entity NDA or BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or BLA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under the PDUFA, each NDA or BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are 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 NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

The FDA may refer an application for a novel drug or 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 an NDA or 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 are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or 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.

After evaluating the NDA or 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 generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or 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 require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. 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, it 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.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, as amended, or PREA, certain NDAs and BLAs and certain NDA and BLA supplements must contain data that can be used to assess the safety and efficacy of the 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 FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to a drug or biologic for an indication for which orphan designation has been granted, except that the PREA will apply to an original NDA or BLA for a new active ingredient that is orphan-designated if the drug or biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

A 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.

U.S. post-approval requirements for drugs and biologics

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product and manufacturing deviations, 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 company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Promotional materials for approved drugs and biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or BLA or NDA 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 an NDA or 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, manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs and biologics 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 cGMPs, which impose certain procedural and documentation requirements on sponsors and their 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 a sponsor may use. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying 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 may 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 user fee for any marketed product.

The FDA may withdraw approval of a product 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;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval 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;

- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and issuance of corrective information.

United States biosimilars and exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or 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 in the United States. Biosimilarity, requires, among other things, that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, including that the proposed biosimilar product has the same strength and concentration as the reference biological product. These criteria 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 Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

In contrast to biosimilars, a follow-on version of a previously-approved biological reference product containing alterations to the reference product's chemical structure, delivery system, or other functional features that provide a clinical benefit over the original reference product (unofficially referred to as a "biobetter") would not meet the regulatory criteria to be a biosimilar, and the product would be ineligible for approval under the biosimilar pathway of section 42 U.S.C. 351(k).

While the enactment of the BPCIA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products, but not for proposed "biobetter" products, there is still considerable uncertainty with respect to the FDA's approval process. While applications based on biosimilarity may not be required to duplicate the entirety of preclinical and clinical testing used to establish the underlying safety and effectiveness of the reference product, the FDA may refuse to approve an application if there is insufficient information to show that the active ingredients are the same or to demonstrate that any impurities or differences in active ingredients do not affect the safety, purity or potency of the product. In addition, applications based on biosimilarity will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency. Due to the uncertainty surrounding the approval of biosimilar/biobetter products, our product candidates may never result in commercially viable products.

Other regulatory matters

Manufacturing, labeling, packaging, distribution, sales, promotion and other activities of product candidates following product approval or commercialization are also potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject. Additionally, the activities associated with the commercialization of product candidates is subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare and Medicaid Services, an agency within the U.S. Department of Health and Human Services ("CMS"), other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety and Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including state licensing requirements, extensive recordkeeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example, with respect to our potential products: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other healthcare laws

Coverage and reimbursement

Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In the United States and markets in other countries, patients generally rely on these governmental or other payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree.

Further, due to the ongoing COVID-19 global pandemic, millions of individuals have lost or may lose employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

Payers determining reimbursement level consider multiple factors, including whether the 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.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such 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 August 2022, the Inflation Reduction Act, or IRA, was enacted and established the Medicare Drug Price Negotiation Program, or Negotiation Program, which requires Medicare for the first time to negotiate directly with drug and biological product manufacturers to establish a maximum fair price, or MFP, for certain Medicare Part B and Part D drugs, referred to as selected drugs. The MFP creates a cap on the amount manufacturers can charge Medicare beneficiaries and their providers for selected drugs. To be identified as a selected drug, a drug or biological must be a negotiation-eligible drug, defined as the 50 qualifying single source drugs with the highest total spending over the most recent 12-month period under Part D or Part B (50 for each part), subject to an exemption for small biotech products for 2026-2028. Qualifying single source drugs are drugs that have had market approval for at least 7 years (for drug products) or 11 years (for biological products) that lack a marketed generic or biosimilar product. The IRA excludes from the definition of a "qualifying single source drug": (1) orphan drugs that are approved to treat only one rare disease or condition, (2) plasma-derived products, and (3) drugs that account for less than $200 million in annual Medicare spending (adjusted annually for inflation).

The IRA also established a process by which a biosimilar manufacturer, who can demonstrate that there is a "high likelihood" that it can bring a biosimilar to market within a year following the publication of the relevant selected drug list, may request a one-year delay in the selection of the reference biological product for the Negotiation Program. If CMS grants the delay and the biosimilar comes to market within the specified timeframe, the reference biological will no longer qualify for Medicare Negotiation and no MFP will be established for the product. The biosimilar can come to market and compete directly with the reference biological product without a price cap. The IRA also provides an opportunity for the biosimilar manufacturer to obtain up to one additional year of delay. If the biosimilar fails to come to market, the reference biological product may be selected for negotiation to establish the MFP. Once established and published, the MFP will set the price cap for the biological product, which will affect Medicare payment for the biosimilar.

For the first year of the Negotiation Program, the Secretary of HHS will select 10 Part D high-expenditure, single-source drugs for negotiation. CMS expects to publish the list of 10 Medicare Part D drugs selected for negotiation in September 2023, thus beginning the negotiation process. The MFPs that are negotiated for these drugs will apply beginning in 2026. The Secretary of HHS will select an additional 15 Part D drugs for negotiation for 2027, 15 Part B and Part D drugs for 2028, and 20 Part B and Part D drugs for 2029 and subsequent initial price applicability years.

Once a negotiation-eligible drug is selected, manufacturers must submit information to CMS relating to costs and other data as part of the negotiation process. Manufacturers who fail to comply with negotiation requirements are subject to an excise tax on all U.S. sales of their products, regardless of the entity to which the selected drug is sold. In the Spring of 2023, CMS plans to issue initial guidance for the Negotiation Program process for initial price applicability year 2026 and invite public comment on key elements, such as the offer and counteroffer process between Medicare and prescription drug companies, and the methodology for applying maximum fair prices.

The IRA also established a requirement for manufacturers to pay rebates on Medicare Part B and Part D drugs for single source drugs and biological products, including certain biosimilars, with prices that increase faster than the rate of inflation. In addition, the IRA redesigned the structure of the Part D program, including to eliminate the Medicare Part D coverage gap and replace the Medicare coverage gap discount program, established by the Affordable Care Act, with a Manufacturer Discount Program that similarly requires manufacturers to offer discounts at the point of sale.

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.

Other healthcare laws and compliance requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, CMS, other divisions of the U.S. Department of Health and Human Services (the "HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. Our clinical research, sales, marketing, scientific/educational grant programs, collaboration agreements, and partnerships with third-party payers, providers, pharmacy benefit managers, and other entities may be subject to the following laws, each as amended, as applicable:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and providers, prescribers, purchasers and formulary managers, among others, on the other. The U.S. Department of Health and Human Services, Office of Inspector General, or OIG, heavily scrutinizes relationships between pharmaceutical companies and persons in a position to generate referrals for or the purchasing of their products such as healthcare providers and pharmacy benefit managers;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims.
- the False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (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 and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Further, on November 20, 2020, HHS published a rule 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 a manufacturer. However, Congress has since enacted legislation temporarily prohibiting CMS from implementing the rule. Most recently, the Inflation Reduction Act, or IRA, further delayed implementation of the rule until 2032. If the rule is implemented, we may be required to structure our arrangements with pharmacy benefit managers in a way that ensures compliance with all of the elements of any applicable safe harbors.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payer.

Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payers, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare reform

Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. Following its enaction in 2010, the ACA has subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden 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 ACA 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 ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through April 1, 2022 due to the COVID-19 pandemic. Reductions of 1% were imposed from April 1 through June 30, 2022. As of July 1, 2022, payment reductions of 2% were reimposed. Additionally, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average Manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed 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, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden 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.

Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates.

Building on many of the concepts described in President Biden's drug pricing Executive Order, the Inflation Reduction Act, or IRA, was signed into law on August 16, 2022. The IRA established the Medicare Drug Price Negotiation Program, or Negotiation Program, which requires Medicare for the first time to negotiate directly with drug and biological product manufacturers to establish a maximum fair pricing, or MFP, for certain Medicare Part B and Part D drugs, referred to as selected drugs. The MFP creates a cap on the amount manufacturers can charge Medicare beneficiaries and their providers for selected drugs.

To be identified as a selected drug, a drug or biological product must be a negotiation-eligible drug, defined as the 50 qualifying single source drugs with the highest total spending over the most recent 12-month period under Part D or Part B (50 for each part), subject to an exemption for small biotech products for 2026-2028. Qualifying single source drugs are drugs that have had market approval for at least 7 years for drug products or 11 years for biological products that lack a marketed generic or biosimilar product. The IRA excludes from the definition of a "qualifying single source drug": (1) orphan drugs that are approved to treat only one rare disease or condition, (2) plasma-derived products, and (3) drugs that account for less than $200 million in annual Medicare spending (adjusted annually for inflation).

The IRA also established a process by which a biosimilar manufacturer, who can demonstrate that there is a high likelihood that it can bring a biosimilar to market within a year following the publication of the relevant selected drug list, may request a one-year delay in the selection of the reference biological product for the Negotiation Program. If CMS grants the delay and the biosimilar comes to market within the specified timeframe, the reference biological product will no longer qualify for Medicare Negotiation, and no MFP will be established for the product. The biosimilar can come to market and compete directly with the reference biological product without a price cap. The IRA also provides an opportunity for the biosimilar manufacturer to obtain up to one additional year of delay. If the biosimilar fails to come to market, the reference biological product may be selected for negotiation to establish the MFP. Once established and published, the MFP will set the price cap for the biological product, which will affect Medicare payment for the biosimilar. If an MFP is established for a reference biological product for which we are developing a biosimilar, it may materially and adversely affect the price we receive for any of our product candidates.

For the first year of the Negotiation Program, the Secretary of HHS will select 10 Part D high-expenditure, single-source drugs for negotiation. CMS expects to publish the list of 10 Medicare Part D drugs selected for negotiation in September 2023, thus beginning the negotiation process. The MFPs that are negotiated for these drugs will apply beginning in 2026. The Secretary of HHS will select an additional 15 Part D drugs for negotiation for 2027, 15 Part B and Part D drugs for 2028, and 20 Part B and Part D drugs for 2029 and subsequent initial price applicability years.

Once a negotiation-eligible drug is selected, manufacturers must submit information to CMS relating to costs and other data as part of the negotiation process. Manufacturers who fail to comply with negotiation requirements are subject to an excise tax on all U.S. sales of their products, regardless of the entity to which the selected drug is sold. In the Spring of 2023, CMS plans to issue initial guidance for the Negotiation Program process for initial price applicability year 2026 and invite public comment on key elements, such as the offer and counteroffer process between Medicare and prescription drug companies, and the methodology for applying maximum fair prices.

The IRA also established a requirement for manufacturers to pay rebates on Medicare Part B and Part D drugs for single source drugs and biological products, including certain biosimilars, with prices that increase faster than the rate of inflation. In addition, the IRA redesigned the structure of the Part D program, including to eliminate the Medicare Part D coverage gap and replace the Medicare coverage gap discount program, established by the ACA and described above, with a Manufacturer Discount Program that similarly requires manufacturers to offer discounts at the point of sale. These provisions of the IRA could adversely and materially affect the price we may receive for any of our product candidates.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Employees

As of December 31, 2022, we had 12 full-time employees and 1 part-time employee. None of our employees are represented by a collective bargaining agreement and we have never experienced a work stoppage. We believe our employee relations are good.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission (the "SEC"). The SEC maintains an Internet website at www.sec.gov that contains reports, proxy and information statements and other information about issuers, like us, that file electronically with the SEC. We also maintain a website at https://comeralifesciences.com/. Information contained on our website is not a part of or incorporated by reference into this Report and the inclusion of our website and investor relations website addresses in this Report is an inactive textual reference only.

ITEM 1A. Risk Factors.

Risk Factor Summary

This summary briefly states the principal risks and uncertainties facing our business that could make an investment in our securities speculative or risky, which are only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth immediately following this summary, which is qualified in its entirety by that more complete statement. You should carefully read the entire statement and "Risk Factors" when considering the risks and uncertainties as part of your evaluation of an investment in our common stock.

- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq or that we will be able to regain compliance with the Market Value of Listed Securities standard pursuant to Nasdaq listing rule 5550(b)(2) within the requisite cure period.
- We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- We do not have, and may never have, any products approved for commercial sale and may never become profitable.
- Our success depends on our ability to respond and adapt to changes in the drug development industry, including payer, medical practice, medical provider and prescriber behavior.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.
- We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop.
- Drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and clinical trials are not always predictive of future results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.
- Our current or future product candidates may cause adverse or other undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if obtained.
- We may experience fluctuations in our operating results, which could make our future operating results difficult to predict or cause our operating results to fall below analysts' and investors' expectations.
- Our success depends on broad market acceptance of our products if approved, which we may never achieve.
- The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, inflation, stagflation, supply chain and interest rate pressures, foreign currency exchange rate fluctuations, the ongoing conflict between Russia and Ukraine and political developments in Hong Kong and Taiwan, natural disasters and other macroeconomic and geopolitical events may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.
- Our success depends on our ability to retain key members of our management team and on our ability to hire, train, retain and motivate new employees.
- 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 securities.
- We expect to enter into in-license agreements under which we will acquire rights to use, develop, manufacture and/or commercialize our product candidates. If these collaborations are not successful, our business could be adversely affected.
- We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.
- We may be required to pay certain milestones and royalties under our license or collaboration agreements with third-party licensors or collaborators.

- We may rely on third parties to conduct our future clinical trials of our product candidates, in the U.S. and other jurisdictions. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide a supply of our current product candidates or any future product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.
- The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used in the preclinical testing and clinical trials for our product candidates are currently our sole source of supply, and the loss of any of these suppliers could significantly harm our business.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad or we are delayed in bringing product candidates to market such that those products have a shorter period of patent exclusivity than expected, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.
- Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.
- Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.
- We are subject to cybersecurity risks and experienced a diversion of funds through a business email compromise fraud.
- Our management has limited experience in operating a public company.
- There may be sales and issuances of a substantial amount of our common stock, including sales, if any, that may be made to Arena pursuant to the Arena Purchase Agreement, and these sales and issuances could dilute the interest of our stockholders and cause the price of our securities to fall.
- Our product candidates may be subject to government price controls in certain jurisdictions that may affect our revenue.

Risk Factors

In evaluating an investment in our securities, you should carefully review and consider the following risk factors and the other information contained in this Report, including the information contained in the "Management's Discussion and Analysis of Financial Condition and Results of Operations," the financial statements and the accompanying notes to the financial statements, and the other documents we file with the SEC. The risks discussed below may not prove to be exhaustive and are based on certain assumptions made by us that later may prove to be incorrect or incomplete. We may face additional risks and uncertainties that are not presently known, or that are currently deemed immaterial, which may also impair our business or financial condition.

Risks Related to Our Financial Status, Business Model and Growth Plans

We are a preclinical stage biotechnology company and do not currently have, and may never have, any products approved for commercial sale and have not, and may never, generate revenue from product sales or become profitable.

To become profitable and grow our revenue, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third-party relationships with payers, completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements.

We are a preclinical stage biotechnology company and currently do not have any products approved for commercial sale. We have not, and may never, generate revenue from product sales or become profitable. We cannot guarantee that we will ever receive necessary regulatory approvals to commercialize any products. Our ability to become profitable depends upon our ability to generate revenue from services and product sales or execute other business arrangements. Our current product candidates are in various early stages of development and we do not expect to generate any revenue from the sale of approved products in the near future. We do not expect to generate significant additional revenue unless and until we obtain regulatory approval of, and begin to sell, one or more of our products, if approved. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete internal preclinical validation of our pipeline programs and their respective product candidates;
- obtain rights from third parties to utilize third party cell lines or to develop these internally;
- successfully complete our ongoing and planned preclinical and clinical studies for our pipeline programs;
- timely file and gain acceptance of investigational new drug applications for our programs in order to commence planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, our ongoing and planned clinical trials;
- obtain data and other development support from our third-party contractors and collaborators;
- initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for our product candidates, and additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates;
- successfully demonstrate to the satisfaction of the FDA, the European Medicines Agency (“EMA”), or similar foreign regulatory authorities the safety, efficacy, purity and potency, and acceptable risk to benefit profile of our product candidates or any future product candidates;
- successfully manage the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any;
- obtain the timely receipt of necessary marketing approvals from the FDA, EMA and similar foreign regulatory authorities;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payers;
- position our product candidates to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement for our products;
- hire additional clinical, regulatory and scientific personnel;
- enforce and defend intellectual property rights and claims; and
- maintain a continued acceptable safety profile of our products following approval.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, or the extent of any losses. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant enough to achieve profitability on any product candidate. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure in any of the above activities could jeopardize our revenue growth and profitability and could decrease the value of our securities and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our business model is untested and may never be successful or generate sufficient growth to sustain profitability.

We are building a pipeline of innovative new biologic product candidates aimed at transforming essential biologic medicines from intravenous to subcutaneous forms, or to produce improved versions of current subcutaneous biologics. Leveraging our proprietary SQore™ technology platform and excipient library of over 200 compounds — primarily well-established biological products, most with known toxicology profiles — we intend to continue partnering with biopharmaceutical companies to develop their assets into new or improved subcutaneous formulations while advancing our own novel pipeline programs. Although our products are in the preclinical stage and none are approved for sale, we believe that we are also positioned to be able to develop biosimilar versions of currently approved products. However, each aspect our business model is untested in the biopharmaceutical industry, and any of the assumptions underlying our expectations may be incorrect. There can be no assurance that our assumptions are correct or that, if correct, our strategy will succeed.

Our business model may never be successful or generate sufficient growth to sustain profitability. Our competitors or new market entrants may adopt similar or otherwise more favorable products and strategies, leading to significant price competition and/or reducing or eliminating our competitive advantage, each of which could adversely affect our revenues.

Our business model requires us to scale our pipeline through drug engineering collaborations, in-licensing or otherwise acquiring additional product candidates, and developing such product candidates, which we may be unable to successfully achieve or maintain.

Our business model requires us to scale through the development or acquisition of many additional product candidates, which we may be unable to achieve or maintain. Our business model requires that we continually review, evaluate and consider potential development and acquisitions of additional product candidates and that we evaluate and enter into collaborations with partners for our SQore™ platform. In such evaluations, we will be required to make difficult judgments regarding the potential value of such additional product candidates or collaboration partners. We may not be successful in identifying attractive opportunities and our research and development agreements with partners may not evolve into collaborations for our SQore™ platform. Even if we are successful in identifying attractive opportunities, we may not successfully execute development or acquisition of such opportunities on terms acceptable to us. We may also experience increased competition for attractive assets from other pharmaceutical companies, many of which have significantly more resources than we do. We may also experience additional challenges in the acquisition of certain assets, including but not limited to geopolitical considerations when acquiring assets from outside the United States.

Even if we are successful in acquiring additional product candidates, we may not successfully integrate them into our existing operations or derive the anticipated benefits of such acquisitions, which may result in the investment of our capital resources without realizing the expected returns on such investments. Given our limited resources, we may also forego acquisition of product candidates that later prove to have greater commercial potential. Product candidates that we acquire will also be subject to the risks and uncertainties associated with developing product candidates. The time and effort involved in attempting to identify acquisition candidates and consummate acquisitions may also divert the attention of members of our management from the operations of our company.

In addition, we may not be successful in our efforts to identify, engineer, or develop additional product candidates in the future either internally or through our current or future collaboration partners. Research programs to identify new product candidates require substantial technical, financial and human resources. Product candidates that we develop internally through our own efforts or with our partners may be more expensive to discover, develop or manufacture than we expect, which could require us to adjust our pricing model, or de-emphasize internal development efforts in the near or long-term. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including our inability to design such product candidates with the properties that we desire. Potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. We may also be limited in our ability to pursue multiple indications with one product, due to financial or other resource constraints, development issues or regulatory obstacles. Even if we are able to pursue multiple indications, we may not be able to do so as quickly or successfully as our competitors, which may affect our ability to gain market acceptance across multiple indications for any one product. If we are unable to identify suitable additional candidates for development or acquisition, our opportunities to successfully develop and commercialize therapeutic products will be limited.

Failure to manage our growth effectively could cause our business to suffer and have an adverse effect on our ability to execute our business strategy, as well as operating results and financial condition.

As of December 31, 2022, we had 12 full-time employees and 1 part-time employee. As we continue development of our product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, commercial and other capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of our management. Our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to these growth activities, including identifying, recruiting, integrating, maintaining, and motivating additional employees, managing our research and development efforts effectively, including the clinical trials and the FDA's or comparable foreign regulatory authorities' review process for our product candidates, while complying with our contractual obligations to contractors and other third parties and improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company or could disrupt our operations.

Our success depends on our ability to respond and adapt to changes in the drug development industry, including payer, medical practice, medical provider and prescriber behavior. We may be unsuccessful in achieving acceptance or changing prescribing or purchasing habits of healthcare system participants.

Our success and future growth largely depend on our ability to increase awareness of our offerings, and on the willingness of healthcare system participants, assuming that our products are approved for sale, to purchase our products — all of which are preclinical and not approved for sale — for the treatment of patients. To effectively market our products, we must educate healthcare system participants about the benefits of our offerings. We cannot assure you that we will be successful in changing prescribing or purchasing habits of healthcare system participants or that we will achieve broad market education or awareness among healthcare system participants. Even if we are able to raise awareness among healthcare system participants, they may be slow in changing their habits and may be hesitant to use our products for a variety of reasons, including but not limited to:

- lack of experience with our company, products, and concerns that we are relatively new to the industry;
- perceived health, safety or quality risks associated with the use of new products;
- competition and negative selling efforts from competitors, including competing offerings and price matching programs;
- concerns that our product candidates are not as safe or effective as first-to-market medicines, including because clinical development of our product candidates in some cases will have been performed by third parties; and
- pre-existing or intractable prescribing habits among doctors or guidelines among payers that limit products like ours from gaining market share.

If we are unsuccessful in changing prescribing or purchasing habits of healthcare system participants, our business, financial condition and results of operations would be adversely affected.

We may be unable to continue to attract and retain third-party collaborators, including collaboration partners and licensors, or may fail to do so in an effective manner. Our collaborations with third-party collaborators are also subject to certain risks.

Our success depends in part on our ability to effectively attract third-party collaborators and retain our existing collaborators, across several strategic areas, including acquiring additional product candidates, and conducting research collaborations. We have made significant investments related to attracting, acquiring and retaining third-party collaborators but cannot assure you that our efforts will be effective or that benefits realized from our partnerships with any new third-party collaborators will ultimately exceed the costs incurred in attracting, acquiring or retaining such collaborators. If we are unable to attract or retain third-party collaborators, our business, financial condition and results of operations would be adversely affected.

Our collaborations with third-party business collaborators are also subject to a number of risks, including but not limited to:

- adverse decisions by a third party regarding the amount and timing of resource expenditures for the development and commercialization of product candidates;
- possible disagreements as to the timing, nature and extent of development plans, including clinical trials or regulatory approval strategy;
- delays or non-performance by our collaborators in performance of their contractual obligations, including delivery of data to us;
- lack of alignment between specifications for products and specifications that have or might be approved by regulatory authorities;
- the right of a third-party business collaborator to terminate its agreement with us on limited notice upon the occurrence of certain defined events;
- loss of significant rights if we fail to meet our obligations under a collaboration agreement;
- withdrawal of support by a third-party business collaborator following change of that collaborator's corporate strategy or due to competing priorities;
- changes in key management personnel at a third-party business collaborator that are members of the collaboration's various operating committees; and
- possible disagreements with a third-party business collaborator regarding a collaboration agreement or ownership of proprietary rights, including with respect to inventions discovered under the applicable collaboration agreement.

Due to these factors and other possible disagreements with a third-party collaborator, including potential disputes over intellectual property ownership or timely access to clinical data, we may be delayed or prevented from developing, manufacturing or commercializing product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may have an adverse impact on our product candidates.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. If we do engage in a strategic transaction, our business objectives may change depending upon the nature of the transaction. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or the prices of our securities. We also cannot predict the impact on securities prices if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is expensive and time-consuming. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, third parties may not view our product candidates as having sufficient potential, or for other reasons. Any delays in entering into a strategic partnership related to our product candidates could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

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

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We do not believe the cash, cash equivalents, and restricted cash of $2.0 million as of December 31, 2022 will be sufficient to fund our operations and capital expenditure requirements for the next twelve months from the date hereof. We will be required to raise additional capital to continue to fund operations and capital expenditures. Such funding may not be available on acceptable terms, or at all. If we are unable to access additional funds when needed, we may not be able to continue operations or we may be required to delay, scale back or eliminate some or all of our ongoing research and development efforts and other operations. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations. These uncertainties create substantial doubt about our ability to continue as a going concern.

Additional information regarding our ability to continue as a going concern can be found in the notes to the financial statements, included elsewhere in this Report.

We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

We are a preclinical stage biotechnology company and do not currently have any products approved for commercial sale. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our current product candidates and future product candidates. Our business or operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We will need to raise additional capital before we can progress any of our product candidates into a pivotal clinical trial. We expect to finance our subsequent cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital.

However, we may not be able to secure funding when we need it or on favorable terms and we may not be able to raise sufficient funds to commercialize our current and future product candidates we intend to develop. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our product candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our product candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our product candidates for which we may receive marketing approval;
- the costs 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 of any patents or other intellectual property rights;
- the costs of operating as a public company;

- macro-economic factors, including inflation, stagflation, supply chain issues and a shortage in the labor market that have impacted local and global economies; and
- the impact of the COVID-19 pandemic, including as a result of any resurgence in infection rates or new variants, adverse social, political and economic conditions, such as inflation, rising interest rates and the risk of global or regional recession, which may exacerbate the magnitude of the factors discussed above.

Although we entered into the Arena Purchase Agreement with Arena in August 2022, the number of shares of our common stock that we decide to sell to Arena under the Arena Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell all, some or none of the shares of our common stock that may be available to us to sell to Arena pursuant to the Arena Purchase Agreement and, depending on market liquidity at the time, resales of those shares by Arena may cause the public trading price of shares of our common stock to decrease. Because the purchase price per share to be paid by Arena for the shares of our common stock that we may elect to sell to Arena under the Purchase Agreement, if any, will fluctuate based on the market prices of the common stock during the applicable period for each sale made pursuant to the Arena Purchase Agreement, if any, it is not possible for us to predict prior to any such sales the number of shares of our common stock that will ultimately sell to Arena under the Arena Purchase Agreement, the purchase price per share that Arena will pay for the shares purchased from us under the Arena Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases from Arena under the Arena Purchase Agreement, if any.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have limited committed sources of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Furthermore, if we were to secure additional capital, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our securities to decline. 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 may be diluted, and the terms of those securities may include liquidation or other preferences that may adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, declaring dividends or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

Our PPP Loan was forgiven, but we may still be subject to audit and any resulting adverse audit findings of non-compliance could result in the repayment of a portion or all of the PPP Loan and may restrict our flexibility in operating our business or otherwise adversely affect our results of operations.

On April 24, 2020, the Company executed a promissory note pursuant to which it received proceeds of $161 thousand under the Paycheck Protection Program (“PPP Loan”) established under the CARES Act, as amended by the Paycheck Protection Program Flexibility Act of 2020 in response to the COVID-19 pandemic and is administered by the U.S. Small Business Administration (the “SBA”). We received total proceeds of $161,000 from the PPP Loan. Under the terms of the program, the Company could apply for and be granted forgiveness for all or a portion of the loan, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of payroll costs and any payments of mortgage interest, rent and utilities. The Company applied for forgiveness on November 23, 2020. On January 7, 2021, the Company received notice that forgiveness of all amounts due had been approved.

We may be subject to CARES Act-specific lookbacks and audits for six years from the date of forgiveness of the PPP Loan that may be conducted by federal agencies, including several oversight bodies created under the CARES Act. These bodies have the ability to coordinate investigations and audits and refer matters to the Department of Justice for civil or criminal enforcement and other actions. Complying with such SBA audit could divert management resources and attention and require us to expend significant time and resources, which could have an adverse effect on our business, financial condition and results of operations. If we were to be audited and receive an adverse outcome in such an audit, we could be required to return the full amount of the PPP Loans and may potentially be subject to civil and criminal fines and penalties. If it is subsequently determined that the PPP Loans must be repaid, we may be required to use a substantial portion of our available cash and/or cash flows from operations to pay interest and principal on the PPP Loans, and any future repayment of such loans, would adversely impact our operations and financial results.

Macroeconomic pressures in the markets in which we operate, including, but not limited to, the effect of the COVID-19 pandemic, political developments, geopolitical unrest or other conflicts or natural disasters in foreign nations, including the ongoing conflict between Russia and Ukraine, political developments in Hong Kong and Taiwan, and inflationary pressures may alter the ways in which we conduct our business operations and manage our financial capacities.

To varying degrees, the ways in which we conduct our business operations and manage our financial capacities are influenced by macroeconomic conditions that affect companies directly involved in or providing services related to the drug and biological product development. For example, real GDP growth, business and investor confidence, the COVID-19 pandemic, inflation, employment levels, oil prices, interest rates, tax rates, availability of consumer and business financing, housing market conditions, foreign currency exchange rate fluctuations, costs for items such as fuel and food and other macroeconomic trends can adversely affect not only our decisions and ability to engage in research and development and clinical trials, but also those of our management, employees, third-party contractors, manufacturers and suppliers, competitors, stockholders and regulatory authorities. Additionally, access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our product candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile and at times have adversely affected our access to capital and increased the cost of capital. For example, the ongoing military conflict between Russia and Ukraine, the possibility of a wider European or global conflict, global sanctions imposed in response thereto and the possibility of a global energy crisis resulting therefrom, has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, higher inflation and macro turmoil and uncertainty could also adversely affect our customers, which could reduce demand for our products. Moreover, we rely and intend to rely on third parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Our limited operating history and our evolving business make it difficult to evaluate our future prospects and the risks and challenges we may encounter.

Our predecessor, Legacy Comera, was formed in January 2014. Our limited operating history and our evolving business make it difficult to evaluate and assess the success of our business to date, our future prospects and the risks and challenges that we may encounter. These risks and challenges include our ability to:

- accurately forecast our revenue and plan our expenses;
- successfully introduce new products and services;
- successfully compete with current and future competitors;
- successfully expand our business in existing markets and enter new markets and geographies;
- comply with existing and new laws and regulations applicable to our business and the industry in which we operate;
- anticipate and respond to macroeconomic changes as well as changes in the markets and geographies in which we operate;
- maintain and enhance the value of our reputation and brand;

- maintain and expand our relationships with partners and payers;
- successfully execute on our sales and marketing strategies;
- hire, integrate and retain talented people at all levels of our organization;
- expand through future acquisitions and successfully identify and integrate acquired entities;
- successfully in-license or acquire other products and technologies and the terms of these transactions;
- pursue viable product candidates across a variety of indications and disease areas;
- successfully prepare, file, prosecute, maintain, expand, defend and enforce patent claims related to our programs; and
- effectively manage our growth.

If we fail to address the risks and difficulties that we face, including those associated with the challenges listed above as well as those described elsewhere in this "Risk Factors" section, our business, financial condition, results of operations and prospects could be adversely affected. Further, because we have limited historical financial data and our business continues to evolve, any predictions about our future revenue and expenses may not be as accurate as they would be if we had a longer operating history, operated a more predictable business or operated in a less regulated industry. We have encountered and will continue to encounter multiple risks and uncertainties that are frequently experienced by growing companies with limited operating histories and evolving business that operate in rapidly changing, highly regulated and competitive industries. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be adversely affected.

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

We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop.

We have not yet demonstrated our ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Our product candidates are still in preclinical development and may never advance to clinical development. If we are required to conduct additional preclinical studies or clinical trials of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements; or
- experience having the product removed from the market after obtaining regulatory approval.

Our failure to complete the regulatory approval process for one or more of our product candidates, or if the results of trials and testing result in delays, limitations, requirements, withholding or withdrawal in connection with the regulatory approval process, our business, financial condition and results of operations would be adversely affected.

Drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and clinical trials are not always predictive of future results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Currently, all our product candidates are in preclinical development. It is impossible to predict when or if any of our product candidates will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety, purity and potency of our biological product candidates in humans to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. Our preclinical studies may not be successful, which will limit our ability to execute on our business model effectively.

Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or comparable regulatory authorities. The FDA or other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or they may object to elements of our clinical development program, requiring their alteration. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Furthermore, the outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are not as positive as we expect or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

In addition, even if the clinical trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, EMA or comparable foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA, EMA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, efficacy, purity or potency necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, efficacy, purity or potency of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in or prevented from obtaining marketing approval.

Additionally, some of the clinical trials we conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. 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. Moreover, patients selected for early clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new 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 clinical trial may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control.

Our current or future product candidates may cause adverse or other undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a more unfavorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing have later been found to cause undesirable or unexpected side effects that prevent further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, EMA or comparable foreign regulatory authorities, IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA, EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that receive our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates will likely be conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in initiating or completing our preclinical studies or clinical trials for various reasons, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or IRBs or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- preclinical studies or clinical trials of our product candidates may fail to show safety, efficacy, purity or potency, or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- clinical trials of our product candidates may be delayed due to complications associated with the evolving COVID-19 pandemic;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates;
- collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the FDA may require us to conduct clinical trials comparing our product candidates against the current standard of care in the U.S.; and
- the FDA may refuse to file a BLA or NDA within 60 days of our submission if it is incomplete or insufficient.

We could encounter delays if a clinical trial is suspended or terminated by us or our partners, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or 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.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, including those that could be caused by the COVID-19 pandemic, also could 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 would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects.

We may investigate our product candidates in combination with other therapies, which exposes us to additional risks.

We may investigate our product candidates in combination with one or more other approved or unapproved therapies to treat medical conditions. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

Risks Related to Our Business Operations and Industry

We may experience fluctuations in our operating results, which could make our future operating results difficult to predict or cause our operating results to fall below analysts' and investors' expectations.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the difficulty of manufacture, quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions, international conflicts, or a pandemic;
- the changing and volatile U.S. and global economic conditions, including increasing interest rates and inflation; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our securities could decline substantially. Such price decline could occur even when we have met any previously publicly stated guidance we may provide.

Our success depends on broad market acceptance of our products if approved, which we may never achieve.

Our proposed product candidates may include new versions of existing approved intravenous biological products, with reduced viscosity and other features designed to allow our products to be administered by subcutaneous injection; new improved versions of existing subcutaneous biologics; or biosimilar versions of existing subcutaneous biologics. Thus, the success of our product candidates will depend primarily on our products demonstrating advantages over the existing products in terms of safety, efficacy, convenience, or other factors. If FDA and other regulatory authorities do not approve our products with labeling that allows us to promote such advantages, we may not be able to compete with the existing reference biologic products. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale with desirable labeling regarding advantages of our products, they still may not gain acceptance among physicians, patients, third-party payers, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not grow or maintain profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third-party payers will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. Physicians and healthcare providers earn revenue from intravenous infusion procedures and may be reluctant to switch patients to products that allow in-home self-administration. If public perception is influenced by claims that the use of our products is unsafe, our products, once approved, may not be accepted by the general public or the medical community. Future adverse events could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates.

Efforts to educate the medical community and third-party payers on the benefits of our current product candidates and any future product candidates may require significant resources and may not be successful. If our current product candidates or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our current product candidates and any future product candidates will depend on a number of factors, including:

- our ability to obtain regulatory approval of labeling to support our products' advantages over competing products with the same active molecule used for the same indication(s);
- the efficacy of our current product candidates and any future product candidates;
- the prevalence and severity of adverse events associated with our current product candidates and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which our product candidates are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, or in applicable clinical practice guidelines, any of which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our current product candidates and any future product candidates and any products with which they are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payers;
- the price concessions required by third-party payers to obtain coverage;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of our current product candidates and any future product candidates;
- the cost, safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;

- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a Risk Evaluation and Mitigation Strategy ("REMS") or voluntary risk management plan;
- the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our current product candidates and any future product candidates may be co-administered;
- the approval of other new products;
- adverse publicity about our current product candidates and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

We may not be successful in addressing these or other factors that might affect the market acceptance of our product candidates. Failure to achieve widespread market acceptance of our product candidates would materially harm our business, operating results, financial condition and prospects.

We operate in an intensely competitive market that includes companies with greater financial, technical and marketing resources than us.

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive and characterized by rapidly advancing technologies and a strong emphasis on intellectual property. We face substantial competition from many different sources, including pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions across various components of our product and service offerings.

Our competitors include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Any product candidate that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety, convenience and cost of our products. We believe principal competitive factors to our business include, among other things, the scalability of our pipeline and business, our innovative technology, and our access to, and ability to raise capital.

Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing approved products than we do. These companies will also be able to efficiently develop and market products in multiple indications or disease areas faster than we can. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our strategy.

Our commercial opportunity could be reduced or eliminated if our competitors engage in more extensive research and development efforts, undertaking more impactful marketing campaigns, adopt more aggressive pricing strategies, which may allow them to increase their market share or generate revenue more effectively than we do. Also, some of our current competitors have, and potential competitors may have, longer operating histories, greater brand recognition, greater global infrastructures, greater resources and technical capabilities, significantly greater financial, marketing and other resources and larger customer bases than we do. In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products sooner than we may obtain approval for ours and for multiple indications in parallel, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of competition, and availability of reimbursement from government and other third-party payers.

From time to time, stockholders, competitors and activist investors may attempt to influence us, which could adversely affect our operations, financial condition and the value of our stock.

Market participants, such as our direct and indirect competitors and activist stockholders, may propose a variety of actions for our company, including seeking to acquire a controlling stake in our company, engaging in proxy solicitations, involving themselves in the governance and strategic direction of our company, or otherwise attempting to effect changes at our company. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases, or sales of assets or the entire company or changes to our business strategy. Such campaigns can be led by stockholders that have interests that are different from the majority of our stockholders and our board of directors and may not be in the best interests of the company. Responding to proxy contests and other actions by stockholders can be costly and time-consuming, could disrupt our operations and divert the attention of our board of directors and senior management from the pursuit of our business strategies, and otherwise adversely affect our operations, financial condition and the value of our securities.

The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The coronavirus pandemic is evolving, and has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus or other pandemic, epidemic or other outbreak of an infectious disease impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the outbreak and the actions to contain the outbreak or treat its impact, among others. The spread of an infectious disease could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to the virus if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we or our collaborators may experience delays in initiating studies, protocol deviations, enrolling clinical trials, or dosing of patients in clinical trials as well as in activating new trial sites. COVID-19 or a future pandemic or outbreak of an infectious disease may also affect employees of third-party contract research organizations located in affected geographies that we or our collaborators rely upon to carry out clinical trials. Any negative impact COVID-19 or a future pandemic or outbreak of an infectious disease has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Our employees, agents, contractors, consultants, and vendors as well as our license, research and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot provide assurance that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, consultants, commercial partners, and vendors that would violate the law or regulation of the jurisdictions in which we operate, 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 comparable foreign regulatory authorities, fails to provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities, fails to comply with manufacturing standards, 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. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws and regulations may impact, among other things, proposed and future sales, marketing, and education programs. 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 our operations are found to be in violation of any of the laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal and state 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment.

Negative media coverage could adversely affect our business and commitments to self-regulation may subject us to investigations and litigation.

The healthcare industry receives a high degree of media coverage in the United States. Unfavorable publicity regarding, for example, the healthcare industry, litigation or regulatory activity, our offerings and products, medication pricing, pricing structures in place amongst the industry participants, our data privacy or data security practices or our revenue could adversely affect our reputation. Such negative publicity also could have an adverse effect on our ability to attract and retain collaborators, partners, or employees, and result in decreased revenue, which would adversely affect our business, financial condition and results of operation.

In addition, commitments to self-regulation in the healthcare industry may subject us to investigation by government or self-regulatory bodies, government or private litigation, and harm our reputation, brand, business, operating results and financial condition.

Our success depends on our ability to retain key members of our management team and on our ability to hire, train, retain and motivate new employees.

Our success depends on the skills, experience and performance of key members of our senior management team. The individual and collective efforts of these and other members of our senior management team will be important as we continue to develop product candidates, establish strategic partnerships and build out our operations. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers have signed employment agreements with us, but their service is at-will and may end at any point in time.

Our research and development initiatives and laboratory operations depend on our ability to attract and retain highly skilled scientists, technicians and engineers. We may not be able to attract or retain qualified scientists, clinical personnel, technicians or engineers in the future due to the competition for qualified personnel among life science and technology businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified personnel across functions that we deem critical to our success. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors might impede the achievement of our research, development, regulatory and commercialization objectives.

We rely on, and intend to continue to rely on third parties to conduct our preclinical testing, research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We have been relying on third parties for our preclinical studies, and we expect to continue to rely on third parties, such as CROs, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. These third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we are required to enter into alternative arrangements, it could delay our product development activities.

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with GCP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 securities.

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, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities. We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, 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 of the Sarbanes-Oxley Act. 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 financial statement restatements and require us to incur the expense of remediation.

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

Risks Related to Our Strategic Agreements and Relationships with Third Parties

We expect to enter into in-license agreements under which we will acquire rights to use, develop, manufacture and/or commercialize product candidates. If these collaborations are not successful, our business could be adversely affected.

In the future, we expect to seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates. We may not realize the benefits of any acquisitions, in-licenses or strategic alliances that we enter into. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, we may not be able to realize the benefits of such future acquisitions or in-licenses if we are unable to successfully integrate them into our operations and company culture. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these programs or both, which would adversely affect our business and prospects.

Any collaborations we enter into may pose several risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay or provide insufficient funding for development efforts or undertake efforts that create questions of safety and efficacy regarding or related programs, and they may not provide us with the necessary data and support needed to facilitate our planned development and regulatory strategy;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any programs or product candidates, may cause delays or termination of the research, development, manufacture or commercialization of such programs or product candidates, may lead to additional responsibilities for us with respect to such programs or product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful development and commercialization of products, or if one of any future collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under the collaboration. If we do not receive the payments we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization summarized and described in this document also apply to the activities of our collaborators.

In addition, if any collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation among the business and financial communities could be adversely affected.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those 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 similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of 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 collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

We may be required to pay certain milestones and royalties under our license or collaboration agreements with third-party licensors or collaborators.

Under our future license or collaboration agreements, we may be required to pay milestones, royalties and other payments based on our revenues, including revenues from product sales, and these milestones and royalty payments could adversely affect the overall profitability of any products that we may seek to commercialize. In order to maintain our rights under these agreements, we may need to meet certain specified milestones in the development of our product candidates. Further, our licensors (or their licensors), licensees or other strategic collaborators may dispute the terms, including amounts, that we are required to pay under the respective license or collaboration agreements. If these claims result in a material increase in the amounts that we are required to pay to our licensors or collaborators, or in a claim of breach of the license, our ability to research, develop and obtain approval of product candidates or to commercialize our products could be significantly impaired.

We may rely on third parties to conduct our future clinical trials of our product candidates, in the U.S. and other jurisdictions. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We expect to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We, our principal investigators and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, www.ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Many of our current and planned clinical trials are conducted by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;

- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with 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, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or manufacturing personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If any CMO, with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with 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:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved 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. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. 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 or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide a supply of our current product candidates or any future product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

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

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used in the preclinical testing and clinical trials for our product candidates are currently our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients ("API") and drug product we may use in all of our product candidates are currently supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API and drug product for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API and drug product prior to submission of an application for approval with the FDA, EMA or other applicable regulatory authority. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API and drug product used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API and drug product used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad or we are delayed in bringing product candidates to market such that those products have a shorter period of patent exclusivity than we expect, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current and future product candidates, as well as for their respective compositions, formulations, methods used to manufacture them, and methods of treatment, in addition to successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current and future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, in jurisdictions outside the United States, a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership.

Furthermore, patents have a limited lifespan. In the United States, and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally 20 years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a product candidate, the patent term of a patent that covers an FDA-approved product may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five (5) years beyond the expiration of the patent. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents directed to those candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of the relevant patents, or otherwise failing to satisfy applicable requirements. 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, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until at least 18 months after the earliest priority date of patent filing, or, in some cases, not at all.

Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office (the "USPTO") the European Patent Office (the "EPO"), or in other countries. In addition, we may be subject to a third-party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, and/or support. In litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current and future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current and future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third-party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition or dosage that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current and future product candidates could be negatively affected, which would harm our business, operating results, financial condition and prospects.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. 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. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and partnership and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes or our business processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property and trade secrets to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the proprietary information and inventions assignment agreements with employees provide that the employees shall assign and transfer, and will assign and transfer, to us the rights, title, and interest in all inventions that (a) relate to our business or that of our affiliates, our customers or suppliers, or any of the products or services being researched, developed or sold by us or our affiliates; (b) result from tasks assigned by us; or (c) result from the use of our premises or personal property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter parties review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are 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. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or product candidate 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. Conversely, an adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing.

Post-grant proceedings provoked by third-parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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, there could 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 substantial adverse effect on the price of our securities.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents we may own or license that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may from time to time be party to license, funding and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to comply with such obligations, our counterparties might therefore terminate the license, funding or collaboration agreements or require us to grant them certain rights, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these agreements.

Any termination of these may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under those agreements, including our rights to important intellectual property or technology, which could harm our ability to commercialize our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products and technology in fields of use and territories not included in enforcement, and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our therapeutic candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. 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 obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our 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, misappropriate or otherwise violate intellectual property rights 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 current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Any granted patents we may own or in-license covering our product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third-party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, 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. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, 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, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners 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 current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase the uncertainties and costs surrounding the prosecution of our owned and potential future in-licensed patent applications and the maintenance, enforcement or defense of our owned and potential future in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first-inventor-to-file" system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, operating results, financial condition and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. As mentioned previously, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including excipients that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Government Regulation

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with 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. If we fail to comply with the regulatory requirements in international markets and/or 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.

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

Our product candidates may be subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the United States, China, the European Union, Japan and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Inflation Reduction Act. enacted in August 2022, established the Medicare Drug Price Negotiation Program, or Negotiation Program, which requires Medicare for the first time to negotiate directly with drug and biological product manufacturers to establish a maximum fair price, or MFP, for certain Medicare Part B and Part D drugs, referred to as selected drugs. The MFP creates a cap on the amount manufacturers can charge Medicare beneficiaries and their providers for selected drugs. If a reference biological product for which we are developing a biosimilar becomes a selected drug under the Negotiation Program, and an MFP is established, this will create a Medicare price cap for the selected drug, and this will have an impact on the price of the biosimilar, which may adversely affect what we are able to negotiate with partners to develop the biosimilar. Although a biosimilar manufacturer may be able to delay and even preclude the establishment of an MFP by obtaining a delay in the negotiation of the reference biological product MFP and coming to market within one or two years of the reference biological product becoming a selected drug, if we or our partners are unable to obtain a delay in the negotiation and bring a biosimilar to market in this timeframe, an MFP will be established for the referenced biological product and this Medicare price cap may adversely affect the price of the biosimilar and our ability to successfully commercialize the biosimilar.

At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for some of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. The Consolidated Appropriations Act, enacted on December 29, 2022, includes the Food and Drug Omnibus Reform Act, or FDORA, which enhances the FDA's authority over the post-approval study requirements for an accelerated approval and specifically authorizes FDA to establish a target date for study completion. FDORA also established a withdrawal process for an accelerated approval if the confirmatory studies are not completed by a pre-set target date for study completion. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product, if approved. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and we may not be able to complete any required post-approval confirmatory studies within a receiving accelerated approval does not provide assurance of ultimate FDA approval.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability under the FDCA, the False Claims Act, or other federal or state laws. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, in August 2021 the FDA finalized a rule clarifying its position on the types of evidence it will consider when determining a medical product's intended use. In the final rule, the FDA declined to narrow its interpretation of evidence of intended use to a firm's promotional claims and indicated its intent to look broadly at any relevant evidence to establish intended use. While the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, intentionally or unintentionally, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA was enacted. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed 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, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At a federal level, President Biden 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 the 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. The 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, the CMS stated that 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, HHS published a rule 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. However, Congress has since enacted legislation temporarily prohibiting CMS from implementing the rule. Most recently, the Inflation Reduction Act, or IRA, enacted in August 2022, further delayed implementation of the rule until 2032. The effect of these legislative and executive activities on our business model and operations is currently unclear.

The IRA also established a requirement for manufacturers to pay rebates on Medicare Part B and Part D drugs for single source drugs and biological products, including certain biosimilars, with prices that increase faster than the rate of inflation. In addition, the IRA redesigned the structure of the Part D program, including to eliminate the Medicare Part D coverage gap and replace the Medicare coverage gap discount program, established by the ACA and described above, with a Manufacturer Discount Program that similarly requires manufacturers to offer discounts at the point of sale.

The IRA also established the Medicare Drug Price Negotiation Program, or Negotiation Program, which requires Medicare for the first time to negotiate directly with drug and biological product manufacturers to establish a maximum fair price, or MFP, for certain Medicare Part B and Part D drugs, referred to as selected drugs. The MFP creates a cap on the amount manufacturers can charge Medicare beneficiaries and their providers for selected drugs. To be identified as a selected drug, a drug or biological must be a negotiation-eligible drug, defined as the 50 qualifying single source drugs with the highest total spending over the most recent 12-month period under Part D or Part B (50 for each part), subject to an exemption for small biotech products for 2026-2028. Qualifying single source drugs are drugs that have had market approval for at least 7 years (for drug products) or 11 years (for biological products) that lack a marketed generic or biosimilar product.

The IRA also established a process by which a biosimilar manufacturer, who can demonstrate that there is a high likelihood that it can bring a biosimilar to market within a year following the publication of the relevant selected drug list, may request a one-year delay in the selection of the reference biological product for the Negotiation Program. If CMS grants the delay and the biosimilar comes to market within the specified timeframe, the reference biological will no longer qualify for Medicare Negotiation and no MFP will be established for the product. The biosimilar can come to market and compete directly with the reference biological product without a price cap. The IRA also provides an opportunity for the biosimilar manufacturer to obtain up to one additional year of delay. If the biosimilar fails to come to market, the reference biological product may be selected for negotiation to establish the MFP. Once established and published, the MFP will set the price cap for the biological product, which will affect Medicare payment for the biosimilar.

For the first year of the Negotiation Program, the Secretary of HHS will select 10 Part D high-expenditure, single-source drugs for negotiation. CMS expects to publish the list of 10 Medicare Part D drugs selected for negotiation in September 2023, thus beginning the negotiation process. The MFPs that are negotiated for these drugs will apply beginning in 2026. The Secretary of HHS will select an additional 15 Part D drugs for negotiation for 2027, 15 Part B and Part D drugs for 2028, and 20 Part B and Part D drugs for 2029 and subsequent initial price applicability years.

Once a negotiation-eligible drug is selected, manufacturers must submit information to CMS relating to costs and other data as part of the negotiation process. Manufacturers who fail to comply with negotiation requirements are subject to an excise tax on all U.S. sales of their products, regardless of the entity to which the selected drug is sold. In the Spring of 2023, CMS plans to issue initial guidance for the Negotiation Program process for initial price applicability year 2026 and invite public comment on key elements, such as the offer and counteroffer process between Medicare and prescription drug companies, and the methodology for applying maximum fair prices.

If CMS establishes an MFP for a reference biological product for which we are developing a biosimilar, the MFP could have an adverse effect on our ability to successfully commercialize a biosimilar.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are subject to federal and state laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets where we conduct our business in those markets. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. For example, on June 28, 2018, California enacted the California Consumer Privacy Act (the "CCPA"), which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers, increases the privacy and security obligations of entities handling certain personal information, requires new disclosures to California individuals and affords such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, HIPAA, as amended by HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules published in January 2013 (commonly referred to as the "Final HIPAA Omnibus Rule"), imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule. There are European and other foreign law equivalents of each of such laws with similar requirements. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief.

European data collection is also governed by restrictive regulations governing the use, processing and cross-border transfer of personal information. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Union (the "EU"), including personal health data, is subject to the EU General Data Protection Regulation ("GDPR"), which imposes strict requirements for processing the personal data of individuals within the European Economic Area (the "EEA"). The GDPR is directly applicable in each EU member state and is extended to the EEA. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR implements more stringent operational requirements than its predecessor legislation. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. For example, the GDPR applies extraterritorially, requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that EEA countries may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union ("CJEU"). The CJEU upheld the adequacy of the Standard Contractual Clauses ("SCCs"), a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. New SCCs were adopted by the European Commission on June 4, 2021, replacing the 2001, 2004, and 2010 SCCs that were previously in use. Use of the SCCs must nonetheless now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to cybersecurity risks to operational systems, security systems, infrastructure, and customer data processed by us or third-party vendors or suppliers, and experienced a diversion of funds through a business email compromise fraud, and any material failure, weakness, interruption, cyber event, incident or breach of security could prevent us from effectively operating its business.

We are at risk for interruptions, outages and breaches of: operational systems, including business, financial, accounting, product development, data processing or production processes, owned by us or our third-party vendors or suppliers; facility security systems, owned by us or our third-party vendors or suppliers; in-product technology owned by us or our third-party vendors or suppliers; or customer or driver data that we process or our third-party vendors or suppliers process on our behalf. Such cyber incidents could materially disrupt operational systems; result in loss of funds, intellectual property, trade secrets or other proprietary or competitively sensitive information; compromise certain information of customers, employees, suppliers, drivers or others; or jeopardize the security of our facilities. A cyber incident could be caused by disasters, insiders (through inadvertence or with malicious intent) or malicious third parties (including nation-states or nation-state supported actors) using sophisticated, targeted methods to circumvent firewalls, encryption and other security defenses, including hacking, fraud, trickery or other forms of deception.

In February 2022, we became aware that we had been a victim of a criminal fraud commonly referred to as "business email compromise fraud." The incident involved impersonation of one of our senior personnel through unauthorized access to his email account which resulted in a diversion of funds to unknown parties and a loss of $136,000 for the year ended December 31, 2021. Subsequent to December 31, 2021, as part of the same incident, an additional $590,000 was diverted, resulting in a total loss of $726,000, before we became aware of the problem. We notified federal law enforcement and the relevant bank involved, which are working with us to recover the amount lost. At this time, we have recovered insurance proceeds of $300,000 to partially offset the loss. We retained a technology consulting company to assist in our cyber investigation and remedial measures. Based on our investigation to date, the incident was financially motivated and impacted a single email account. In response to the incident, we conducted a review of our corporate information technology and email policies and are implementing additional security and training measures, including full penetration test of our network, enacted multi-factor authorization protocols, implemented an employee education program, and implementing improvements to current network.

Although we did not experience any interruptions in our operations or material disruption of our development programs or business operations, the incidents have been a distraction to our management and any future incidents could interrupt our operations or materially disrupt our development programs. For example, the loss of clinical trial data from completed, ongoing 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, our ability to commercialize products depends on third parties to conduct clinical trials and manufacture products, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

A significant cyber incident could impact production capability, harm our reputation, cause us to breach our contracts with other parties or subject us to regulatory actions or litigation, any of which could materially affect our business, prospects, financial condition and operating results. In addition, as was the case with the fraud discovered in February 2022, our insurance coverage for cyber-attacks may not be sufficient to cover all the losses we may experience as a result of a cyber-incident.

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

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

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

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 for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have 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.

Risks Related to the Company

We will continue to incur increased costs as a result of operating as a public company, and our management is devoting substantial time to new compliance initiatives.

We will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"). As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will continue to need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs will increase the Company's net loss. For example, these rules and regulations could make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance and as a result, we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs it may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Management has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage its transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal securities laws. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities which will result in less time being devoted to the management and growth of the company. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the U.S. The development and implementation of the standards and controls necessary for the us to achieve the level of accounting standards required of a public company in the U.S. may require costs greater than expected. It is possible that we will be required to expand its employee base and hire additional employees to support our operations as a public company, which will increase its operating costs in future periods.

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

Our common stock and our publicly traded warrants to purchase common stock (the "Public Warrants") are listed on Nasdaq. There can be no assurance that we will continue to meet Nasdaq's listing standards. On November 18, 2022, we received a letter from the listing qualifications department staff of Nasdaq notifying us that, for the then prior 30 consecutive business days, the minimum Market Value of Listed Securities ("MVLS") was below the minimum $35 million required for continued listing on Nasdaq, pursuant to Nasdaq listing rule 5550(b)(2). In accordance with Nasdaq listing rule 5810(c)(3)(C), we have 180 calendar days, or until May 17, 2023 (the "Compliance Period"), to regain compliance. The notice states that to regain compliance, the Company's MVLS must close at or above $35 million for a minimum of ten consecutive business days (or such longer period of time as the Nasdaq staff may require in some circumstances, but generally not more than 20 consecutive business days) during the Compliance Period. We may also regain compliance by meeting the continued listing standard of a minimum stockholders' equity of at least $2.5 million. If we do not regain compliance by May 17, 2023, Nasdaq staff will provide written notice to the Company that its securities are subject to delisting. At that time, we may appeal any such delisting determination to a Nasdaq hearings panel. If we do not regain compliance, we and our stockholders could face significant material adverse consequences, including:

- a limited availability of market quotations for its securities;
- reduced liquidity for its 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 its 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 National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock remains listed on Nasdaq, it will be considered a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. While we are not aware of a state, other than the State of Idaho, having used these powers to prohibit or restrict the sale of securities issued by blank check companies, certain state securities regulators view blank check companies unfavorably and might use these powers, or threaten to use these powers, to hinder the sale of securities of blank check companies in their states. Further, if we were not listed on Nasdaq, our securities would not be covered securities and we would be subject to regulation in each state in which it offers its securities.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business, operating results and financial condition.

We are required to provide management's attestation on internal controls pursuant to the requirements of Section 404(a) of the Sarbanes-Oxley Act ("Section 404(a)"). The standards required for a public company under Section 404(a) are significantly more stringent than those that were required of Legacy Comera as a privately-held company. Management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404(a) in a timely manner or with adequate compliance, it may not be able to assess whether its internal controls over financial reporting are effective or may result in a finding that there is a material weakness in our internal controls over financial reporting, which may subject it to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

A market for our securities may not continue, which would adversely affect the liquidity and price of our securities.

The price of our common stock and the Public Warrants has fluctuated and may continue to fluctuate significantly due to the market's reaction to the Transaction and general market and economic conditions. An active trading market for our common stock and the Public Warrants may never develop or, if developed, it may not be sustained. In addition, the price of our common stock and the Public Warrants can vary due to general economic conditions and forecasts, our general business condition and the release of its financial reports. If its securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of its securities may be more limited than if it were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your Company securities unless a market can be established or sustained.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, then the price and trading volume of our common stock or the Public Warrants could decline.

The trading market for our common stock and the Public Warrants will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market, or our competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of our company, our common stock and the Public Warrants price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our common stock and Public Warrants adversely, or provide more favorable relative recommendations about the Company's competitors, the price of our common stock and Public Warrants would likely decline. If any analyst who may cover us fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price or trading volume of common stock or Public Warrants to decline.

The JOBS Act permits "emerging growth companies" like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act. As a result, our stockholders may not have access to certain information they deem important. 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 the Transaction, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates equals or exceeds $700.0 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period.

We cannot predict if investors will find our securities less attractive because it relies on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market and share price for our common stock or Public Warrants may be more volatile. Once we cease to qualify as an emerging growth company, we will incur increased legal, accounting and compliance costs associated with Section 404 of the Sarbanes-Oxley Act.

Our amended and restated certificate of incorporation contain anti-takeover provisions that could adversely affect the rights of our stockholders.

Our amended and restated certificate of incorporation contain provisions to limit the ability of others to acquire control of us or cause us to engage in change-of-control transactions, including, among other things:

- provisions that authorize its board of directors, without action by its stockholders, to issue additional shares of our common stock and preferred stock with preferential rights determined by its board of directors;
- provisions that permit only a majority of its board of directors, the chairperson of the board of directors or the chief executive officer to call stockholder meetings and therefore do not permit stockholders to call special meetings of the stockholders;
- provisions limiting stockholders' ability to act by written consent; and
- a staggered board whereby our directors are divided into three classes, with each class subject to retirement and re-election once every three years on a rotating basis.

These provisions could have the effect of depriving our stockholders of an opportunity to sell their common stock at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. With our staggered board of directors, at least two annual or special meetings of stockholders will generally be required in order to effect a change in a majority of our directors. Our staggered board of directors can discourage proxy contests for the election of its directors and purchases of substantial blocks of our shares by making it more difficult for a potential acquirer to gain control of our board of directors in a relatively short period of time.

Our amended and restated certificate of incorporation provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation provide that unless we consent in writing to the selection of an alternative forum, and subject to applicable jurisdictional requirements, the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the Company, (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, employee, agent or stockholder of the Company to the Company or the Company's stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL, the Company's amended and restated certificate of incorporation, or (4) any action asserting a claim governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks jurisdiction over such action or proceeding, then the United States District Court for the District of Delaware or another court of the State of Delaware). Our amended and restated certificate of incorporation also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in the amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As noted above, our amended and restated certificate of incorporation provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Accordingly, there is uncertainty as to whether a court would enforce such provision. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated certificate of incorporation.

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

Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. Any adverse determination in litigation could also subject the Company to significant liabilities.

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

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our common stock unless you sell our common stock for a price greater than that which you paid for it.

General Risk Factors

Our business is subject to the risks of earthquakes, fires, floods and other natural catastrophic events, global pandemics and interruptions by man-made problems, such as terrorism or war. Material disruptions of our business or information systems resulting from these events could adversely affect its operating results.

A significant natural disaster, such as an earthquake, fire, flood, hurricane or significant power outage or other similar events, such as infectious disease outbreaks or pandemic events, including the ongoing COVID-19 pandemic, could have an adverse effect on our business and operating results. The ongoing COVID-19 pandemic or a future pandemic or outbreak of an infectious disease may have the effect of heightening many of the other risks described in this "Risk Factors" section, such as the demand for our products, our ability to achieve or maintain profitability and our ability to raise additional capital in the future. In addition, natural disasters, international conflicts, acts of terrorism or war could cause disruptions in our remaining manufacturing operations, our or our customers' or channel partners' businesses, suppliers' or the economy as a whole. We also rely on information technology systems to communicate among our workforce and with third parties. Any disruption to our communications, whether caused by a natural disaster or by manmade problems, such as power disruptions, could adversely affect our business. We do not have a formal disaster recovery plan or policy in place and do not currently require that our suppliers' partners have such plans or policies in place. To the extent that any such disruptions result in delays or cancellations of orders or impede our suppliers' ability to timely deliver product components, or the deployment of our products, our business, operating results and financial condition would be adversely affected.

Interruption or failure of our information technology and communications systems could impact ability to effectively provide its products and services.

We plan to include services and functionality that utilize data connectivity to monitor performance and timely capture opportunities to enhance performance and functionality. The availability and effectiveness of our services depend on the continued operation of information technology and communications systems. Our systems will be vulnerable to damage or interruption from, among others, physical theft, fire, terrorist attacks, natural disasters, power loss, war, telecommunications failures, viruses, denial or degradation of service attacks, ransomware, social engineering schemes, insider theft or misuse or other attempts to harm our systems. We utilize reputable third-party service providers or vendors for all of its data other than its source code, and these providers could also be vulnerable to harms similar to those that could damage our systems, including sabotage and intentional acts of vandalism causing potential disruptions. Some of our systems will not be fully redundant, and our disaster recovery planning cannot account for all eventualities. Any problems with our third-party cloud hosting providers could result in lengthy interruptions in our business. In addition, our services and functionality are highly technical and complex technology which may contain errors or vulnerabilities that could result in interruptions in our business or the failure of its systems.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located at 12 Gill Street, Suite 4650, Woburn, Massachusetts. Our current lease for approximately 6,000 square feet of office and lab space will expire in June 2024. The lease agreement provides for a base monthly rent, and we are also responsible for real estate taxes, maintenance and other operating expenses applicable to the leased premises. Our future minimum lease payments under the lease agreement are as follows:

Year	Amounts
2023	$ 217,545
2024	123,077
Total	$ 340,622

We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in litigation or legal proceedings relating to claims arising from the ordinary course of business.

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 and the Public Warrants trade on Nasdaq Capital Market ("Nasdaq") under the symbols CMRA and CMRAW, respectively.

Holders

As of March 15, 2023 there were 67 holders of record of our common stock and 10 holders of the Public Warrants.

The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in street name or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid any cash dividends on shares of our common stock, and we do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities and Use of Proceeds

The Arena Purchase Agreement

As previously disclosed in the Company's Current Report on Form 8-K filed on August 31, 2022, the Company entered into the Arena Purchase Agreement with Arena. As of March 17, 2023, the Company has sold an aggregate of 512,985 shares of its Common Stock at a weighted average price of approximately $1.71 per share for aggregate gross proceeds of approximately

$879 thousand pursuant to the Arena Purchase Agreement. The purchase price of the shares sold to Arena was equal to 96% of the simple average of the daily VWAP of the Company's Common Stock immediately preceding the time of sale, as computed under the Arena Purchase Agreement. The issuances of the shares of the Company's Common Stock pursuant to the Arena Purchase Agreement were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act as a sale to an "accredited investor" as defined in Rule 501(a) of the Securities Act.

Issuer Purchases of Equity Securities

None.

ITEM 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections of this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. For periods prior to the closing of the Transaction, the use of "our", "we" and words of similar import in this Item 7 refer to our predecessor, Legacy Comera.

Overview

Comera is a preclinical stage biotechnology company dedicated to promoting a compassionate new era in medicine by applying a deep knowledge of formulation science and technology to transform essential biologic medicines from intravenous ("IV") to subcutaneous ("SQ") forms. Although Comera's product candidates are at the preclinical stage and none have been approved for commercial sale, Comera's internal portfolio of proprietary techniques known as the SQore™ platform, is designed to potentially transform essential biologic medicines from IV to SQ forms, optimize current versions of subcutaneous biologics, and produce biosimilar versions of existing subcutaneous products. If successful, this transformation in administration could provide patients using biological products through intravenous infusion, and their families, the freedom of self-injectable care which, Comera believes, would allow them to enjoy both the potential benefits of biologic treatments and the potential of their own lives while simultaneously lowering healthcare costs. To accomplish this, Comera is developing an internal portfolio of proprietary therapeutic product candidates using our innovative proprietary formulation platform, SQore™. Comera also collaborates with pharmaceutical and biotechnology companies, applying the SQore™ platform to our partners' biologic medicines to deliver enhanced SQ formulations.

Since our founding in 2014, we primarily engaged in early-stage, preclinical studies, commissioned on a fee-for-service basis by larger pharmaceutical companies and have not yet developed any products approved for marketing. Our studies for larger companies were generally early-stage investigations, often amounting to proof-of-concept work, aimed at moving existing formulations from IV infusion to SQ delivery via injection.

In 2021, we brought on a new leadership team and carried out a transition of our business model. We shifted away from simple "fee for services" formulation work and focused our efforts on engaging with higher-value-add partners in integrated, collaborative projects to develop formulations for their key products. We are currently working with multiple companies under research and development service agreements. These agreements typically have a term of less than 12 months and provide for an initial payment by the company of a fee to us for the evaluation by us of our proprietary technology for viscosity reduction with the other company's proprietary biotherapeutic agent. The agreements set forth the detailed research plans and the related timeline for completion of the research. The agreements provide that each party retains ownership of its technology throughout the process. Upon completion of the project, the parties may negotiate in good faith the terms of a license agreement. If the parties do not successfully negotiate a license, each party retains ownership of its technology and neither party may use the joint invention. Because these research and development service agreements may result in the future negotiation and execution of licensing agreements, we believe these projects provide far greater opportunities for generating revenue. When we meet our partners' defined project criteria for the formulations, we will seek a license agreement to receive license fees, milestone payments, and longer-term and more stable royalty revenue on commercial assets that are vital to our partners.

On April 30, 2021, we completed a corporate reorganization (the "Reorganization") and, on January 7, 2022, we changed our name to Comera Life Sciences, Inc. to emphasize our vision of a compassionate new era in medicine.

On May 19, 2022, we consummated an acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. ("OTR") and Legacy Comera. The transaction was accounted for as a reverse recapitalization.

SQore™ Platform

Comera's SQore™ platform, supported by an extensive patent portfolio and encompassing years of development and experience, is designed to enable the conversion of IV biologics to SQ versions. We believe that our team of experienced scientists includes industry-leading experts in polymer engineering and interfacial dynamics who are inventors on dozens of patents and have published widely-cited research in their fields. This expertise complements our solid grounding in traditional protein chemistry. Our combined polymer and small molecule capability allows us to leverage a mechanistic understanding of protein-protein and protein-solvent interactions to tailor excipient selection for specific formulation needs. This scientific foundation supports the SQore™ platform for our formulation work. Based on this platform, our technology has the potential to lower healthcare costs, increase patient compliance and enhance patient lives – all major factors which we believe will help set Comera apart from its peers in the years ahead.

The Transaction

On May 19, 2022 (the "Closing Date"), we consummated a business combination (the "Transaction"), in accordance with the Business Combination Agreement dated January 31, 2022 (as amended on May 19, 2022, the "Business Combination Agreement") by and among the Company, Legacy Comera, OTR, CLS Sub Merger 1 Corp., a Delaware corporation, ("Comera Merger Sub"), and CLS Sub Merger 2 Corp., a Delaware corporation ("OTR Merger Sub"). Pursuant to the Business Combination Agreement, CLS Sub Merger 1 Corp. merged with and into Legacy Comera and CLS Sub Merger 2 Corp. merged with and into OTR, resulting in Legacy Comera and OTR becoming a wholly-owned subsidiaries of Holdco.

The Transaction was accounted for as a reverse recapitalization because Legacy Comera has been determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction was treated as Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded. All outstanding equity instruments, prior to the Transaction, have been retroactively adjusted to share amounts reflecting the Company's current capital structure, including adjustments based on the exchange ratio ("Exchange Ratio") established in the Transaction. Accordingly, certain amounts have been reclassified and adjusted to reflect the reverse recapitalization pursuant to the Transaction for all periods presented within the consolidated balance sheets and statements of convertible preferred stock, stockholders' deficit and members' equity. See Notes 1, 2 and 3 to our consolidated financial statements elsewhere in this Report for additional information.

Financial Overview

Revenue

Through December 31, 2022, we have generated revenue from research agreements with various partners. These arrangements generally represent formulation development collaborations with rights to negotiate product-specific licenses for a broad spectrum of protein-based therapeutics. Initially, arrangements have provided compensation for research efforts. The arrangements also provide that if the research efforts are successful, additional development and commercialization arrangements may be separately negotiated and executed, which may include upfront payments, milestones, and royalties on commercial sales. We generally expect revenue to increase as we execute additional research agreements and as planned development and collaboration arrangements are executed.

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If development efforts for our pipeline programs are successful and result in regulatory approval, we may generate product revenue in the future if our commercialization efforts are successful.

Cost of Revenue

Cost of revenue generally consists of personnel expenses (comprised of salaries, bonuses, employee benefits and stock-based compensation expenses), and direct materials costs, third-party laboratory costs, and other costs necessary to complete the research arrangements. In addition, costs include allocated depreciation of laboratory equipment and amortization of leasehold improvements, and certain overhead expenses including facilities costs. Costs associated with revenue are recorded as the research is performed. We generally expect cost of revenue to increase as revenue increases, however margin on our customer contracts may vary widely.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the enhancement of our product platform and with the discovery and development of our pipeline programs. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, and contract manufacturing organizations, as well as consultants that conduct research and development activities on our behalf;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Research and development activities are central to our business model. Current activities primarily relate to the enhancement of our SQore™ technology platform and other research activities, as well as initiation of formulation development work and manufacturing activities for our pipeline programs. We expect that our research and development expenses will increase substantially over the next several years including increased costs related to the development of pipeline programs, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs and direct costs paid to contract research, development, and manufacturing organizations to conduct pipeline research and development activities on our behalf. In addition, if we elect to in-license or otherwise acquire additional pipeline products or additional intellectual property, we will also incur additional expenses which may include upfront, milestone and royalty payments payable to third parties.

The successful discovery, development and commercialization of our pipeline programs is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the discovery or development of any of our potential pipeline programs or when, if ever, material net cash inflows may commence from any of our pipeline programs.

Our research and development expenses are not currently tracked on a program-by-program basis. Our research and development expenses consist primarily of external costs, such as fees paid to outside consultants, contract research organizations, contract manufacturing organizations, and central laboratories, and internal costs such as employee costs and facility expenses, including depreciation or other indirect costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include D&O insurance and professional fees for legal, consulting, accounting and audit services. In addition, general and administrative expenses also include costs incurred in connection with the Transaction, expenses primarily related to advisory, legal, and accounting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities, and as a result of operating as a public company, including compliance with federal securities laws, legal, audit, additional insurance expenses, investor relations activities, and other administrative and professional services. We anticipate the additional costs for these services will substantially increase our general and administrative expenses. Additionally, if and when we believe a regulatory approval of a pipeline programs appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our pipeline programs.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. 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, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. 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.

Revenue Recognition and Contract Balances

The Company's principal sources of revenue during the years ended December 31, 2022 and 2021, were derived from research and development service agreements with customers.

At inception, management determines whether contracts are within the scope of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), or other topics, including ASC 808, *Collaborative Arrangements* ("ASC 808"). For contracts or units of account that are determined to be within the scope of ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which management expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, management applies the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Identification of Performance Obligations. Performance obligations promised in a contract are identified at contract inception based on the goods and services that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation. In general, the Company's contracts typically contain one performance obligation to perform research services on behalf of its customers, which are generally performed over a short period of time, typically less than twelve months. These contracts typically include rights to negotiate for a license or other products and services upon completion of the research services.

Transaction Price. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. The Company's contracts typically contain upfront payments or fees for research services.

Research and Development Services. The promises under the Company's arrangements generally include research and development services to be performed by the Company on behalf of the counterparty. Payments or reimbursements from customers resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts. The Company uses an input method, according to the ratio of direct labor hours incurred to the total direct labor hours expected to be incurred in the future to satisfy the performance obligation. In management's judgment, this input method is the best measure of the transfer of control of the performance obligation. Reimbursements from and payments to the counterparty that are the result of a collaborative relationship, instead of a customer relationship, such as co-development activities, are recognized as the services are performed and presented as a reduction to research and development expense. To date, the Company has determined that all arrangements which include research and development services have been transacted with customers and recognized on a gross basis using ASC 606.

Customer Options. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Derivative Warrant Liabilities

The Company classifies as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any warrants that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the company's control), (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement) or (iii) that contain reset provisions that do not qualify for the scope exception. The Company assesses classification of its common stock warrants and other freestanding warrant instrument at each reporting date to determine whether a change in classification between assets and liabilities is required.

The Company's freestanding warrant instruments consist of private placement warrants to purchase shares of common stock ("Private Placement Warrants") and public warrants to purchase shares of common stock ("Public Warrants") that were converted in connection with the Transaction. Following the Transaction, the Public Warrants are considered equity classified instruments since the shares underlying the Public Warrants are not redeemable and the Company has one single class of voting common stock, which does not preclude them from being considered indexed to the Company's equity and allows the Public Warrants to meet the criteria for equity classification per ASC 815, *Derivatives and Hedging* ("ASC 815"). Warrants that are determined to require equity classification are measured at fair value upon issuance and are not subsequently remeasured unless they are required to be reclassified.

The Private Placement Warrants are considered liability classified instruments because their settlement amount differs depending on the identity of the holder which precludes them from being considered indexed to the Company's equity. Accordingly, the Company recognizes the Private Placement Warrants as liabilities at fair value and adjusts the instruments to fair value using quoted prices of instruments with similar terms. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's consolidated statements of operations and comprehensive loss.

Results of Operations

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

The following table sets forth our results of consolidated operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		Change	
	2022	2021	Dollar	Percentage
Revenue	$ 633,102	$ 319,832	$ 313,270	98%
Cost of revenue	210,390	161,008	49,382	31%
Operating expenses:				
Research and development	1,739,833	1,752,669	(12,836)	(1)%
General and administrative	10,652,894	3,941,783	6,711,111	170%
Total operating expenses	12,392,727	5,694,452	6,698,275	118%
Loss from operations	(11,970,015)	(5,535,628)	(6,434,387)	116%
Other (expense) income, net	(6,034,083)	83,850	(6,117,933)	(7,296)%
Net loss and comprehensive loss	$ (18,004,098)	$ (5,451,778)	$(12,552,320)	230%

Revenue

Revenue was $633 thousand for the year ended December 31, 2022, compared to $320 thousand for the year ended December 31, 2021. The increase of $313 thousand is primarily related to an increase in research activities performed under customer contracts during the year ended December 31, 2022.

Cost of Revenue

Cost of revenue was $210 thousand for the year ended December 31, 2022, compared to $161 thousand for the year ended December 31, 2021. The increase of $49 thousand is primarily related to higher direct labor costs incurred during the year ended December 31, 2022, due to an increase in research activities performed under customer contracts which had more favorable margins compared with the prior period.

Research and Development Expenses

The following table sets forth our research and development expenses for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		Change	
	2022	2021	Dollar	Percentage
Employee related	$ 934,064	$ 1,257,231	$ (323,167)	(26)%
Lab supplies and materials	394,600	230,829	163,771	71%
Occupancy and facility related	167,374	156,174	11,200	7%
Other	243,795	108,435	135,360	125%
Total research and development expense	$ 1,739,833	$ 1,752,669	$ (12,836)	(1)%

Research and development expenses were $1.7 million for the year ended December 31, 2022, compared to $1.8 million for the year ended December 31, 2021. The decrease of $13 thousand is primarily related to stock compensation expense recorded in the prior period related to the vested awards in connection with the corporate reorganization (the "Reorganization"), when the Company underwent a conversion from an LLC to a corporation. This is partially offset by an increase in lab supplies and materials of $164 thousand, as well as an increase in payroll and benefits. The increase in lab supplies and materials is primarily associated with an increase in research activities in the year ended December 31, 2022 as compared to the year ended December 31, 2021 as the Company continues to develop its platform.

General and Administrative Expenses

General and administrative expenses were $10.7 million for the year ended December 31, 2022, compared to $3.9 million for the year ended December 31, 2021. The increase of $6.7 million is primarily related to $1.5 million of transaction related expenses, along with increases in expenses in connection with the Company's growth and preparation to, and subsequent running of, a public company. These increases include $1.3 million of consulting fees, $1.3 million of accounting fees, $847 thousand of legal fees, and $214 thousand of patent fees. In addition, there were increases related to directors and officers liability insurance of $1.6 million, including $634 thousand associated with a tail policy related to the Transaction. The increase was also due to higher payroll and benefits expenses and additional headcount as of December 31, 2022, partially offset by stock compensation expense recorded in December 31, 2021 related to the vested awards in connection with the Reorganization.

Other Income (Expense), Net

For the year ended December 31, 2022, total other expense, net of $6.0 million was primarily comprised of $6.6 million expense related to stock issuance costs which exceeded the net tangible assets received from the Transaction, $1.0 million expense related to the Arena Purchase Agreement (the "Arena Purchase Agreement"), and a $590 thousand loss from payments related to a business email compromise fraud which resulted in a diversion of the Company's capital to unknown parties which was partially offset by $164 thousand of insurance proceeds for a net loss of $426 thousand. These expenses were partially offset by a $2.0 million decrease in fair value of the Company's derivative warrant liabilities which were assumed in the Transaction.

For the year ended December 31, 2021, total other income, net of $84 thousand primarily consisted of a $161 thousand gain on debt extinguishment resulting from forgiveness of the Company's notes payable issued under the Paycheck Protection Program which was established as part of the Coronavirus Aid, Relief and Economic Security Act and is administered by the U.S. Small Business Administration, offset by $77 thousand change in fair value of convertible notes.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We do not have any products approved for sale and have not generated any revenue from product sales. As of December 31, 2022, we have generated revenue from research agreements with various partners. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual licensing and/or commercialization of one or more of our current or future pipeline programs as well as continued successful execution of pharmaceutical research collaborations and subsequent execution of collaboration programs. Our net loss was $18.0 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of $34.9 million. We expect to continue to incur significant expenses for at least the next several years as we continue to develop our technology platform and conduct research and development activities on our pipeline programs. In addition, we expect our expenses to significantly increase as our pipeline programs advance into clinical development and eventual regulatory approval stages. If we obtain marketing approval for any of our pipeline programs, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. As of December 31, 2022, the Company has not engaged in any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, results of operations or cash flows.

On January 2, 2023, we entered into the purchase agreement (the "2023 PIPE Purchase Agreement") with the purchasers party thereto (the "Purchasers"), pursuant to which we agreed to issue and sell to the Purchasers in a private placement of our securities (the "January 2023 PIPE Financing") an aggregate of 2,406,242 Units ("Units"), each Unit consisting of (i) one share of our common stock and (ii) one warrant (the "2023 PIPE Warrants") to purchase two shares of our common stock (the "Warrant Shares") at an exercise price of $1.23 per Warrant Share, for an aggregate purchase price of approximately $3.6 million, consisting of $1.48 per Unit, inclusive of $0.25 per Private Placement Warrant.

Upon the execution of the 2023 PIPE Purchase Agreement on January 2, 2023, $1.5 million of current restricted cash was released and reclassified as cash. The total gross proceeds collected from the January 2023 PIPE Financing was $3.6 million, all of which is classified as cash as of January 2, 2023.

We will receive up to an aggregate of $127.0 million if all of the outstanding Public Warrants and $5.9 million if all of the outstanding 2023 PIPE Warrants are exercised for cash. However, we will only receive such proceeds if and when the warrant holders exercise such warrants, and we believe the likelihood that holders of the Public Warrants will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the market price of our common stock. The closing price of Comera common stock on Nasdaq on December 31, 2022 was $1.23, which is $10.27 below the exercise price of the Public Warrants. If the market price for Comera common stock does not increase from the current level, it is unlikely that any of the Public Warrants will be exercised.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, government and other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government and other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, pipeline programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or pipeline programs that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We do not believe the cash and cash equivalents as of December 31, 2022 will be sufficient to fund our operations for the next twelve months from the date of issuance of the consolidated financial statements. We will be required to raise additional capital to continue to fund operations and capital expenditures. Such funding may not be available on acceptable terms, or at all. If we are unable to access additional funds when needed, we may not be able to continue operations or we may be required to delay, scale back or eliminate some or all of our ongoing research and development efforts and other operations. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations. These uncertainties create substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table sets forth the sources and uses of cash, cash equivalents, and restricted cash for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (9,771,770)	$ (3,757,949)
Net cash used in investing activities	(28,607)	(142,013)
Net cash provided by financing activities	5,242,469	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (4,557,908)	$ 6,379,713

Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was $9.8 million which consisted of a $18.0 million net loss, partially offset by $5.7 million of net noncash adjustments and $2.4 million of changes in operating assets and liabilities. Our noncash adjustments were primarily comprised of $6.6 million related to stock issuance costs in excess of gross proceeds associated with the Transaction and a $1 million private placement of our common stock entered into with Maxim Group LLC immediately prior to the Transaction (the "Maxim Private Placement") and $650 thousand related to noncash common stock issuance costs related to the Arena Purchase Agreement, partially offset by $2.0 million decrease in fair value of the derivative warrant liabilities. The net cash inflows associated with changes in operating assets and liabilities was primarily due to increases of $863 thousand in accounts payable, $789 thousand in accrued expenses and other current liabilities, $800 thousand in prepaid expenses and other current assets, and $144 thousand in deferred revenue, partially offset by an increase of $34 thousand in accounts receivable.

During the year ended December 31, 2021, net cash used in operating activities was $3.8 million which consisted of a $5.5 million net loss and partially offset by $1.1 million of net noncash adjustments and $574 thousand of changes in operating assets and liabilities. Our noncash adjustments were primarily comprised of $1.1 million of stock-based compensation expense, $86 thousand in depreciation expense, and $77 thousand of change in fair value of convertible notes, partially offset by $161 thousand of gain on debt extinguishment. The net cash inflows associated with changes in operating assets and liabilities was primarily due to an increase of $319 thousand in accounts payable, $400 thousand in accrued expenses and other current liabilities, $231 thousand in prepaids and other current assets, and a decrease of $110 thousand in accounts receivable and $29 thousand in deferred revenue.

Investing Activities

The cash outflows from investing activities for the years ended December 31, 2022 and 2021 related to the purchase of property, plant, and equipment.

Financing Activities

Cash from financing activities during the year ended December 31, 2022 was $5.2 million, driven by $3.3 million of net proceeds received from the Transaction and Maxim Private Placement, $1.5 million of advanced deposits related to the January 2023 PIPE Financing, $829 thousand of proceeds from the Arena Purchase Agreement, and $660 thousand of proceeds from the exercise of stock options, and partially offset by $1.1 million of repayments under our insurance premium financing arrangement.

Financing activities during the year ended December 31, 2021 was $10.3 million, driven by $9.3 million of net proceeds from the issuance of preferred stock, $750 thousand of proceeds from the issuance of convertible notes, and $180 thousand of proceeds from the exercise of stock options.

Known Trends, Events and Uncertainties

Other than as discussed elsewhere in this report, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included elsewhere in this Report.

ITEM 7A. Quantitative and Qualitative Disclosure About Market Risk

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. Financial Statements and Supplementary Data.

The consolidated financial statements required by this Item 8 are presented at the end of this Report starting on page F-1.

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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2022, have concluded that, based on such evaluation, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

This Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies (Instruction 1 to Item 308, Regulation S-K).

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2022 that has materially affected, or is 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.

Management and Board of Directors

The following table sets forth the persons who serve as our executive officers and directors. For periods prior to the closing of the Transaction, the use of "our", "we" and words of similar import in this Item 10 refer to our predecessor, Legacy Comera.

Name	Age	Position
Executive Officers:		
Jeffrey S. Hackman	61	Chairman, President, Chief Executive Officer and Director
Neal Muni, MD	49	Executive Vice President and Chief Operating Officer
Dr. Robert Mahoney	59	Chief Scientific Officer
Michael G. Campbell, CPA	55	Executive Vice President and Chief Financial Officer
Janice McCourt	61	Chief Business Officer
Class I Directors:		
Rev. Dr. Jim Sherblom	67	Director
Stuart Randle	63	Director
Class II Directors:		
Jeffrey S. Hackman	61	Chairman, President, Chief Executive Officer and Director
Edward Sullivan, CPA	60	Director
Class III Directors:		
Roopom Banerjee, MPP	46	Director
Kirsten Flowers	48	Director
William A. Wexler	63	Director

Management

Jeffrey S. Hackman has served as the President, Chief Executive Officer and as a member of our board of directors since September 2021. Prior to joining Comera, he was President of U.S. Operations from 2019 to 2021 for EUSA Pharma, a global pharmaceutical company focused on cancers and rare diseases. Previously, from 2017 to 2018, Mr. Hackman filled several roles at Aegerion Pharmaceuticals Inc., a biopharmaceutical company, finishing as acting CEO of its parent company, Novelion Therapeutics Inc. (NVLNF). Under his leadership, Novelion reached profitability. He joined Novelion from Shire Inc., a biopharmaceutical company, where he had been Senior VP and Head of U.S. Internal Medicine / Oncology Franchise from 2016 to 2017. Previously, he established the North American oncology commercial division for Baxalta, a biopharmaceutical company, following two years leading US commercial operations for Sigma Tau, a research-based pharmaceutical company. He has also held senior roles in several other pharmaceutical companies. Mr. Hackman is well qualified to serve as our President and Chief Executive Officer and as a director due to his extensive industry experience in senior management and leadership positions.

Neal Muni, MD, MD MSPH, has served as our Executive Vice President and Chief Operating Officer since September 2021. Concurrently, Dr. Muni retains his role as Managing Director of RTK Group, LLC, a family-office backed biopharma advisory and venture fund, which he has held since December 2019; Advisor and Acting Chief Medical Officer to Unravel Biosciences, Inc., a therapeutics company, which he has held since May 2021; partner and advisor to Romeg Therapeutics, LLC, a specialty pharmaceutical company, which he has held since May 2015; advisor to Limax Biosciences, Inc., a bioadhesive device company, which he has held since October 2021; advisor to Azurity Pharmaceuticals, Inc. a privately-held pharmaceutical company focusing on 505(b)(2) therapeutics, where he held the position of President and CEO from July 2014 to January 2020; and has been a Visiting Scholar at Harvard University's Wyss Institute of Biologically Inspired Engineering since October 2020. Under Dr. Muni's tenure at Azurity as CEO, he led two successful private equity transactions including recapitalization and company sale, and oversaw the FDA approval and commercial launch of two pipeline drugs in the infectious disease and pediatric cardiology markets, as well as four IND filings. Dr. Muni also previously served as an engagement manager at the healthcare investment bank Leerink Swann (now SVB Leerink). Dr. Muni's notable other experience includes over 20 years of ongoing affiliation with Harvard Medical School and three of its leading teaching hospitals, including the Brigham and Women's Hospital, Dana Farber Cancer Center, and Brigham Faulkner Hospital as Associate Physician and Instructor in Medicine, and his prior appointment to the FDA as a Medical Officer in the Division of Cardiovascular Devices, serving as the lead medical reviewer for drug-eluting intracoronary stents.

Dr. Robert Mahoney has served as our Chief Scientific Officer since October 2021, as a member of our advisory board from 2014 to May 2022, and as Comera's Vice President of Research & Development since 2014. Dr. Mahoney has spent over 25 years leading the development and commercialization of disruptive new products and processes for industries including pharmaceuticals, agrochemicals, oilfield technologies, water treatment, and process treatment. From 2015 to 2017 he served as Vice President of Research & Development at Crop Enhancement Inc., an agriculture technology corporation, where the nontoxic barrier coating CropCoat® was developed and commercialized as an alternative to pesticides to increase yields in cocoa, coffee, citrus, and other high value crops. Prior to that, he served as Vice President of Research & Development at Soane Energy, a specialty materials company, under David Soane, leading to the outlicense and deployment of an innovative self-suspending proppant technology. Prior to joining Dr. Soane at Soane Energy, he was Vice President of Research & Development at Polymer Ventures, Inc., which produces and distributes polymer additives, from 1996 to 2009 where he led the design and commercialization of many new specialty polymer products. Previously, Dr. Mahoney was a Senior Research Chemist at Nalco Water, an Ecolab Company (NYSE: ECL) from 1991 to 1996 where he developed new performance additives for water purification and treatment. Dr. Mahoney received his Ph.D. in physical organic chemistry from the University of Colorado at Boulder and has authored over 50 U.S. patents, plus additional publications, and presentations.

Michael G. Campbell, CPA has served as our Chief Financial Officer since June 2022 and served as Interim Chief Financial Officer prior to that since April 2022. He previously served as a consultant through Monomoy Advisors LLC, a finance, strategy, human resources and operations advisory firm. Previously, Mr. Campbell filled several senior finance leadership roles at Ortho Clinical Diagnostics (OCDX), a medical equipment manufacturing company, from 2014 to 2021, including serving in the Office of the CFO and as Vice President, Corporate Controller and Head of Global Tax. From 1995 to 2014, Mr. Campbell held various senior leadership positions across the Global Finance organization within Boston Scientific Corporation (BSX), a biomedical/biotechnology engineering firm and multinational manufacturer of medical devices, including Vice President of Investor Relations between 2012 and 2014 and regional CFO as Vice President of Finance, Asia Pacific and Emerging Markets based in Singapore from 2008 to 2012. In this position, he was responsible for the financial leadership and oversight of all business segments covering more than 40 countries, including start-up organizations in China and India. Prior to Boston Scientific, Mr. Campbell worked as a Financial and Information Systems Assurance Manager at Ernst & Young, a multinational professional services partnership. Mr. Campbell received a B.S. degree in Accountancy from Bentley University and is a Certified Public Accountant.

Janice Marie McCourt has served as our Chief Business Officer since November 2022. Prior to joining Comera, Ms. McCourt was the Chief Business and Corporate Development Officer at Lyvgen Biopharma Co., ("Lyvgen") Ltd since June 2021, a private biotechnology company focused on developing innovative immuno-oncology therapies, where she focused on corporate strategy, business and clinical operations, finance, corporate development, alliance management, negotiation of partnerships, licensing deals and research and development collaborations. Prior to Lyvgen, Ms. McCourt served as the Chief Corporate Development Officer at Cato Bioventures and Vice President of Sales and Marketing at Cato Research, a global contract research and development organization, from 2019 to 2021 where she led commercial strategy and development; as Executive VP of Business Development & Alliances for Nighthawk Biosciences Inc. (formerly Heat Biologics Inc.) (NYSE American: NHWK), a U.S. biotechnology company focused on immunotherapy from 2016 to 2019; as Chief Corporate Development Officer for Edgemont Pharmaceuticals LLC, a biotechnology company focused on neuroscience from 2015 to 2016; as Vice President of Business Development for Agenus Inc. (NASDAQ: AGEN), a biotechnology company focused on immunotherapy from 2013 to 2015; and as Chief Business Officer for Amakem Therapeutics, a kinase platform company focusing on new treatments for ophthalmology and respiratory conditions from 2007 to 2012.

Ms. McCourt also served as Senior Vice President of Business Development and Marketing for Ingenix Pharmaceutical Services, Inc. from January 2003 to January 2007, a health care information, technology and research company and a wholly owned subsidiary of UnitedHealth Group Inc. Prior to Ingenix, from January 2002 to May 2003, Ms. McCourt served as Vice President of Corporate Development and Marketing at ActivBiotics, Inc., a biotechnology company focused on developing and commercializing antibiotics and combination therapies for the treatment of acute and chronic infections. Ms. McCourt's prior biotechnology and pharmaceutical experience also includes roles in business development, marketing, medical affairs, training, corporate communications, and investor relations at Praecis Pharmaceuticals Inc., a biotechnology company focused on the development of novel compounds to address unmet medical needs or improve existing therapies as Chief Commercial Officer from 1998 to 2002 and Abbott Laboratories/Takeda Global from 1991 to 1998.

Ms. McCourt holds a B.S.in Pharmacy, with a specialization in Industrial Pharmacy from the Massachusetts College of Pharmacy and Health Sciences, and graduated summa cum laude with an MBA from the University of Phoenix in General Management.

Board of Directors

Rev. Dr. Jim Sherblom has served as a member of our board of directors since January 2021. Until February 2022, he also served as our Executive Chairman, leading our corporate reorganization and Series B fundraising effort, repositioning our mission and vision, recruiting a new senior management team, building out a diverse and inclusive board of directors, and seeking future funding. Dr. Sherblom has served as a member of the Holdco Board since May 2022. We are proud to have such an unusual and timely set of skills and life experiences available as we enter this compassionate new era in medicine. From 1980 to 1983 he worked for Bain and Company, a management consulting firm, in Boston, London, and Munich. From 1984 to 1989 he served as Senior Vice President and Chief Financial Officer of Genzyme Corporation (Nasdaq:GENZ), a biotechnology company, and successfully transitioned Genzyme from a private to a public company. From 1989 to 1993 Dr. Sherblom served as Chairman and CEO of Transgenic Sciences Inc. (Nasdaq: TSI), a biotechnology company, which he also transitioned to public company status. For fifteen years, from 1996 to 2011, he was the founding Managing Partner of Seaflower Ventures, a life sciences venture fund. From 2005 to 2015, he also served as Senior Minister at First Parish Unitarian Universalist in Brookline, MA. Since 2016 Dr. Sherblom has been focused on his investments in three private technology oriented social impact companies: GrainPro Inc., which produces and distributes hermetic post-harvest solutions addressing hunger and extreme poverty in the developing world; Connected Homecare, which utilizes proprietary software and smart phones to monitor and provide better care for patients at home; and Comera. Dr. Sherblom holds a B.A. from Yale, an MBA from Harvard, and a Master's in Divinity and Doctor of Ministry from Andover Newton Theological School. Dr. Sherblom is well-qualified to serve as our director due to his extensive experience in senior management, finance, strategy, and investment, as well as the compassionate vision he brings to the industry.

Stuart Randle has served as a member of our board of directors since June 2021. Mr. Randle has 30 years of biomedical experience including as Division President of Baxter Healthcare and its spin-off Allegiance Healthcare from 1993 to 1998, President and CEO of ACT Medical, a medical device company, from 1998 to 2001, President and CEO of GI Dynamics Inc. (ASX: GID) from 2004 to 2014, and most recently, President and CEO of Ivenix, Inc., a medical technology manufacturer, from 2015 to 2018. He serves on the Board of Directors of Teleflex (NYSE: TFX) and Beacon Roofing Supply (Nasdaq: BECN) and was previously on the Boards of Flex Pharma (Nasdaq: FLKS), Specialized Health Products International, Inc. (OTCBB: SHPI), and GI Dynamics Inc. (ASX: GID). He was also an Entrepreneur-in-Residence for Advanced Technology Ventures, LP, a healthcare and IT venture capital firm. Mr. Randle holds a B.S. from Cornell University and MBA from Northwestern University. Mr. Randle is well-qualified to serve as our director due to his extensive experience in industry senior management.

Edward Sullivan, CPA, has served as a member of our board of directors since September 2021. Mr. Sullivan began his career with KPMG, a global network of professional firms providing audit, tax, and advisory services, in 1985 as an auditor and retired from KPMG in 2020. He is a comprehensive business strategist and financial expert with 35 years of experience advising public and private companies at all stages of development from early stage, pre-IPO businesses to multi-billion-dollar market cap public companies. He has counselled multinational corporations in various industries and advised businesses through years of growth and transformational change. Mr. Sullivan holds a B.S.in Accounting from Bryant University. Mr. Sullivan is well-qualified to serve as our director due to his extensive strategic and financial experience.

Roopom Banerjee MPP, has served as a member of our board of directors since September 2021. Mr. Banerjee has over 25 years of experience spanning corporate strategy, investment banking, private equity, company formation, operating leadership and scientific research. Mr. Banerjee is the Founder and Managing Partner of WhiteLeaf Advisors, an advisory firm for healthcare clients in biotechnology, medical devices, tools and diagnostics, since 2017, a Senior Advisor to Bain Capital, a management consulting firm, since 2020 and an Operating Partner at CRG Investments, a private investment firm, since 2018. Previously, Mr. Banerjee was President and CEO of Raindance Technologies, a company specialized in the development and application of droplet microfluidic technology, from 2010 to 2016, which pioneered the first liquid biopsy blood tests for noninvasive cancer detection, Director of Investment Banking at Leerink Swann, an investment bank, from 2005 to 2009, a Management Consultant at McKinsey, a consulting firm, from 1999 to 2005, and a Summer Associate at Goldman Sachs in 1998. Mr. Banerjee started his career as a scientist at the Dana Farber Cancer Institute, Whitehead Institute/MIT Center for Genome Research, and Massachusetts General Hospital. Mr. Banerjee holds dual B.S. degrees in Biology and Economics from Massachusetts Institute of Technology, and a Master's in Public Policy from Harvard University. Mr. Banerjee is well-qualified to serve as our director due to his extensive management, strategic, and investment experience.

Kirsten Flowers has served as a member of our board of directors since August 2021. Since January 2020, Ms. Flowers has served as the Chief Commercial Officer of Kura Oncology, Inc. (Nasdaq: Kura), a biotechnology company, and brings more than 15 years of pharmaceutical and biotech experience. She has been the Chief Commercial Officer for Kura since January 2020 and previously served as Senior Vice President of Commercial Operations at Array Biopharma Inc. (Nasdaq: ARRY), ("Array") a biopharmaceutical company, from 2017 to 2019 where she built and led the commercial organization that delivered the successful launch of Braftovi® + Mektovi® for patients with BRAF-mutant melanoma. Before joining Array, Kirsten was with Pfizer Inc. (NYSE: PFE), a pharmaceutical and biotechnology company, where she held several leadership positions, including the U.S. commercial lead for the launch of the blockbuster drugs IBRANCE® in breast cancer and INLYTA® in renal cell carcinoma. Ms. Flowers also serves on the board of directors for PMV Pharmaceuticals, Inc. (Nasdaq: PMVP). Ms. Flowers earned her MBA from Harvard Business School, and her B.S. in Molecular & Cellular Biology and Psychology from the University of Arizona. Ms. Flowers is well-qualified to serve as our director due to her extensive industry commercialization and launch experience.

William A. Wexler has served as a member of our strategic advisory board since November 17, 2020 and as a member of our board of directors since May 2022. Over the course of his career, Mr. Wexler has worked on over 150 individual projects, serving in various capacities including as Chairman, Chief Executive Officer, Chief Restructuring Officer and other designated roles of senior responsibility. Since April 2017, he has served as Chairman of the Board and in August 2017 he was also appointed Chief Executive Officer of Homer City Holdings, LLC, a holding company which owns and operates a multiple unit merchant power plant located in Pennsylvania. From July 2012 to December 2019, he served in various roles, including as Chairman of the Board, interim Chief Executive Officer, Chief Executive Officer and sole director and shareholder representative of Upstate New York Power Producers, Inc., a holding company that owned and operated power plants throughout upstate New York. In May 2016, he helped facilitate a sale of the company to an energy-specific hedge fund, generating a significant aggregate return to shareholders. From January 2012 to April 2013, Mr. Wexler served as Chief Restructuring Officer of VMR Electronics, LLC, a manufacturer of cable assembly products for the electronics interconnect industry. Between 2006 and 2011, he served as a Managing Director and national finance practice lead at BBK, Ltd., a turn-around advisory firm. From 2002 to 2005, he served as group Managing Director of corporate restructuring at Huron Consulting Group, LLC. From 2000 to 2002, he was a Managing Director at Berenson Minella & Co., a boutique investment-banking firm. Between 1986 and 2000 he served as a Senior Director at BNP Paribas, where he established and led Paribas Properties, Inc., a real estate investment arm of the bank, and also where he was a lead officer of the then newly created U.S. asset workout group. Mr. Wexler started his professional career in 1981 in commercial lease brokerage, asset management and investment sales at Jones Lang Wootton (now Jones Lang LaSalle) where he worked until 1986. He earned a B.A. in Political Science from Johns Hopkins University.

Corporate Governance

We have structured our corporate governance in a manner we believe will closely align our interests with those of our stockholders. Notable features of this corporate governance include:

- we have independent director representation on our audit, compensation and nominating and corporate governance committees;
- our independent directors will meet regularly in executive sessions without the presence of our corporate officers or non-independent directors;
- at least one of our directors, Edward Sullivan, qualifies as an "audit committee financial expert" as defined by the SEC; and

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors, which is staggered in three classes, and each director has been assigned to one of the three classes. At each annual meeting of stockholders, a class of directors will be elected for a 3-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the year 2023 for Class I directors, 2024 for Class II directors and 2025 for Class III directors. Our Class I directors consist of Rev. Dr. Jim Sherblom and Stuart Randle; our Class II directors consist of Jeffrey S. Hackman and Edward Sullivan; and our Class III directors consist of Roopom Banerjee, MPP, Kirsten Flowers and William A. Wexler.

Board Committees

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and standing committees. We have a standing audit committee, nominating and corporate governance committee and compensation committee. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

Audit Committee

Our audit committee consists of Edward Sullivan (Chair), Kirsten Flowers, and Roopom Banerjee. Our board of directors has determined that each member is independent under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. Our board of directors has determined that Edward Sullivan is an "audit committee financial expert" within the meaning of SEC regulations. Our board of directors has also determined that each member of the audit committee has the requisite financial expertise required under the applicable Nasdaq requirements. In arriving at this determination, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to 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

The compensation committee consists of Roopom Banerjee (Chair), Kirsten Flowers and Stuart Randle. Our board of directors has determined that each member is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Service Code of 1986, as amended ("the Code"). The primary purpose of the compensation committee is to discharge the responsibilities of our board of directors 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 includes:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to the our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- 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 of directors 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

Our nominating and corporate governance committee consists of Stuart Randle (Chair), Edward Sullivan, and William A. Wexler. Our board of directors has determined that each member is independent under Nasdaq listing standards.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying, evaluating and selecting, or recommending that our board of directors approve, nominees for election to our board of directors;
- evaluating the performance of our board of directors 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 of directors regarding corporate governance guidelines and matters.

Risk Oversight

We do not have a standing risk management committee, but rather administer this oversight function directly through our board of directors as a whole, as well as through various standing committees that address risks inherent in their respective areas of oversight. Our board of directors focuses on our general risk management strategy, the most significant risks facing us, and oversees the implementation of risk mitigation strategies by management. Our audit committee is also responsible for discussing our policies with respect to risk assessment and risk management. Our compensation committee is responsible for overseeing the management of risks relating to executive compensation plans and arrangements and assesses and monitors whether compensation plans, policies and programs comply with applicable legal and regulatory requirements. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors leadership structure.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee (or other committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of our code of business conduct and ethics is posted on the corporate governance section of our corporate website at https://comeralifesciences.com/. The information on any of our websites is deemed not to be incorporated in this Report or to be part of this Report.

Delinquent Section 16(a) Reports

Our executive officers and directors and persons who own beneficially more than 10% of our equity securities are required under Section 16(a) of the Securities Exchange Act of 1934 to file reports of ownership and changes in their ownership of our securities with the SEC. They must also furnish copies of these reports to us. Based solely on a review of those reports and written representations from the reporting persons, we believe that for our 2022 fiscal year our executive officers, directors and 10% beneficial owners complied with all applicable Section 16(a) filing requirements, except as provided herein. Each of Edward Sullivan, Roopom Banerjee, Kirsten Flowers, James Sherblom and Stuart Randle, our current non-employee directors, and Barbara Finck and John Yee, our former non-employee directors, each failed to disclose one transaction that should have been disclosed on a Form 4 on a timely basis. Each of these individuals have since filed a Form 5 on a timely basis to disclose the omitted transaction. Each of David Soane and The Soane Family Trust, Charles Cherington, 10% beneficial owners, and Michael G. Campbell, our chief financial officer, did not timely file a Form 3 due on May 29, 2022, but has subsequently filed such Form 3.

ITEM 11. Executive Compensation.

Executive Summary

This section discusses the material components of our executive compensation program. As an emerging growth company, we comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. These three current officers are referred to as our named executive officers.

In 2022, our "named executive officers" and their positions were as follows:

- Jeffrey Hackman, Chief Executive Officer, President and Director
- Michael Campbell, Chief Financial Officer and Executive Vice President
- Neal Muni, MD, Chief Operating Officer and Executive Vice President

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-equity incentive plan compensation ($)(2)	All Other Compensation ($)	Total ($)
Jeffrey Hackman Chief Executive Officer (3)	2022	400,000	—	535,200	—	—	935,200
	2021	132,543	51,052	161,640	—	—	345,235
Michael Campbell, Chief Financial Officer(4)	2022	201,882	—	954,900	—	—	1,156,782
	2021	—	—	—	—	—	—
Neal Muni, MD Chief Operating Officer(5)	2022	350,000	—	89,200	—	—	439,200
	2021	106,178	45,989	121,230	—	—	273,397

(1) Amounts reflect the full grant-date fair value of stock options granted, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. For more information, see footnote 2 "*Basis of Presentation and Significant Accounting Policies— Stock-Based Compensation Expense*" found elsewhere in this Report.

(2) In Furtherance of the Company's cash conservation efforts and to align the interests of the named executive officers with those of the Company's stockholders, our board of directors decided not to grant any cash bonuses to the named executive officers for the fiscal year ended December 31, 2022. In lieu of a cash bonus, on February 14, 2023, our board of directors awarded each of the named executive officers the following options to purchase shares of our common stock at an exercise price equal to the grant date fair value of $1.30 per share:

Name	Option Awarded in Lieu of a Cash Bonus
Jeffrey Hackman	100,000
Michael Campbell	25,000
Neal Muni	100,000

Twenty-five percent of the shares underlying such options vest on February 14, 2024, with the remaining shares vesting on a monthly basis on the 14th day of each month thereafter.

(3) Mr. Hackman became our Chief Executive Officer on September 1, 2021.
(4) Mr. Campbell became our Chief Financial Officer on June 15, 2022.
(5) Mr. Muni became our Chief Operating Officer on September 13, 2021.

Narrative Disclosure to Summary Compensation Table

2022 Base Salaries

The named executive officers receive a base salary to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. The 2022 annual base salaries for our named executive officers were:

Name	2022 Annual Base Salary ($)
Jeffrey Hackman	400,000
Michael Campbell	375,000
Neal Muni	350,000

2022 Non-Equity Incentive Compensation

We pay cash incentive compensation to reward our executives for their performance over the fiscal year, based on performance goals established by our board of directors. For the year ended December 31, 2022, the Compensation Committee of the Board approved the following target bonuses for each named executive officer: up to 50% of Mr. Hackman's base salary, up to 40% of Mr. Campbell's base salary and up to $140,000 for Mr. Muni.

Equity Compensation

We grant stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program pursuant to the Comera Life Sciences Holdings, Inc. 2022 Equity and Incentive Plan (the "2022 Plan"). The 2022 Plan is administered by our board of directors or a committee appointed by it to administer the 2022 Plan. Typically, options granted under the 2022 Plan vest as to 25% of the underlying shares on the first anniversary of the date of grant and in equal monthly installments over the following three years, subject to the holder's continued employment with us, and expire ten years after the date of grant. Our stock options are intended to qualify as "incentive stock options" to the extent permitted under the Code.

The following table sets forth the stock options granted to our named executive officers during 2022. These options were granted under the 2022 Plan, with exercise prices equal to the fair market value of our common stock on the date of grant. The number of securities reflected in the table below represent shares of our common stock.

Named Executive Officer	2022 Stock Options Granted
Jeffrey Hackman	300,000 (1)
Michael Campbell	450,000 (1)
Neal Muni, MD	50,000 (1)

_____

(1) The option vests (subject to continued service)as to 25% of the underlying shares on the first anniversary of the date of grant and in equal monthly installments over the following three years.

In furtherance of our cash conservation efforts and to align the interests of the named executive officers with those of our stockholders, our board of directors decided to grant, in lieu of a cash bonus, options to purchase shares of our common stock, which were granted on February 14, 2023.

Other Elements of Compensation — Employee Benefits and Perquisites

Health/Welfare Plans. During their employment, our named executive officers are eligible to participate in our employee benefit plans and programs, including medical and dental benefits, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans.

Outstanding Equity Awards at 2022 Fiscal Year End

The following table summarizes the number of shares of our common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2022. The number of securities underlying unexercised options as of December 31, 2022, represent shares of our common stock.

Name	Grant Date	Underlying Unexercised Options(#) Exercisable	Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Jeffrey Hackman	9/16/2021 (1)(2)	86,749	190,849	0.59	9/16/2031
	8/09/2022 (1)(3)	—	300,000	2.77	8/9/2032
Michael Campbell	6/15/2022 (1)(3)	—	450,000	3.72	6/15/2032
Neal Muni, MD	9/16/2021(1)(2)	65,062	143,136	0.59	9/16/2031
	8/09/2022 (1)(3)	—	50,000	2.77	8/9/2032

_____

(1) 25% of the underlying shares of the option (subject to continued service)vests on the first anniversary of the date of grant and in equal monthly installments over the following three years.
(2) Originally issued pursuant to the Comera Life Sciences, Inc. 2021 Stock Option and Grant Plan (the “2021 Plan”).
(3) Issued pursuant to the 2022 Plan.

Employment Offer Letters

Each of the named executive officers has entered into an offer letter agreement with us. The employment of each officer is “at will” and the agreement may be terminated by either party, with or without cause, without the payment of any severance. In addition, Mr. Campbell entered into an offer letter agreement with us subsequent to the Closing of the Transaction.

Pursuant to Mr. Hackman’s offer letter, Mr. Hackman is entitled to an initial annual base salary of $400,000 and he is also eligible for a performance-based cash bonus of up to $140,000, each subject to adjustment from time to time, at the board’s discretion. For the year ended December 31, 2021, Mr. Hackman received a bonus equal to $51,052 and his target bonus for the year ended December 31, 2022 was increased to 50% of his base salary.

Pursuant to Mr. Campbell’s offer letter, he is entitled to an initial annual base salary of $375,000 and a target bonus of 40% of his base salary (pro-rated in 2022), with the payment amount based upon performance as determined by the Company’s board of directors. Mr. Campbell’s base salary and target bonus are subject to adjustment from time to time in the board’s discretion.

Pursuant to Dr. Muni’s offer letter, Dr. Muni is entitled to an initial annual base salary of $350,000 and he is also eligible for a performance-based cash bonus of up to $140,000, each subject to adjustment from time to time, at the board’s discretion. For the year ended December 31, 2021, Dr. Muni received a bonus equal to $45,989.

Executive Employment Agreements

We do not currently have employment agreements with any of our executive officers. Each of Jeffrey S. Hackman, Michael Campbell and Neal Muni, our named executive officers, have entered into offer letter agreements with us. We intend to negotiate new employment agreements with our named executive officers at some point in the future. Such agreements will be entered into only with the approval of our Compensation Committee. For more information related to the offer letter agreements, see the section herein titled "*Item 11. Executive Compensation — Employment Offer Letters*".

Severance and Change in Control Arrangements with our Named Executive Officers

The employment of each of our named executive officers is at-will. Each of Mr. Hackman's and Dr. Muni's offer letters provide that if he is terminated "for cause" or resigns without "good reason" (as such terms are defined in the offer letter), he is paid his accrued but unpaid salary and reimbursement for any business expense (collectively, the "accrued obligations"). If either of Mr. Hackman or Dr. Muni is terminated "without cause" or resigns for "good reason", he will receive payments that equal the accrued obligations and six months of base salary as of the termination date, subject to execution, delivery and non-revocation of a separation agreement and release and compliance with restrictive covenant obligations set forth in the offer letter, with payments to commence within 60 days of the termination date and be made on the normal payroll schedule.

Mr. Campbell's employment offer letter provides that in the event of Mr. Campbell's termination without cause or his resignation for good reason (each as defined in his offer letter), in either case, Mr. Campbell will receive continued payment of his base salary for 180 days following termination; provided, however, that if Mr. Campbell's employment is terminated by the Company without cause prior to the first anniversary of his start date, Mr. Campbell will receive continued payment of his base salary for 90 days following termination. Mr. Campbell's right to receive severance payments pursuant to the terms of the offer letter is conditioned upon his: (i) entering into and complying with the terms of a separation agreement and release and (ii) compliance with his restrictive covenant obligations (as defined in his offer letter) in all respects.

Director Compensation

During 2022, our non-employee directors received the following cash and equity compensation for their service in such capacity.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(2)(3)	All Other Compensation ($)	Total ($)
Barbara Finck, MD(1)	48,333	—	—	48,333
Edward Sullivan, CPA	62,917	—	—	62,917
James Sherblom	81,250	—	—	81,250
John Yee, MD(1)	48,333	—	—	48,333
Kirsten Flowers	58,542	—	—	58,542
Roopom Banerjee, PhD	62,917	—	—	62,917
Stuart Randle	73,125	—	—	73,125
William A. Wexler	23,333	25,063	—	48,396

_____

(1) Resigned as of January 4, 2023.

(2) The table below shows the aggregate number of option awards held as of December 31, 2022 by each of our current non-employee directors who was serving as of that date.

Name	Number of Shares Underlying Options Outstanding as of December 31, 2022
Barbara Finck	37,111
Edward Sullivan, CPA	44,981
James Sherblom	36,241
John Yee, MD	41,608
Kirsten Flowers	44,981
Roopom Banerjee, PhD	44,981
Stuart Randle	44,981
William A. Wexler	14,200

_____

(3) Amounts reflect the full grant-date fair value of stock options granted, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. For more information see footnote 2 "*Basis of Presentation and Significant Accounting Policies—Stock-Based Compensation Expense*" found elsewhere in this Report.

Effective June 1, 2022, our board of directors approved a compensation program under which our non-employee directors are entitled to receive the following annual cash retainer and committee fees for their service as directors:

- for service as a director, an annual retainer of $40,000;
- for service as lead independent director, an annual retainer of $65,000;
- for service as a chair of the audit committee, $20,000;
- for service as a member of the audit committee other than as chair,$10,000;
- for service as a chair of the compensation committee, $15,000;
- for service as a member of the compensation committee other than as chair,$7,500;
- for service as a chair of the nominating committee, $10,000; and
- for service as a member of the nominating committee other than as a chair, $5,000.

In addition, our board of directors approved the following equity compensation program for non-employee directors effective as of June 1, 2022:

- an initial stock option award to purchase 14,200 shares of our common stock will be made to each non-employee director upon their initial election to the board of directors and such options will have a three year vesting period, with one-third of the shares vesting on the one year anniversary of the date of grant and the remaining shares vesting monthly thereafter, in each case, subject to continued service as a non-employee director; and
- an annual stock option award to purchase 7,100 shares of our common stock (with no proration for directors initially elected in the twelve months preceding the date of the annual award) and such options will vest on the one-year anniversary of the date of grant subject to continued service as a non-employee director.

Options awarded to non-employee directors will: (i) have a term of ten years, (ii) have an exercise price equal to the closing price on the date grant and (iii) be subject to the terms and conditions of the 2022 Plan.

On February 14, 2023, our board of directors approved a temporary modification to our compensation program for non-employee directors. Effective as of January 1, 2023 and continuing until the date that we receive at least $10.0 million (the "Funding Threshold") from (i) gross proceeds from sales of our securities; (ii) revenues pursuant to contracts with strategic partners; and/or (iii) grants from government agencies or non-profit organizations (the "Modification Period"), the Company will cease to pay any cash compensation to non-employee directors and in lieu of such cash compensation, promptly after the filing of the Company's Form 10-Q or Form 10-K, as applicable, for the preceding quarter, starting with the Form 10-Q for first quarter of 2023, the board of directors shall grant to each non-employee director a stock option to purchase a number of shares of our common stock equal in value (using a Black-Scholes model) to the amount of cash that would otherwise be payable to such director for such quarter pursuant to our compensation program for non-employee directors, multiplied by 1.5.

For the avoidance of doubt, each quarterly option grant during the Modification Period will only be made with respect to each full fiscal quarter during the Modification Period and for the fiscal quarter in which the Funding Threshold is achieved, the Company will revert back to the compensation program for non-employee directors and pay its non-employee directors cash compensation for that quarter. Each quarterly option granted during the Modification Period will have an exercise price per share equal to the closing price of our common Stock on the date of grant, be fully vested on the date of grant, have a term of ten years and be subject to the terms and conditions of the 2022 Plan. The temporary modification to the compensation program for our non-employee directors does not modify the elements of the program that relate to (i) annual grants of stock options for non-employee directors or (ii) stock options granted to non-employee directors upon their initial election to the board of directors.

Promptly after the expiration of the Modification Period, the Company shall make a cash payment to each non-employee director equal to 50% of the cash that would have been paid to such non-employee director for each full fiscal quarter during the Modification Period if the temporary modification had never been implemented.

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

The following table shows the beneficial ownership of our common stock as of March 6, 2023 by:

- each person who is known by Holdco to be the beneficial owner of more than 5% of issued and outstanding shares of our common stock on an as-converted to our common stock basis;
- each named executive officer of Holdco; and
- all executive officers and directors of Holdco 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 that are currently exercisable or exercisable within 60 days. Beneficial ownership below includes shares that may be issuable to a person pursuant to the terms of the earn-out provision of the Business Combination Agreement (the "Earn-Out Shares").

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all of our common stock beneficially owned by them. Unless otherwise indicated below, we have based our calculation of the percentage of beneficial ownership on 22,302,693 shares of our common stock and 4,305 shares of our Series A Convertible Perpetual Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock") issued and outstanding as of January 20, 2023 (all of which are held by Maxim Partners LLC), representing 342,754 votes on an as converted basis, for an aggregate of 22,645,447 total votes as of March 6, 2023.

Name of Beneficial Owner(1)	**Common Stock Shares**	**Percent**	**% of Total Voting Power**
Named Executive Officers and Director			
Rev. Dr. James Sherblom(2)	710,724	3.2%	3.1%
Jeffrey S. Hackman(3)	157,482	*	*
Neal Muni, MD(4)	82,412	*	*
Michael G. Campbell, CPA	25,000	*	*
Stuart Randle(5)	165,512	*	*
Edward Sullivan, CPA(6)	57,388	*	*
Roopom Banerjee, MPP(7)	85,261	*	*
Kirsten Flowers(8)	64,990	*	*
William A. Wexler(9)	62,245	*	*
All executive officers and directors as a group (11 persons)	1,552,776	6.8%	6.7%
5% or More Holders			
David Soane et al.(10)	4,509,208	19.9%	19.6%
Phoenix Venture Partners LP(11)	3,830,836	17.2%	16.9%
OTR Acquisition Sponsor LLC(12)	1,305,917	5.9%	5.8%
Purchase Capital LLC(13)	1,184,393	5.1%	5.1%
OTR Founders LLC(14)	1,645,000	6.9%	6.8%
Cherington et al.(15)	4,434,410	18.6%	18.4%
IAF, LLC(16)	2,170,180	9.3%	9.2%
Freebird Partners LP(17)	1,313,423	5.7%	5.6%

* Indicates less than 1%

(1) Unless otherwise noted, the business address of each of our stockholders listed is c/o Comera Life Sciences Holdings Inc., 12 Gill Street, Suite 4650, Woburn, Massachusetts 01801.

(2) Consists of (a) 452,244 shares of our common stock, (b) 162,162 shares of our common stock subject to warrants exercisable for $1.23 per share, (c) 13,288 shares of our common stock subject to stock options exercisable for $0.59 per share and 1,183 shares of our common stock exercisable for $1.30 per share, in each case within 60 days of March 6, 2023 and (d) 81,847 Earn-Out Shares.

(3) Consists of (a) 47,600 shares of our common stock and (b) 109,882 shares of our common stock subject to stock options exercisable for $0.59 per share within 60 days of March 6, 2023.

(4) Consists of 82,412 shares of our common stock subject to stock options exercisable for $0.59 per share within 60 days of March 6, 2023.

(5) Consists of (a) 42,469 shares of our common stock, 67,566 shares of our common stock subject to warrants exercisable for $1.23 per share and 2,213 Earn-Out Shares held directly by Stuart Randle,(b) 12,369 shares of our common stock subject to stock options exercisable for $0.59 per share and 1,183 shares of our common stock exercisable for $1.30 per share, in each case within 60 days of March 6, 2023 held directly by Stuart Randle, and (c) 31,647 shares of our common stock and 8,065 Earn-Out Shares held by The Stuart A. Randle Trust of 1998 (the "Randle Trust"). Stuart Randle, a director of Holdco, is the trustee of the Randle Trust and may be deemed to indirectly beneficially own the shares of our common stock held by the Randle Trust.
(6) Consists of (a) 19,665 shares of our common stock, (b) 21,958 shares of our common stock subject to warrants exercisable for $1.23 per share, (c) 12,369 shares of our common stock subject to stock options exercisable for $0.59 per share and 1,183 shares of our common stock exercisable for $1.30 per share, in each case within 60 days of March 6, 2023, and (c) 2,213 Earn-Out Shares.
(7) Consists of (a) 28,956 shares of our common stock, (b) 40,540 shares of our common stock subject to warrants exercisable for $1.23 per share, (c) 12,369 shares of our common stock subject to stock options exercisable for $0.59 per share and 1,183 shares of our common stock exercisable for $1.30 per share, in each case within 60 days of March 6, 2023, and (d) 2,213 Earn-Out Shares.
(8) Consists of (a) 22,199 shares of our common stock, (b) 27,026 shares of our common stock subject to warrants exercisable for $1.23 per share, (c) 12,369 shares of our common stock subject to stock options exercisable for $0.59 per share and 1,183 shares of our common stock exercisable for $1.30 per share, in each case within 60 days of March 6, 2023, and (d) 2,213 Earn-Out Shares.
(9) Consists of (a) 11,062 shares of our common stock (b) 50,000 shares of our common stock subject to warrants exercisable for $11.50 per share and (c) 1,183 shares of our common stock subject to options exercisable for $1.30 per share, within 60 days of March 6, 2023.
(10) Consists of (a) 470,007 shares of our common stock and 119,779 Earn-Out Shares held by David Soane, (b) 2,673,274 shares of our common stock, 135,134 shares of our common stock subject to warrants exercisable for $1.23 per share, and 663,288 Earn-Out Shares, held by The Soane Family Trust, (c) 84,431 shares of our common stock, 135,134 shares of our common stock subject to warrants exercisable for $1.23 per share and 4,298 Earn-Out Shares, in each case, held by each of The Alexander V. Soane 2019 Irrevocable Trust and The Nicholas V. Soane 2019 Irrevocable Trust (together with The Soane Family Trust, the "Soane Trusts"). David Soane is the trustee of each of the Soane Trusts and may be deemed to indirectly beneficially own the shares of our common stock held thereby. The business address for each of the Soane Trusts and David Soane is c/o Soane Labs, LLC, 380 NE 72nd Terrace, Miami, Florida 33138. The information provided herein is based on an Amendment No. 1 to a Schedule 13D filed by David Soane and The Soane Family Trust with the SEC on January 6, 2023.
(11) Consists of 3,052,835 shares of our common stock and 778,001 Earn-Out Shares held by Phoenix Venture Partners LP (the "Phoenix Fund"). Phoenix General Partner LLC is the sole general partner of the Phoenix Fund and has sole authority to vote (or direct the vote of), and to dispose (or direct the disposal) of, these shares on behalf of the Phoenix Fund. Phoenix Fund disclaims beneficial ownership of the listed shares of our common stock, except to the extent of its pecuniary interest therein. The business address of the beneficial owners named herein is 1700 El Camino Real, Suite 355, San Mateo, California 94402. The information provided herein is based on a Schedule 13G filed by the Phoenix Fund and Phoenix General Partner LLC with the SEC on May 31, 2022.
(12) The business address of the stockholder is 1395 Brickell Avenue, Suite 800, Miami, Florida 33131. (13) Consists of (a) 421,759 shares of our common stock and (b) 762,634 shares subject to warrants to purchase our common stock at an exercise price of $11.50 per share. The business address of the stockholder is 1395 Brickell Avenue, Suite 800, Miami, Florida 33131.
(14) Consists of (a) 245,000 shares of our common stock and (b) 1,400,000 shares of our common stock subject to warrants exercisable for $11.50 per share. The business address of the stockholder is 1221 Brickell Avenue, Suite 2660, Miami, Florida 33131.
(15) Consists of (a) 1,276,398 shares of our common stock, 1,486,486 shares of our common stock subject to warrants exercisable for $1.23 per share and 116,782 Earn-Out Shares held directly by Charles Cherington, (b) 1,011,089 shares of our common stock and 257,672 Earn-Out Shares held by Cherington Holdings LLC, (c) 75,968 shares of our common stock and 19,360 Earn-Out Shares, in each case held by each of the Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington and Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington, and (d)75,967 shares of our common stock and 19,360 Earn-Out Shares held by the Ashley S. Pettus 2012 Irrevocable Trust FBO Cyrus B. Cherington (together with the Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington and Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington, the "Cherington Trusts"). Charles Cherington is the trustee of each of the Cherington Trusts and a partner of Cherington Holdings LLC, and may be deemed to beneficially own the shares of our common stock held thereby. The business address of Charles Cherington, Cherington Holdings LLC and each of the Cherington Trusts is c/o ARA Partners, 222 Berkeley Street, Suite 1270, Boston, MA 02116. The information disclosed herein is based on an Amendment No.1 to Schedule 13D filed by Charles Cherington with the SEC on January 6, 2023.

(16) Consists of (a) 1,010,583 shares of our common stock, (b) 1,033,782 shares of our common stock subject to warrants exercisable for $1.23 per share, and (c) 125,815 Earn-Out Shares. David W. Laughlin is the Sole Manager of IAF, LLC and may be deemed share beneficial ownership of the securities held of record thereby. Mr. Laughlin disclaims beneficial ownership in the securities held by IAF, LLC, except to the extent of any pecuniary interest therein. The business address of each of IAF, LLC and Mr. Laughlin is 15 Church Street, Charleston, South Carolina 29401.

(17) Consists of (a) 529,856 shares of our common stock, (b) 743,242 shares of our common stock subject to warrants exercisable for $1.23 per share, and (c) 40,325 Earn-Out Shares. Freebird Investments LLC serves as the general partner of Freebird Partners LP. Mr. Curtis Huff is the sole member and 100% owner of Freebird Investments LLC, the President of Freebird Partners LP and the Managing Member of Freebird Investments LLC. By virtue of these relationships, each of Freebird Investments LLC and Mr. Huff may be deemed to share beneficial ownership of the securities held of record by Freebird Partners LP. The business address of each of Freebird Partners LP, Freebird Investments LLC and Curtis Huff is 2800 Post Oak Blvd, Suite 2000. The information disclosed herein is based on a Schedule 13G filed by Freebird Partners LP, Freebird Investments LLC and Curtis Huff with the SEC on January 10, 2023.

Securities Authorized for Issuance Under Equity Compensation Plans

Prior to the consummation of the Transaction, Legacy Comera maintained the 2021 Plan. All awards under the 2021 Plan that were outstanding as of the close of the Transaction continue to be governed by the terms, conditions and procedures set forth in the 2021 Plan and any applicable award agreement, as those terms were equitably adjusted in connection with the Transaction, but these awards (the "Rollover Options") are considered outstanding under the 2022 Plan, which is described in more detail below. Both the 2022 Plan and 2021 Plan were approved by our or Legacy Comera's, as applicable, stockholders. The table below provides information regarding securities authorized for issuance as of December 31, 2022, under our equity compensation plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights, and vesting of outstanding restricted stock units	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
	(a)	(b)	(c)
Equity compensation plans approved by security holders	2,002,641	$ 1.70	57,198 (1)
Equity compensation plans not approved by security holders	150,000 (2)	1.36	—
Total	2,152,641	$ 1.69	851,165

(1) Includes shares issuable under our 2022 Plan, which may be issued in the form of stock options, stock appreciation rights restricted stock, unrestricted stock, restricted stock unites, dividend equivalent rights and cash awards. This number includes the automatic increase in shares to our 2022 Plan by its terms, added January 1 of each year and calculated as a 4% increase of the number of shares of our common stock issued and outstanding on the last day of immediately preceding fiscal year or such lesser number of shares of our common stock as determined by the 2022 Plan administrator.

(2) Consists of 150,000 shares subject to inducement options granted to Janice McCourt on November 8, 2022.

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

Policy on Related Person Transactions

We have adopted a formal written policy that became effective upon the completion of the Transaction which provides that our officers, directors, nominees for election as directors, beneficial owners of more than 5% of our common stock, any member of the immediate family of any of the foregoing persons and any firm, corporation or other entity in which any of the foregoing persons is employed or is a general partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, are not permitted to enter into a related party transaction with us without the approval of our Audit Committee, subject to certain exceptions. This written policy on transactions with related persons is in conformity with the requirements for issuers having publicly held common stock that is listed on Nasdaq.

The Audit Committee is responsible 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.

Indemnification Agreements

Prior to the closing of the Transaction, Legacy Comera has entered into contractual indemnification agreements with each of its directors and executive officers in addition to the indemnification provided for in the certificate of incorporation of Legacy Comera (as amended, the "Comera Charter"). These agreements, among other things, required Legacy Comera to indemnify the indemnitees for (a) attorneys' fees, judgments, penalties, fines, and settlement amounts incurred by an indemnitee in any proceeding other than a proceeding by or in the right of Legacy Comera; and (b) subject to certain limitations, attorneys' fees and certain expenses incurred by these individuals in any proceedings by or in the right Legacy of Comera.

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

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

Equity Financings

January 2023 PIPE Financing

On January 2, 2023, we entered into the "2023 PIPE Purchase Agreement with Purchasers", pursuant to which we agreed to issue and sell to the Purchasers in the January 2023 PIPE Financing an aggregate of 2,406,242 Units ("Units"), each Unit consisting of (i) one share of our common stock and (ii) one warrant (the "2023 PIPE Warrants") to purchase two shares of our common stock (the "Warrant Shares") at an exercise price of $1.23 per Warrant Share, for an aggregate purchase price of approximately $3.6 million, consisting of $1.48 per Unit, inclusive of $0.25 per Private Placement Warrant.

The Purchasers consisted of a select group of existing stockholders who were qualified institutional buyers, institutional accredited investors or accredited investors and include Rev. Dr. James Sherblom, Stuart Randle, Edward Sullivan, Roopom Banerjee and Kirsten Flowers, members of our board of directors and Barbara Finck, a former member of our board of directors, who participated on the same terms and subject to the same conditions as all other Purchasers.

The participating investors also included certain of our existing stockholders of who beneficially owned in excess of 5% of our issued and outstanding shares of common stock, at the time of the January 2023 PIPE Financing including: (i) The Alexander V. Soane 2019 Irrevocable Trust, The Nicholas V. Soane 2019 Irrevocable Trust and The Soane Family Trust, whose trustee in each case is David Soane, who in the aggregate may be considered to beneficially own in excess of 10% of our common stock currently issued and outstanding, and (ii) Charles Cherington, a former director of Legacy Comera and who may be considered to beneficially own in excess of 10% of our common stock currently issued and outstanding. The following table summarizes the dollar value of the investment of each related person in January 2023 PIPE Financing:

Purchaser Name	Relationship	Units Purchased (#)	Investment ($)
Rev. Dr. James Sherblom	Director	81,081	$ 120,000
Stuart Randle	Director	33,783	$ 49,999
Edward Sullivan	Director	10,979	$ 16,249
Roopom Banerjee	Director	20,270	$ 30,000
Kirsten Flowers	Director	13,513	$ 19,999
Barbara Finck	Former Director	6,756	$ 9,999
Charles Cherington	Former Director and 10% or more Shareholder	743,243	$ 1,100,000
The Alexander V. Soane 2019 Irrevocable Trust	10% or more Shareholder	67,567	$ 99,999
The Nicholas V. Soane Irrevocable Trust	10% or more Shareholder	67,567	$ 99,999
The Soane Family Trust	10% or more Shareholder	67,567	$ 99,999

Series B Preferred Stock Financing

From May 26, 2021 through July 15, 2021, Legacy Comera sold an aggregate of 3,970,465 shares of Legacy Comera Series B-1 Preferred Stock at a purchase price of $2.37 per share for an aggregate purchase price of $9.4 million, and issued 403,287 shares of Legacy Comera Series B-2 Preferred Stock to settle outstanding convertible notes with a principal balance of $750,000.

In connection with the Series B preferred stock financing, Legacy Comera also entered into the following agreements with investors, including each of Phoenix Venture Partners LP, The Soane Family Trust, Charles Cherington, and Cherington Holdings LLC:

- an investor rights agreement which granted registration rights, certain financial information rights and the right to examine the books and records of Legacy Comera. The agreement also granted to Phoenix Venture Partners LP and Cherington Holdings LLC the right to send a representative to attend meetings of the Legacy Comera board of directors in a nonvoting observer capacity; and
- a voting rights agreement which provided for the election of board members, the increase of authorized common stock, and drag-along rights; and
- a right of first refusal and co-sale agreement which granted the right to purchase stock that is part of a transfer and the right to sell stock as part of a transfer.

The following table summarizes purchases of Legacy Comera Series B Preferred Stock by related persons and their affiliated entities. None of Legacy Comera's executive officers were issued shares of Legacy Comera Series B Preferred Stock.

Stockholder	Shares of Series B-1 Preferred Stock	Shares of Series B-2 Preferred Stock(1)	Total Purchase Price
Phoenix Venture Partners, LP[(2)]	—	134,429	255,415
The Soane Family Trust[(3)]	210,971	134,429	755,416
Cherington et al[(4)]	210,971	134,429	755,416
The Stuart A. Randle Trust of 1998[(5)]	42,194	—	100,000

(1) The purchase price for each investor includes $250,000 plus accrued interest associated with convertible notes that were settled for shares of Legacy Comera Series B-2 Preferred Stock.

(2) Zachariah Jonasson is a former member of the Legacy Comera board of directors and is affiliated with Phoenix Venture Partners LP.

(3) The Soane Family Trust is owned and controlled by David Soane, the founder of Legacy Comera and a former board member and Chief Executive Officer.

(4) Cherington et al includes Charles Cherington, Cherington Holdings LLC, the Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington, the Ashley S. Pettus 2012 Irrevocable Trust FBO Cyrus B. Cherington, and the Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington. Cherington et al is a principal owner of the Company.

(5) Stuart Randle is a member of the our board of directors and is affiliated with The Stuart A. Randle Trust of 1998.

Conversion from LLC to Corporation

On April 30, 2021, Legacy Comera filed a Certificate of Conversion with the Secretary of State of Delaware converting from a limited liability company to a corporation. Upon conversion, the capital units issued and outstanding were converted into the same number of shares of Legacy Comera Series A Preferred Stock. Each Incentive Unit issued and outstanding was cancelled upon the conversion.

The following table summarizes the converted Legacy Comera Series A Preferred Stock by related persons and their affiliated entities.

Stockholder	Capital Units in the LLC	Shares of Series A Preferred Stock
Phoenix Venture Partners, LP(1)	3,935,845	3,935,845
Soane et al(2)	3,169,699	3,169,699
Cherington et al(3)	1,517,490	1,517,490

(1) Zachariah Jonasson was a member of the Legacy Comera board of directors and is affiliated with Phoenix Venture Partners LP. The shares of Series A Preferred Stock include 3,000,000, 333,333, 91,777, 333,334, 147,834, and 29,567 shares of Legacy Comera Series A-1 Preferred Stock, Comera Series A-2 Preferred Stock, Comera Series A-3 Preferred Stock, Comera Series A-4 Preferred Stock, Legacy Comera Series A-5 Preferred Stock, and Legacy Comera Series A-6 Preferred Stock, respectively, held by Phoenix Venture Partners LP.

(2) Soane et al includes The Soane Family Trust, The Alexander V. Soane 2019 Irrevocable Trust, and The Nicholas V. Soane 2019 Irrevocable Trust. The shares of Series A Preferred Stock include (a) 3,000,000, 918, 16,667, 89,287, 17,857, 210,971, and 134,429 shares of Legacy Comera Series A-1 Preferred Stock, Legacy Comera Series A-3 Preferred Stock, Legacy Comera Series A-4 Preferred Stock, Legacy Comera Series A-5 Preferred Stock, and Legacy Comera Series A-6 Preferred Stock, respectively, held by The Soane Family Trust, (b) 22,485 shares of Legacy Comera Series A-3 Preferred Stock held by The Alexander V. Soane 2019 Irrevocable Trust, and (c) 22,485 shares of Legacy Comera Series A-3 Preferred Stock held by The Nicholas V. Soane Irrevocable Trust.

(3) Cherington et al includes Charles Cherington, Cherington Holdings LLC, the Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington, the Ashley S. Pettus 2012 Irrevocable Trust FBO Cyrus B. Cherington, and the Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington. Cherington et al is a principal owner of the Company. The shares of Series A Preferred Stock include (a) 933,334, 73,421, 29,477, 147,834, and 29,567 shares of Legacy Comera Series A-2 Preferred Stock, Legacy Comera Series A-3 Preferred Stock, Legacy Comera Series A-4 Preferred Stock, Legacy Comera Series A-5 Preferred Stock, and Legacy Comera Series A-6 Preferred Stock, respectively, held by Cherington Holdings LLC, (b) 101,286 shares of Legacy Comera Series A-4 Preferred Stock held by Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington, (c) 101,285 shares of Legacy Comera Series A-4 Preferred Stock held by Ashley S. Pettus 2012 Irrevocable Trust FBO Cyrus B. Cherington, and (d) 101,286 shares of Legacy Comera Series A-4 Preferred Stock held by Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington.

Convertible Debt Financing

On January 14, 2021, Legacy Comera entered into a Convertible Promissory Note Purchase Agreement with Phoenix Venture Partners LP, The Soane Family Trust, and Cherington Holdings LLC for an aggregate principal amount of up to $1,000,000. The notes under this agreement provided for conversion into capital units upon a financing at 80% of the per unit price sold in the financing.

On January 19, 2021, Legacy Comera entered into Convertible Promissory Note agreements with each of Phoenix Venture Partners LP, The Soane Family Trust, and Cherington Holdings LLC for principal amounts of $250,000 each. These arrangements were modified upon the completion of the corporate reorganization to, among other things, adjust for the conversion to be into preferred stock. These convertible notes accrued interest at an annual rate of 6.5%. On May 26, 2021, these convertible notes converted into 403,287 shares of Legacy Comera Series B-2 Preferred Stock.

Class B1 Capital Unit Financing

From February 19, 2020 to August 4, 2020, Legacy Comera sold an aggregate of 514,932 Class B1 Capital Units in the LLC at a purchase price of $2.80 per unit, for an aggregate purchase price of $1.4 million; and in connection with the issuance of Class B1 Capital Units, Legacy Comera issued 102,986 units of Class B1-A Capital Units that were subject to a distribution threshold value of $2.80 per unit.

The following table summarizes purchases of Legacy Comera Class B1 Capital Units by related persons and their affiliated entities. None of Legacy Comera's executive officers purchased Legacy Comera Class B1 Capital Units, nor were they issued Legacy Comera Class B1-A Capital Units.

Unit Holder	Capital B1 Capital Units	Capital B1-A Capital Units	Total Purchase Price
Phoenix Venture Partners, LP(1)	147,834	29,567	413,935
Soane et al(2)	89,287	17,857	250,004
Cherington et al(3)	147,834	29,567	413,935

(1) Zachariah Jonasson was a member of the Legacy Comera board of directors and is affiliated with Phoenix Venture Partners LP.
(2) The Soane Family Trust is owned and controlled by David Soane, the co-founder of Legacy Comera and a holder of more than 5% of the outstanding shares of our common stock.
(3) Cherington Holdings LLC is owned and controlled by Charles Cherington, and a holder of more than 5% of the outstanding shares of our common stock.

Legacy Comera Stockholder Agreements

Legacy Comera entered into an amended and restated investors' rights agreement, an amended and restated right of first refusal and co-sale agreement and an amended and restated voting agreement, each dated May 26, 2021 (collectively, the "Legacy Comera Stockholder Agreements"), which granted rights to certain holders of its stock, including Phoenix Venture Partners, LP of which Zachariah Jonasson, a former member of the Legacy Comera board of directors, is affiliated, and Soane Family et al, of which David Soane, is affiliated and Cherington et al, of which Charles Cherington is affiliated (collectively, the "Agreement Parties"). Pursuant to the Legacy Comera Stockholder Agreements, certain holders of Legacy Comera Capital Stock, including the Agreement Parties, agreed to vote in a certain way on certain matters, including with respect to the election of directors of Legacy Comera. The Legacy Comera Stockholder Agreements also provided the parties thereto with certain registration rights, preemptive rights, information and inspection rights, drag-along rights, right of first refusal and co-sale rights, among other rights. The Legacy Comera Stockholder Agreements terminated upon the consummation of the Transaction.

In connection with the consummation of the Transaction, we entered into a Registration Rights and Lock-up Agreement with certain of our stockholders, pursuant to which we agreed to register for resale, pursuant to Rule 415 under the Securities Act, our common stock and other Holdco equity securities that are held by the parties thereto from time to time.

Employment Agreements

We have entered into offer letter agreements with each of our executive officers. See "*Item 11. Executive Compensation — Employment Offer Letters*."

Transactions with Board Members and Major Investors

In 2021, Legacy Comera granted stock options to its directors and certain investors to purchase shares of Legacy Comera Common Stock at an exercise price of $0.45 per share. All such grants were non-qualified stock options and were subject to vesting on various schedules. The following table summarizes all such grants during the year ended December 31, 2021. The number of securities underlying the options set forth in the table below represent shares of Legacy Comera Common Stock, and neither such numbers nor the associated exercise prices give effect to the conversion of such options upon the consummation of the Transaction into options to acquire shares of our common stock.

Name	Grant Date	Number of Securities Underlying Award	Option Exercise Price ($)	Option Expiration Date
Zachariah Jonasson	6/8/21(1)	167,106	0.45	6/8/2031
David Soane	6/8/21(1)	626,650	0.45	6/8/2031
Charles Cherington	6/8/21(1)	400,000	0.45	6/8/2031
James Sherblom	6/8/21(2)	475,198	0.45	6/8/2031
V. Bryan Lawlis	6/8/21(3)	96,946	0.45	6/8/2031
Barbara Finck, MD	6/8/21(4)	70,000	0.45	6/8/2031
John Yee, MD	6/8/21(5)	70,000	0.45	6/8/2031
Edward Sullivan, CPA	9/16/21(5)	70,000	0.45	9/16/2031
Roopom Banerjee, PhD	9/16/21(5)	70,000	0.45	9/16/2031
Kirsten Flowers	9/16/21(5)	70,000	0.45	9/16/2031
Stuart Randle	9/16/21(5)	70,000	0.45	9/16/2031

_____

(1) The shares were fully vested upon grant.

(2) 410,966 shares vested immediately and the remaining shares vest in 41 equal monthly installments. On August 18, 2021, Dr. Sherblom exercised his option to purchase 400,000 shares of Comera Common Stock.

(3) 29,018 shares vested immediately and the remaining shares vest in 36 equal monthly installments.

(4) 5,832 shares vested immediately and the remaining shares vest in 44 equal monthly installments.

(5) The shares vest in 48 equal monthly installments.

Soane-Related Company Activities

We obtain services from certain entities affiliated with David Soane and the Company provides administrative services to an entity affiliated with David Soane. The related parties are affiliated entities through common equity ownership with financial and operational interests.

During the year ended December 31, 2020, we Company recognized $3,000 and $300 of general and administrative expense and research and development expense related to these contracts, respectively. The agreement related to these services was terminated on March 31, 2020.

During the years ended December 31, 2021 and 2020, we Company recognized $8,000 and $21,000, respectively, as a reduction to general and administrative expense related to these contracts.

Director Independence

Under Nasdaq listing standards, a majority of the members of our board of directors must qualify as “independent,” as affirmatively determined by our board of directors. Under the rules of Nasdaq, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Each individual serving on our board of directors, other than Jeffrey S. Hackman, qualifies as an independent director under Nasdaq listing standards.

ITEM 14. Principal Accounting Fees and Services.

Audit Fees

The aggregate fees for audit and other services provided by Baker Tilly US, LLP, our independent registered public accounting firm for fiscal years 2022 and 2021 are as follows:

	2022	2021
Audit Fees[(1)]	$ 584,575	$ 107,500
Audit Related Fees	64,000	15,000
Tax Fees	20,500	4,425
Total	$ 669,075	$ 126,925

_____

(1) "Audit Fees" consist of fees in connection with the audit of the Company's annual consolidated financial statements, including audited financial statements presented in its Registration Statement on Form S-4 filed with the SEC in connection with the Business Combination, audited financial statements presented in the Company's annual report on Form 10-K, review of quarterly financial statements presented in our quarterly reports on Form 10-Q and services that are normally provided by the Company's independent registered public accounting firm in connection with statutory and regulatory filings. Included in the 2022 Audit Fees are fees billed in connection with the Business Combination.

Our Audit Committee has adopted procedures requiring the pre-approval of all non-audit (including tax) services performed by our independent registered public accounting firm in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is to be reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the Audit Committee for each engagement of the independent registered public accounting firm to perform other audit-related or other non-audit services. For engagements for audit-related or tax-related services within a specified dollar limit, the Chair of the Audit Committee has authority to provide such prior approval, and he reports to the full committee whenever he has exercised that authority. The Audit Committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

The standard applied by the Audit Committee in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid therefore and other related factors are consistent with the independent registered public accounting firm's independence under guidelines of the SEC and applicable professional standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm's performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm's familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period, would tend to reduce the independent registered public accounting firm's ability to exercise independent judgment in performing the audit.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

Documents filed as part of this Report

(1) All financial statements

(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the financial statements and accompanying notes included in this Report.

(3) Exhibits required by Item 601 of Regulation S-K

The following is a list of exhibits filed as a part of this Report:

Exhibit Number	Description
2.1^	Business Combination Agreement, dated as of January 31, 2022, among the Registrant, OTR Acquisition Corp., CLS Sub Merger 1 Corp., CLS Sub Merger 2 Corp. and Comera Life Sciences, Inc. (incorporated by reference to Exhibit 2.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
2.2	First Amendment to Business Combination Agreement, dated as of May 19, 2022 among the Registrant, OTR Acquisition Corp., CLS Sub Merger 1 Corp., CLS Sub Merger 2 Corp. and Comera Life Sciences, Inc. (incorporated by reference to Exhibit 2.2 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
3.2	Certificate of Designation of the Series A Convertible Perpetual Preferred Stock (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
4.1	Specimen Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.2 to Amendment No. 3 to the registration statement on Form 2-4, filed by the Registrant with the SEC on April 11, 2022).
4.2	Specimen Warrant Certificate of the Registrant (incorporated by reference to Exhibit 4.3 to OTR Acquisition Corp.'s Amendment No. 1 to Registration Statement on Form S-1, filed with the SEC on September 28, 2020).
4.3	OTR Warrant Agreement, dated November 17, 2020, by and between OTR Acquisition Corp. and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.1 to OTR Acquisition Corp.'s Current Report on Form 8-K, filed with the SEC on November 23, 2020).
4.4	Assignment, Assumption and Amendment to OTR Warrant Agreement among OTR Acquisition Corp., the Registrant and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.4 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
4.5	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on January 4, 2023).
4.6*	Description of Securities.

10.1	Securities Purchase Agreement dated January 2, 2023, by and among Comera Life Sciences Holdings, Inc. and the Purchasers defined therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on January 4, 2023).
10.2	Registration Rights Agreement dated January 4, 2023, by and among Comera Life Sciences Holdings, Inc. and the Purchasers defined therein (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant with the SEC on January 4, 2023).
10.3	Purchase Agreement, dated August 31, 2022, between the Registrant and Arena Business Solutions Global SPC II, Ltd. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on August 31, 2022).
10.4#	Comera Life Sciences Holdings, Inc. 2022 Equity and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.5#	Form of Nonstatutory Stock Option Agreement under the Comera Life Sciences Holdings, Inc. 2022 Equity and Incentive Plan (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.6#	Form of Incentive Stock Option Agreement under the Comera Life Sciences Holdings, Inc. 2022 Equity and Incentive Plan (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.7#*	Form of Nonstatutory Stock Option Agreement (Inducement Award).
10.8#	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by the Registrant on May 25, 2022).
10.9#†	Offer Letter Agreement dated October 17, 2016, issued by Reform Biologics LLC to John M. Sorvillo (incorporated by reference to Exhibit 10.8 to Amendment No. 3 to the registration statement on Form S-4, filed by the Registrant with the SEC on April 11, 2022)
10.10#†	Offer Letter Agreement dated March 14, 2017, issued by Reform Biologics LLC to Robert Mahoney (incorporated by reference to Exhibit 10.10 to Amendment No. 3 to the registration statement on Form S-4, filed by the Registrant with the SEC on April 11, 2022).
10.11#	Offer Letter Agreement dated September 1, 2021, issued by Reform Biologics, Inc. to Neal Muni (incorporated by reference to Exhibit 10.9 to Amendment No. 3 to the registration statement on Form S-4, filed by the Registrant with the SEC on April 11, 2022).
10.12#†	Offer Letter Agreement dated September 1, 2021, issued by Reform Biologics, Inc. to Jeffrey S. Hackman (incorporated by reference to Exhibit 10.7 to Amendment No. 3 to the registration statement on Form S-4, filed by the Registrant with the SEC on April 11, 2022).
10.13#	Letter of promotion dated October 12, 2021, issued by Reform Biologics, Inc. to Robert Mahoney (incorporated by reference to Exhibit 10.11 to Amendment No. 3 to the registration statement on Form S-4, filed by the Registrant with the SEC on April 11, 2022).
10.14#†	Offer Letter Agreement dated June 13, 2022, between Comera Life Sciences Holdings, Inc. and Michael Campbell (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 17, 2022).
10.15#	Offer Letter Agreement dated October 25, 2022, between Comera Life Sciences Holdings, Inc. and Janice McCourt (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed by the Registrant with the SEC on February 3, 2023.
10.16	Reform Biologics, Inc. 2021 Stock Option and Grant Plan (incorporated by reference to Exhibit 10.6 to the registration statement on Form S-4, filed by the Registrant with the SEC on March 8, 2022).
10.17	Stockholder Support Agreement, dated as of January 31, 2022, by and among the Registrant, OTR Acquisition Corp., Comera Life Sciences, Inc. and certain stockholders of Comera Life Sciences, Inc. party thereto (incorporated by reference to Exhibit 10.12 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.18	Registration Rights and Lock-up Agreement dated May 19, 2022, by and among the Registrant, OTR Acquisition Sponsor LLC and certain existing stockholders of Comera Life Sciences, Inc. and OTR Acquisition Corp. party thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
10.19	Letter Agreement dated May 19, 2022, by and between the Registrant and OTR Acquisition Sponsor LLC (incorporated by reference to Exhibit 10.14 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.20	Settlement and Release Agreement made and entered into as of May 19, 2022, between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 10.12 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).

10.21	Registration Rights Agreement made and entered into as of May 19, 2022, between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 10.13 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
21.1	List of subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 filed by the Registrant with the SEC on May 5, 2022).
23.1*	Consent of Baker Tilly US, LLP, independent registered accounting firm for the Registrant.
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 herewith.

# Indicates management contract or compensatory plan or arrangement.

^ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

ITEM 16. Form 10-K Summary

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Comera Life Sciences Holdings, Inc. and subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Comera Life Sciences Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock, stockholders' deficit and members' equity, and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that Comera Life Sciences Holdings, Inc. and subsidiaries will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has an accumulated deficit and has incurred recurring net losses since inception. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2021.

Tewksbury, Massachusetts
March 17, 2023

COMERA LIFE SCIENCES HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 446,607	$ 6,510,140
Restricted cash - current	1,505,625	—
Accounts receivable	34,320	—
Due from related parties	—	286
Deferred issuance costs	90,047	—
Prepaid expenses and other current assets	986,499	270,648
Total current assets	3,063,098	6,781,074
Restricted cash - noncurrent	50,000	50,000
Property and equipment, net	257,186	234,167
Right-of-use asset	313,629	320,373
Security deposit	43,200	32,200
Total assets	$ 3,727,113	$ 7,417,814
Liabilities, Convertible Preferred Stock, Stockholders' Deficit and Members' Equity		
Current liabilities:		
Accounts payable	$ 1,458,267	$ 416,941
Accrued expenses and other current liabilities	1,295,764	506,611
Insurance premium financing	455,562	—
Deposit liability	1,505,625	—
Deferred revenue	144,280	—
Lease liability - current	199,184	121,552
Total current liabilities	5,058,682	1,045,104
Derivative warrant liabilities	277,507	—
Lease liability - noncurrent	120,302	201,504
Total liabilities	5,456,491	1,246,608
Commitments and contingencies (Note 17)		
Series A convertible preferred stock	4,517,710	—
Convertible preferred stock	—	20,857,453
Stockholders' deficit:		
Common stock, $0.0001 par value; 150,000,000 shares authorized; 16,709,221 and 308,443 shares issued and outstanding as of December 31, 2022 and 2021, respectively	1,671	31
Additional paid-in capital	28,655,164	2,213,547
Accumulated deficit	(34,903,923)	(16,899,825)
Total stockholders' deficit and members' equity	(6,247,088)	(14,686,247)
Total liabilities, convertible preferred stock, stockholders' deficit and members' equity	$ 3,727,113	$ 7,417,814

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

COMERA LIFE SCIENCES HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2022	2021
Revenue	$ 633,102	$ 319,832
Cost of revenue	210,390	161,008
Operating expenses:		
Research and development	1,739,833	1,752,669
General and administrative	10,652,894	3,941,783
Total operating expenses	12,392,727	5,694,452
Loss from operations	(11,970,015)	(5,535,628)
Other income (expense), net:		
Change in fair value of derivative warrant liabilities	2,008,872	—
Reverse recapitalization issuance costs in excess of gross proceeds	(6,566,821)	—
Common stock purchase agreement issuance costs	(1,029,077)	—
Gain on debt extinguishment	—	160,588
Change in fair value of convertible notes	—	(76,738)
Interest expense	(20,391)	—
Other expense, net	(426,666)	—
Total other (expense) income, net	(6,034,083)	83,850
Net loss and comprehensive loss	(18,004,098)	(5,451,778)
Less: accretion of convertible preferred stock to redemption value	(373,856)	—
Net loss attributable to common stockholders or unit holders	$ (18,377,954)	$ (5,451,778)
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (1.76)	$ (1.81)
Weighted-average number of common shares or units used in computing net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ 10,452,697	$ 3,012,603

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

COMERA LIFE SCIENCES HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' DEFICIT AND MEMBERS' EQUITY

	Series A Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Capital Units		Incentive Units		Additional Paid-in	Accumulated	Total Stockholders' Deficit and Members' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount	Capital	Deficit	
Balance as of December 31, 2020	—	$ —	—	$ —	—	$ —	9,429,006	$ 10,681,040	1,987,474	$ —	$ 918,922	$ (11,448,047)	$ 151,915
Vesting of incentive units	—	—	—	—	—	—	—	—	32,939	—	—	—	—
Conversion of capital units into convertible preferred stock	—	—	9,429,006	10,681,040	—	—	(9,429,006)	(10,681,040)	—	—	—	—	(10,681,040)
Cancellation of incentive units upon corporate reorganization	—	—		—	—	—	—	—	(2,020,413)	—	—	—	—
Issuance of convertible preferred stock, net of issuance costs of $60,327	—	—	4,373,752	10,176,413	—	—	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	308,443	31	—	—	—	—	179,969	—	180,000
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,114,656	—	1,114,656
Net loss	—	—	—	—	—	—	—	—	—	—	—	(5,451,778)	(5,451,778)
Balance as of December 31, 2021	—	—	13,802,758	20,857,453	308,443	31	—	—	—	—	2,213,547	(16,899,825)	(14,686,247)
Issuance of common stock upon exercise of stock options, net of shares withheld to settle tax withholding requirements	—	—	—	—	1,415,124	142	—	—	—	—	659,359	—	659,501
Conversion of convertible preferred stock	—	—	(13,802,758)	(20,857,453)	10,643,403	1,064	—	—	—	—	20,856,389	—	20,857,453
Issuance of common stock in connection with the Transaction and Maxim Private Placement, net of redemptions, net tangible assets, and issuance costs of $7.5 million	—	—	—	—	3,570,215	357	—	—	—	—	3,443,393	—	3,443,750
Issuance of convertible preferred stock, net of issuance costs of $161,535	4,305	4,143,854	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of Public Warrants	—	—	—	—	100	—	—	—	—	—	1,150		1,150
Issuance of common stock in connection with common stock purchase agreement	—	—	—	—	475,755	48	—	—	—	—	829,421	—	829,469
Issuance of Commitment Shares	—	—	—	—	296,181	29	—	—	—	—	649,971	—	650,000
Accretion of convertible preferred stock to redemption value	—	373,856	—	—	—	—	—	—	—	—	(373,856)	—	(373,856)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	375,790	—	375,790
Net loss	—	—	—	—	—	—	—	—	—	—	—	(18,004,098)	(18,004,098)
Balance as of December 31, 2022	4,305	$ 4,517,710	—	$ —	16,709,221	$ 1,671	—	$ —	—	$ —	$ 28,655,164	$ (34,903,923)	$ (6,247,088)

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

COMERA LIFE SCIENCES HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2022	**2021**
Net loss	(18,004,098)	(5,451,778)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	375,790	1,114,656
Depreciation expense	93,947	86,136
Noncash lease expense	3,174	2,683
Gain on debt extinguishment	—	(160,588)
Change in fair value of convertible notes	—	76,738
Reverse recapitalization issuance costs in excess of gross proceeds	6,566,821	—
Noncash common stock purchase agreement issuance costs	650,000	—
Change in fair value of derivative warrant liabilities	(2,008,872)	—
Changes in operating assets and liabilities:		
Accounts receivable	(34,320)	109,868
Prepaid expenses and other current assets	800,149	(230,955)
Due from related parties	286	5,114
Accounts payable	862,920	319,325
Accrued expenses and other current liabilities	789,153	399,801
Security deposits	(11,000)	—
Deferred revenue	144,280	(28,949)
Net cash used in operating activities	(9,771,770)	(3,757,949)
Cash flows from investing activities:		
Purchases of property and equipment	(28,607)	(142,013)
Net cash flows used in investing activities	(28,607)	(142,013)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs	—	9,349,675
Net proceeds from Transaction and Maxim Private Placement	3,307,162	—
Advance deposits related to proceeds from issuances of January 2023 PIPE Financing	1,505,625	—
Repayment of insurance premium financing	(1,060,438)	—
Proceeds from issuance of convertible notes	—	750,000
Proceeds from common stock purchase agreement	829,469	—
Proceeds from exercise of public warrants	1,150	—
Proceeds from exercise of stock options	659,501	180,000
Net cash provided by financing activities	5,242,469	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	(4,557,908)	6,379,713
Cash, cash equivalents, and restricted cash at beginning of year	6,560,140	180,427
Cash, cash equivalents, and restricted cash at end of year	$ 2,002,232	$ 6,560,140
Supplemental information:		
Cash and cash equivalents	$ 446,607	$ 6,510,140
Restricted cash - current	1,505,625	—
Restricted cash - noncurrent	50,000	50,000
Total cash, cash equivalents, and restricted cash shown in consolidated statements of cash flows	$ 2,002,232	$ 6,560,140
Supplemental disclosure of noncash investing and financing activities:		
Property and equipment purchases in accounts payable	$ 88,359	$ —
Right-of-use asset obtained in exchange for lease liability	$ 162,634	$ 404,625
Financing of insurance premiums	$ 1,516,000	$ —
January 2023 PIPE deferred issuance costs in accounts payable	$ 90,047	$ —
Conversion of capital units into convertible preferred stock	$ —	$ 10,681,040
Conversion of convertible preferred stock into common stock	$ 20,857,453	$ —
Settlement of convertible notes for convertible preferred stock	$ —	$ 826,738
Issuance of common stock to settle success fee	$ 3,443,750	$ —
Issuance of Series A preferred stock to settle stock issuance costs	$ 910,000	$ —
Accretion on convertible preferred stock	$ 373,856	$ —
Issuance of Series A preferred stock to settle underwriting fees payable assumed in Transaction	$ 3,395,389	$ —
Derivative warrant liabilities assumed in Transaction	$ 2,286,379	$ —

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

COMERA LIFE SCIENCES HOLDINGS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Formation and Organization

Comera Life Sciences Holdings, Inc. ("CLS Holdings", "Comera" or the "Company") was incorporated in Delaware on January 25, 2022 as a wholly-owned subsidiary of Comera Life Sciences, Inc. ("Legacy Comera") for the purpose of effecting the Transaction (as defined below).

Legacy Comera was formed in the state of Delaware on January 2, 2014 as ReForm Biologics, LLC. On April 30, 2021, Legacy Comera completed a corporate reorganization (the "Reorganization") and changed its name to ReForm Biologics, Inc. As part of the Reorganization, each issued and outstanding capital unit of Legacy Comera as of the date of the Reorganization was exchanged for shares of convertible preferred stock of Legacy Comera and previously outstanding incentive units of Legacy Comera were cancelled. On January 7, 2022, Legacy Comera changed its name to Comera Life Sciences, Inc. to emphasize Comera's vision of a compassionate new era in medicine. On May 19, 2022, in connection with the closing of the Transaction, Legacy Comera became a wholly-owned subsidiary of CLS Holdings.

Comera is a biotechnology company dedicated to promoting a compassionate new era in medicine. The Company applies a deep knowledge of formulation science and technology to transform essential biologic medicines from intravenous ("IV") to subcutaneous ("SQ") forms. This revolutionary technology provides patients and families with the freedom of self-injectable care, allowing them to realize the potential of these life changing therapies, and to unlock the vast potential of their own lives. To accomplish this, Comera is developing an internal portfolio of proprietary therapeutics that incorporate Comera's innovative proprietary formulation platform, SQore™. Comera also collaborates with pharmaceutical and biotechnology companies, applying the SQore™ platform to Comera's partners' biologic medicines to deliver enhanced formulations that facilitate self-injectable care.

Transaction

On May 19, 2022 (the "Closing Date"), the Company consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. ("OTR") and Legacy Comera (the "Transaction"), in accordance with the Business Combination Agreement dated January 31, 2022 (as amended on May 19, 2022, the "Business Combination Agreement") by and among the Company, Legacy Comera, OTR, CLS Sub Merger 1 Corp., a Delaware corporation, ("Comera Merger Sub"), and CLS Sub Merger 2 Corp., a Delaware corporation ("OTR Merger Sub"). Pursuant to the terms of the Business Combination Agreement, a transaction between OTR and Legacy Comera was effected through the merger of Comera Merger Sub with and into Legacy Comera, with Legacy Comera surviving the merger as a wholly-owned subsidiary of CLS Holdings, and through a merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly-owned subsidiary of CLS Holdings. OTR was formed in the state of Delaware for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination with one or more businesses or entities.

As further described in Note 3, the Transaction was accounted for as a reverse recapitalization because Legacy Comera has been determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction treated Legacy Comera as issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and 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 United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Significant discovery, research and development efforts, including clinical testing and regulatory approval, are required prior to commercialization of any potential product candidates. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Through December 31, 2022, the Company has funded its operations primarily with proceeds from the issuance of capital units, convertible notes, common stock, and preferred stock. The Company has incurred recurring losses since its inception, including net losses of $18.0 million and $5.5 million for the years ended December 31, 2022 and 2021, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $34.9 million. The Company expects to continue to generate operating losses for the near future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company does not believe the cash, cash equivalents, and restricted cash on hand as of December 31, 2022 of $2.0 million, and subsequent proceeds from the January 2023 PIPE Financing will be sufficient to fund its operations for the next twelve months from the date the consolidated financial statements are issued. The Company will be required to raise additional capital to continue to fund its operations. Such funding may not be available on acceptable terms, or at all. If the Company is unable to access additional funds when needed, it may not be able to continue operations or the Company may be required to delay, scale back or eliminate some or all of its ongoing research and development efforts and other operations. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm its business, financial condition and results of operations. These uncertainties create substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the valuation of derivative warrant liabilities, valuation of earn-out shares, and revenue recognition. Changes in estimates are recorded in the period in which they become known. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and, given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

Fair Value Measurements

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

Level 1 - Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2 - Inputs to the valuation methodology observable inputs, other than those in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or that can be corroborated by observable market data.

Level 3 - Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Due primarily to their short-term nature, certain financial instruments have fair values that approximate their carrying values. These instruments include restricted cash - current, accounts receivable, due from related parties, accounts payable, accrued expenses, deposit liability, and insurance premium financing.

Concentrations of Credit Risk

The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contacts, or other foreign hedging arrangements. Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, restricted cash and accounts receivable. The Company maintains its cash, cash equivalents and restricted cash with high-credit quality financial institutions which, at times, may exceed federally insured limits. The Company believes it is not exposed to any significant losses due to credit risk on cash, cash equivalents and restricted cash. Accounts receivable are stated at the amount management expects to collect from outstanding balances. The Company performs ongoing credit evaluations of the Company's customers and generally requires no collateral to secure accounts receivable. The Company maintains an allowance for credit losses for accounts receivable. Consequently, the Company believes that its exposure to losses due to credit risk on net accounts receivable is limited.

Segments

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the chief operating decision maker, or CODM, in making decisions regarding resource allocation and assessing performance. The Company's CODM is the chief executive officer and our operations are managed as a single segment for the purposes of assessing performance and making operating decisions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at acquisition to be cash equivalents. The Company maintains its cash and cash equivalents at accredited financial institutions, in amounts that may exceed federally insured limits.

Restricted Cash

Restricted cash relates to amounts that are held on deposit by a financial institution for a specific purpose and are not available to the Company for immediate or general business use. The restricted cash as of December 31, 2022 is primarily associated with $1.5 million of advance deposits received in connection with the January 2023 PIPE Financing prior to the execution of the agreement. Amounts are reported as current or noncurrent based on when the cash is expected to become available to the Company for its general business use.

Accounts Receivable

Accounts receivable are stated at the amount management expects to collect from outstanding balances. An allowance for credit losses is provided for amounts considered to be uncollectible based upon management's assessment of the collectability, which considers historical write-off experience and any specific risks identified in customer collection matters. Credit losses are written off against the allowance when identified. As of December 31, 2022 and 2021, there was no allowance for credit losses.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, as follows:

Laboratory equipment	5 years
Leasehold improvements	Lesser of lease term or 10 years
Computer equipment	3 years
Other equipment	5 years

Impairment of Long-Lived Assets

The Company evaluates long-lived assets, which consist of property and equipment and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be 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 group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group 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 group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment loss during the years ended December 31, 2022 and 2021.

Leases

The Company determines if an arrangement is a lease at inception and the classification of such lease. Operating leases include right-of-use assets and operating lease liabilities, which are recorded in the Company's balance sheets.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses the implicit rate when readily determinable or an incremental borrowing rate applicable to the Company based on the information available at the commencement date, if an implicit rate is not readily available, in determining the present value of lease payments. As the Company has no existing or proposed collateralized borrowing arrangements, to determine a reasonable incremental borrowing rate, the Company considers collateral assumptions, the lease term, the Company's current credit risk profile, and rates for existing borrowing arrangements for comparable peer companies. The Company accounts for the lease and fixed non-lease components as a single lease component for real estate leases. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term.

Fair Value Option for Convertible Notes

As permitted under ASC 825, *Financial Instruments* ("ASC 825"), the Company elected the fair value option to account for its convertible notes issued during 2021 (the "Notes"). The Company recorded the convertible notes at fair value subsequently remeasured them to fair value at each reporting date and upon settlement. Changes in fair value were recognized as a component of other (expense) income, net in the consolidated statements of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the issuance of the convertible notes were recognized as expense as incurred in 2021.

Convertible Preferred Stock

The Company accounts for convertible preferred stock subject to possible redemption in accordance with the guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The Series A Preferred Stock is redeemable at the option of the holder upon the occurrence of a qualified financing. As the Series A Preferred Stock is considered to be contingently redeemable, it has been classified outside of permanent equity. The Series A Preferred Stock has been accreted to its redemption value since the contingent event is considered probable of occurring.

Reverse Recapitalization

The Transaction was accounted for as a reverse recapitalization, with OTR being treated as the "acquired" company and Legacy Comera being treated as the "acquirer" for accounting purposes based upon the pre-merger shareholders of Legacy Comera holding the majority of the voting interests of CLS Holdings, Legacy Comera's existing management team serving as the initial management team of CLS Holdings, Legacy Comera's appointment of the majority of the initial board of directors of CLS Holdings, and Legacy Comera's operations comprising the ongoing operations of the Company. The Transaction was accounted for as the equivalent of Legacy Comera issuing stock for the net assets of OTR, accompanied by a reverse recapitalization. Accordingly, all historical financial information presented in these consolidated financial statements represents the accounts of CLS Holdings and Legacy Comera "as if" CLS Holdings and Legacy Comera, both entities under common control, are the predecessor. The net loss per share or unit, prior to the Transaction, has been adjusted to share amounts reflecting the Exchange Ratio established in the Transaction.

Derivative Warrant Liabilities

The Company classifies as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any warrants that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the company's control), (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement) or (iii) that contain reset provisions that do not qualify for the scope exception. The Company assesses classification of its common stock warrants and other freestanding warrant instrument at each reporting date to determine whether a change in classification between assets and liabilities is required.

The Company's freestanding warrant instruments consist of private placement warrants to purchase shares of common stock ("Private Placement Warrants") and public warrants to purchase shares of common stock ("Public Warrants") that were converted in connection with the Transaction. Following the Transaction, the Public Warrants are considered equity classified instruments since the shares underlying the Public Warrants are not redeemable and the Company has one single class of voting common stock, which does not preclude them from being considered indexed to the Company's equity and allows the Public Warrants to meet the criteria for equity classification per ASC 815, *Derivatives and Hedging* ("ASC 815"). Warrants that are determined to require equity classification are measured at fair value upon issuance and are not subsequently remeasured unless they are required to be reclassified.

The Private Placement Warrants are considered liability classified instruments because their settlement amount differs depending on the identity of the holder which precludes them from being considered indexed to the Company's equity. Accordingly, the Company recognizes the Private Placement Warrants as liabilities at fair value and adjusts the instruments to fair value using quoted prices of instruments with similar terms. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's consolidated statements of operations and comprehensive loss.

Income Taxes

From inception through April 30, 2021, the Company was a Delaware limited liability company for federal and state tax purposes and, therefore, all items of income or loss through April 30, 2021 flowed through to the members of the limited liability company. Accordingly, the Company did not record deferred tax assets or liabilities or have net operating loss carryforwards. Effective April 30, 2021, the Company converted from an LLC to a C corporation for federal and state income tax purposes. The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"), 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 tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. 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 recovered from future taxable income 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 estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. At December 31, 2022 and 2021, the Company has concluded that a full valuation allowance is necessary for its deferred tax assets.

The Company assesses the recording of uncertain tax positions by evaluating the minimum recognition threshold and measurement requirements a tax position must meet before being recognized as a benefit in the consolidated financial statements. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in the Company's statements of operations and comprehensive loss.

Revenue and Contract Balances

The Company's principal sources of revenue during the years ended December 31, 2022 and 2021, were derived from research and development service agreements with customers.

At inception, management determines whether contracts are within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), or other topics, including ASC 808, *Collaborative Arrangements* ("ASC 808"). For contracts or units of account that are determined to be within the scope of ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which management expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, management applies the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as a performance obligation is satisfied. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Identification of Performance Obligations. Performance obligations promised in a contract are identified at contract inception based on the goods and services that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation. In general, the Company's contracts typically contain one performance obligation to perform research services on behalf of its customers, which are generally performed over a short period of time, typically less than twelve months. These contracts typically include rights to negotiate for a license or other products and services upon completion of the research services.

Transaction Price. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. The Company's contracts typically contain upfront payments or fees for research services.

Research and Development Services. The promises under the Company's arrangements generally include research and development services to be performed by the Company on behalf of the counterparty. Payments or reimbursements from customers resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts. The Company uses an input method, according to the ratio of direct labor hours incurred to the total direct labor hours expected to be incurred in the future to satisfy the performance obligation. In management's judgment, this input method is the best measure of the transfer of control of the performance obligation. Reimbursements from and payments to the counterparty that are the result of a collaborative relationship, instead of a customer relationship, such as co-development activities, are recognized as the services are performed and presented as a reduction to research and development expense. To date, the Company has determined that all arrangements which include research and development services have been transacted with customers and recognized on a gross basis using ASC 606.

Customer Options. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Contract Balances. The Company classifies the right to consideration in exchange for deliverables as either a receivable or a contract asset. A receivable is a right to consideration that is unconditional (i.e., only the passage of time is required before payment is due). Such receivables are presented in accounts receivable in the accompanying balance sheets at their net estimated realizable value. An allowance for credit losses is maintained to provide for the estimated amount of receivables and contract assets that may not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and other applicable factors. Contract assets and liabilities are reported in a net position on a contract-by-contract basis at the end of each reporting period. Contract assets include unbilled amounts from contracts when revenue recognized exceeds the amount billed to the customer, and right to payment is not solely subject to the passage of time. Contract assets are included in prepaid expenses and other current assets in the accompanying balance sheets. Contract liabilities, which are presented as deferred revenue, consist of advance payments and billings in excess of revenue recognized. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Cost of Revenue

Cost of revenue primarily represents payroll and related personnel costs as well as allocated overhead, including occupancy and information technology expenses.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, and external costs of outside vendors. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the 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.

The Company has entered into various research and development related contracts. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the underlying activities.

Stock-Based Compensation Expense

Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. The Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock options, and formerly incentive units, with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance- or market-based vesting conditions. The Company accounts for forfeitures as they occur.

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 cash compensation costs are classified.

Given the absence of an active market for Legacy Comera's common stock, prior to the Transaction, the Company and the board of directors were required to estimate the fair value of Legacy Comera's common stock and incentive units at the time of each grant. The Company and the board of directors determined the estimated fair value of Legacy Comera's equity instruments based on a number of factors, including external market conditions affecting the biotechnology industry sector. The Company and the board of directors utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its equity instrument. Each valuation methodology includes estimates and assumptions that require the Company's judgment.

Comprehensive Loss

Comprehensive loss is defined as the change in equity from transactions and other events or circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders' deficit and members' equity that result from transactions and economic events other than those with stockholders and members. For the years ended December 31, 2022 and 2021, comprehensive loss is equal to net loss.

Net Loss per Share or Unit

The Company calculates basic and diluted net loss per share or unit in conformity with the two-class method required for participating securities. Under the two-class method, net loss is allocated between common stock or member units and other participating securities based on their participation rights.

Diluted net loss per unit is computed using the more dilutive of (a) the two-class method, (b) treasury stock method, or (c) if-converted method, as applicable, for potentially dilutive instruments. Potentially dilutive instruments consist of unvested incentive units and the potential issuance of common stock upon exercise of outstanding stock options or conversion of preferred stock. The dilutive effect of the convertible preferred stock is assessed by application of the "if-converted" method in periods where such application would be dilutive.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements and disclosures.

3. Transaction and Reverse Recapitalization

On May 19, 2022, the Company consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. and Comera Life Sciences, Inc., in accordance with the Business Combination Agreement.

Upon closing (i) Comera Merger Sub merged with and into Legacy Comera, with Legacy Comera surviving such merger as a direct wholly-owned subsidiary of CLS Holdings (the "Comera Merger") and (ii) OTR Merger Sub merged with and into OTR, with OTR surviving such merger as a direct wholly-owned subsidiary of CLS Holdings (the "OTR Merger"). At the closing of the Transaction (the "Closing"), by virtue of the Comera Merger, all shares of Legacy Comera common stock, par value $0.001 per share ("Legacy Comera Common Stock"), issued and outstanding immediately prior to the Closing (including shares of Legacy Comera Common Stock issued upon conversion of Legacy Comera preferred stock immediately prior to the Closing) were canceled and converted into the right to receive shares of CLS Holdings common stock, par value $0.0001 per share ("CLS Holdings Common Stock") and all outstanding Legacy Comera unvested stock options and Legacy Comera vested incentive stock options were converted into options to purchase shares of CLS Holdings Common Stock, all Legacy Comera vested in-the-money non-qualified stock options outstanding were net exercised for shares of Legacy Comera Common Stock and, upon the Closing as described above, those shares of Legacy Comera Common Stock were converted into the right to receive shares of CLS Holdings Common Stock.

In addition, at the Closing, CLS Holdings placed 3,150,000 shares of CLS Holdings Common Stock (the "Earn-Out Shares") into escrow. If, at any time during the period beginning on the Closing Date and expiring at the close of business on the second anniversary of the Closing Date (the "Earn-Out Period"), the volume-weighted average price of CLS Holdings Common Stock is equal to or greater than $12.50 for any 20 trading days within a period of 30 consecutive trading days (the "Earn-Out Trigger"), then within 10 business days following the achievement of the Earn-Out Trigger, the Earn-Out Shares will be released to the former holders of Legacy Comera Common Stock on a pro rata basis. If a change of control occurs during the Earn-Out Period that results in the holders of shares of CLS Holdings Common Stock receiving consideration equal to or in excess of $12.50 per share, then the Earn-Out Trigger shall be deemed to be satisfied if (i) the aggregate proceeds paid to, or in the event of an asset sale, available for distribution to, stockholders of CLS Holdings in such change of control transaction divided by (ii) (a) the number of outstanding shares of CLS Holdings Common Stock immediately prior to the consummation of such change of control transaction plus (b) Earn-Out Shares, is equal to or exceeds $12.50.

Upon the Closing, by virtue of the OTR Merger, all shares of common stock of OTR issued and outstanding immediately prior to the Closing were converted on a one-to-one basis into the right to receive shares of CLS Holdings Common Stock and all warrants of OTR outstanding were converted into warrants to purchase shares of CLS Holdings Common Stock. Holders of OTR Common Stock included in the units sold in the initial public offering of OTR were entitled to exercise redemption rights in connection with the Transaction. Holders of 9,769,363 shares of OTR Common Stock exercised their right to have their shares redeemed which resulted in the issuance of 3,472,654 shares of CLS Holdings Common Stock in the Transaction to the former stockholders of OTR.

In connection with the Transaction, CLS Holdings, Legacy Comera, OTR and Maxim Group LLC ("Maxim") entered into a Settlement and Release Agreement ("Settlement Agreement") pursuant to which CLS Holdings, Legacy Comera, OTR and Maxim agreed, among other things that (1) all deferred underwriting fees owed to Maxim pursuant to the underwriting agreement between OTR and Maxim dated November 17, 2020 (the "Underwriting Agreement") would be satisfied by the issuance by CLS Holdings to Maxim of 3,395 shares of CLS Holdings Series A Convertible Perpetual Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock") equal in value to $3.4 million; (2) Maxim would waive its right of first refusal contained in the Underwriting Agreement to act for OTR, or any successor, in future public and private offerings; (3) certain fees owed to Maxim under the advisory agreement between Legacy Comera and Maxim, dated October 13, 2020, as amended on August 16, 2021 and January 25, 2022 (the "Comera Advisory Agreement") would be satisfied by the issuance by CLS Holdings to Maxim of 910 shares of Series A Preferred Stock equal in value to $910 thousand; (4) Maxim would invest $1.0 million in a private placement of CLS Holdings Common Stock (the "Maxim Private Placement") at a value of $10.25 per share for 97,561 shares, which shares would receive certain registration rights under a separate registration rights agreement (the "Maxim Registration Rights Agreement"), (5) the 344,375 shares of CLS Holdings Common Stock issued to Maxim as a success fee for the Transaction under the Comera Advisory Agreement which were previously registered, would be unrestricted and freely tradable; and (6) certain of Maxim's rights to fees for transactions and financings consummated after the Transaction would be limited to transactions and financings with four specified counterparties previously introduced by Maxim.

The following summarizes the shares of CLS Holdings Common Stock issued and outstanding immediately following the Transaction as of May 19, 2022:

	Shares	%
Legacy Comera Stockholders	12,022,595	76%
OTR Public Stockholders	677,987	4%
OTR Founders	2,611,838	16%
Maxim (1)	624,765	4%
Total (2)	15,937,185	100%

(1) Represents (i) 97,561 shares of the CLS Holdings Common Stock purchased by Maxim in a private placement, (ii) 344,375 shares of the CLS Holdings Common Stock issued to Maxim by the Legacy Comera shareholders to settle Maxim's success fee, and (iii) 182,829 shares of the CLS Holdings Common Stock issued to Maxim in exchange for a like number of shares of OTR common stock received in connection with OTR's initial public offering.

(2) Excludes 3,150,000 Earn-Out Shares.

The following table presents the net tangible assets acquired from OTR and reconciles the elements of the Transaction to the consolidated statements of cash flows:

	Transaction
Cash	$ 5,643,508
Deferred underwriting fee payable	(3,395,389)
Derivative warrant liabilities	(2,286,379)
Net tangible assets acquired from OTR	(38,260)
Cash proceeds received from Maxim Private Placement	1,000,000
Gross proceeds from Transaction and Maxim Private Placement	961,740
Less: total issuance costs	(7,528,561)
Reverse recapitalization issuance costs in excess of gross proceeds	(6,566,821)
Add: derivative warrant liabilities assumed	2,286,379
Add: issuance of common stock to settle success fee	3,443,750
Add: issuance of Series A preferred stock to settle stock issuance costs and underwriting fees payable	4,305,389
Less: Series A preferred stock issuance costs	(161,535)
Net cash proceeds from Transaction and Maxim Private Placement	$ 3,307,162

The following table presents the net cash proceeds from the Transaction and Maxim Private Placement and reconciles the elements of the Transaction to the consolidated statements of convertible preferred stock, stockholders' deficit and members' equity:

	Transaction
Net cash proceeds from Transaction and Maxim Private Placement	$ 3,307,162
Add: Series A preferred stock issuance costs	161,535
Add: reverse recapitalization issuance costs in excess of gross proceeds	6,566,821
Less: derivative warrant liabilities assumed	(2,286,379)
Less: issuance of Series A preferred stock to settle stock issuance costs and underwriting fees payable	(4,305,389)
Issuance of common stock in connection with the Transaction and Maxim Private Placement, net of redemptions, net tangible assets, and issuance costs	$ 3,443,750

The Transaction was accounted for as a reverse recapitalization because Legacy Comera was determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction was treated as Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded. All outstanding common stock instruments, prior to the Transaction, have been retroactively adjusted to share amounts reflecting the Company's current capital structure, including adjustments based on the Exchange Ratio. Accordingly, certain amounts have been reclassified and retroactively adjusted to reflect the reverse recapitalization pursuant to the Transaction for all periods presented within the consolidated balance sheets and statements of convertible preferred stock, stockholders' deficit and members' equity.

Earn-Out Shares

The estimated fair value of the Earn-Out Shares at the Closing Date was approximately $8.63 per share, or $27.2 million in the aggregate. If the Earn-Out Trigger is not achieved for the two-year period following the Closing Date, the Earn-Out Shares will be cancelled and returned to treasury. The contingent obligation to issue Earn-Out Shares to Legacy Comera stockholders is considered indexed to the Company's own stock and meets the equity classification under ASC 815.

While the Earn-Out Shares are legally issued and placed into escrow, they are not considered outstanding for accounting purposes until resolution of the earn-out contingency.

The estimated acquisition-date fair value of the Earn-Out Shares was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes on a weekly basis over the Earn-Out Period using the most reliable information available. Assumptions used in the valuation at the Closing Date were as follows:

	Assumptions
Fair value of common stock	$ 9.91
Selected volatility	90.00%
Risk-free interest rate	2.60%
Contractual term (years)	2.0

Transaction Costs

In connection with the Transaction, the Company incurred direct and incremental costs of approximately $7.5 million related to the equity issuance, including $4.4 million of noncash expenses related to common stock and Series A Preferred Stock issued to Maxim, consisting primarily of investment banking and other professional fees. The costs related to the equity issuance were recorded to additional paid-in capital as a reduction of gross proceeds from the Transaction and Maxim Private Placement. The costs related to the equity issuance which exceeded gross proceeds received from the Transaction and Maxim Private Placement were recognized as a loss within other (expense) income, net.

The Company incurred approximately $1.5 million of expenses primarily related to advisory, legal, and accounting fees in conjunction with the Transaction, which were recorded in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

4. Fair Value of Financial Assets and Liabilities

The following table presents the Company's fair value hierarchy for its liabilities, which are measured at fair value on a recurring basis as of December 31, 2022:

	Fair Value Measurements at December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative warrant liabilities	$ —	$ 277,507	$ —	$ 277,507

There were no assets or liabilities for which fair value was required to be disclosed as of December 31, 2021. During the year ended December 31, 2022, there were no transfers between Level 1, Level 2 and Level 3.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2022	2021
Prepaid insurance	$ 913,611	$ —
Contract assets	—	85,018
Insurance recovery receivable	—	136,250
Other	72,888	49,380
Prepaid expenses and other current assets	$ 986,499	$ 270,648

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2022	2021
Lab equipment	$ 587,650	$ 587,650
Leasehold improvements	9,411	17,973
Computer equipment	32,178	21,747
Other equipment	36,149	9,411
Construction in Progress	88,359	—
	753,747	636,781
Less accumulated depreciation	(496,561)	(402,614)
Property and equipment, net	$ 257,186	$ 234,167

Depreciation expense for the years ended December 31, 2022 and 2021 was $94 thousand and $86 thousand, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
Accrued bonus	$ 767,093	$ 349,000
Professional fees	282,454	123,756
Accrued vacation	21,194	25,945
Other	225,023	7,910
Accrued expenses and other current liabilities	$ 1,295,764	$ 506,611

8. Insurance Premium Financing

In May 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is $1.5 million and incurs interest at a rate of 4.00%. The Company is required to make monthly payments of $154 thousand through March 2023. The outstanding balance as of December 31, 2022 was $0.5 million.

9. Legacy Comera Convertible Preferred Stock

As of December 31, 2021 and prior to the Transaction, the authorized capital stock of Legacy Comera included 14,051,702 shares of $0.001 par value preferred stock, of which 9,429,006 shares were designated as Series A Convertible Preferred Stock (“Legacy Comera Series A Preferred Stock”) and 4,622,696 shares were designated as Series B Convertible Preferred Stock (“Legacy Comera Series B Preferred Stock”).

In April 2021, Legacy Comera issued 6,000,000, 1,266,667, 527,752, 1,016,669, 514,932, and 102,986 shares of Series A-1, A-2, A-3, A-4, A-5, and A-6 Preferred Stock, respectively. The Legacy Comera Series A Preferred Stock was issued in settlement of previously outstanding capital units of ReForm Biologics, LLC as part of the Reorganization. During the year ended December 31, 2021, the Company issued 3,970,465 shares of Series B convertible preferred stock for net cash proceeds of $9.4 million and 403,287 shares of Series B convertible preferred stock to settle convertible notes originally issued to certain existing investors with a value of $827 thousand.

Immediately prior to the Transaction, all issued and outstanding shares of Legacy Comera Series A and B Preferred Stock were converted into Legacy Comera Common Stock.

10. Convertible Preferred Stock

As of December 31, 2022, the Company’s amended and restated certificate of incorporation (the “Articles”) provides for a class of authorized stock known as preferred stock, consisting of 1,000,000 shares, $0.0001 par value per share, issuable from time to time in one or more series. In connection with the Transaction, a certificate of designation was filed to designate and authorize the issuance of up to 4,305 shares of Series A Preferred Stock.

Convertible preferred stock consisted of the following as of December 31, 2022:

	Par Value	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	$ 0.0001	4,305	4,305	$ 4,517,710	$ 4,517,710	342,754

In May 2022, the Company issued 4,305 shares of Series A Preferred Stock ("the Preferred Stock"). The Preferred Stock was issued in connection with the Transaction and the Settlement Agreement (Note 3) in settlement of $4.3 million of underwriting and advisory fees owed to Maxim with an original purchase price of $1,000 per share (the "Series A Original Purchase Price"). The Company incurred $162 thousand of issuance costs in connection with the Series A Preferred Stock.

As of December 31, 2022, the holders of the Preferred Stock have the following rights and preferences:

Voting Rights—

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and are entitled to the number of votes equal to the number of whole shares of common stock into which such holders of preferred stock could convert on the record date for determination of stockholders entitled to vote. Except for the actions requiring the approval or consent of the holders of preferred stock, the holders of preferred stock shall vote together with the holders of common stock and vote as a single class.

Dividends—

The holders of the Preferred Stock shall be entitled to receive, prior and in preference to the declaration or payment of any dividend on any other currently-outstanding capital stock, dividends when, as and if declared by the Board of Directors, payable quarterly on January 1, April 1, July 1 and October 1 of each calendar year (each date a "Series A Quarterly Dividend Payment Date"), commencing on and including July 1, 2022, which dividends shall be paid in cash at a rate of 8.0% per annum on the Series A Original Purchase Price for the first six Series A Quarterly Dividend Payment Dates, which shall increase by 2% per annum from and after each successive Series A Quarterly Dividend Payment Date, up to a maximum of 18%. Such dividends shall cumulate quarterly at the Series A Dividend Rate if not declared and paid on a Series A Quarterly Dividend Payment Date. As of December 31, 2022, no cash dividends have been declared or paid and the Company has $213 thousand of cumulative dividends in arrears.

Liquidation Rights—

In the event of any voluntary or involuntary liquidation event, dissolution, winding up of the Company or upon the occurrence of certain events considered to be deemed liquidation events, each holder of the then outstanding Series A Preferred Stock will be entitled to receive a preferential payment equal to the Series A Original Purchase Price plus the aggregate amount of dividends then accrued, prior and in preference to any distributions to the holders of the common stock. After payments have been made in full to the holders of the Series A Preferred Stock, then, to the extent available, the remaining amounts will be distributed among the holders of the common stock, pro rata based on the number of shares of common stock held by each holder.

Conversion—

Each share of preferred stock is convertible into common stock, at any time, at the option of the holder, and without the payment of additional consideration, determined by dividing the Series A Original Issuance Price by $12.56 (as may be adjusted for stock splits, dilutive issuances and the like, the "Series A Conversion Price"); provided, however, in no event shall outstanding shares of the Preferred Stock be converted into more than 19.99% of the outstanding shares of common stock. The Company shall at all times reserve and keep available out of its authorized but unissued shares of common stock to effect the conversion of three hundred percent (300%) of all shares of the Preferred Stock then outstanding.

The Company evaluated its preferred stock and determined that its the Preferred Stock is considered an equity host. In making this determination, the Company's analysis followed the whole instrument approach which compares an individual feature against the entire preferred stock instrument which includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of the preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including: (1) whether the preferred stock included redemption features, (2) how and when any redemption features could be exercised, (3) whether the holders of preferred stock were entitled to dividends, (4) the voting rights of the preferred stock and (5) the existence and nature of any conversion rights. As a result of the Company's conclusion that the preferred stock represents an equity host, the conversion feature for the Preferred Stock is considered to be clearly and closely related to the preferred stock host instrument. Accordingly, the conversion feature for the Preferred Stock is not considered an embedded derivative that requires bifurcation.

Redemption—

The Preferred Stock is redeemable upon the occurrence of certain deemed liquidation events, as discussed above. In addition, the Company, may at any time, redeem the whole or any part of the outstanding Preferred Stock at a redemption price of $1,000 per share, subject to adjustment, plus all accumulated and unpaid dividends (the "Series A Redemption Price"). Further, if the Company closes on the issuance or sale of common stock or equivalents, including, without limitation, pursuant to an equity line of credit facility, a registered offering, a private investment in public equity or otherwise, resulting in net proceeds to the Company of at least $5,000,000, each holder of Series A Preferred Stock shall have the right to cause the Company to apply up to 30% of the aggregate proceeds from such issuance or sale in excess of $5,000,000, to the redemption of any or all of such holder's Series A Preferred Stock at the Series A Redemption Price.

As the preferred stock is considered to be contingently redeemable, it has been classified outside of permanent equity. Since the contingent redemption is considered probable, the Series A Preferred Stock will be accreted to its redemption value at each reporting date. The Company recorded accretion of $0.4 million, inclusive of $161 thousand of issuance costs, for the year ended December 31, 2022, which is considered a deemed dividend.

11. Common Stock

All common stock share amounts have been retroactively adjusted to reflect the Transaction and reverse recapitalization as described in Note 3.

Following the closing of the Transaction, the Company is authorized to issue 150,000,000 shares of common stock, $0.0001 par value. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock, on all matters submitted to the stockholders for a vote. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any, subject to the preferential dividend rights of the preferred stock. Through December 31, 2022, no cash dividends have been declared or paid.

As of December 31, 2022, the Company has reserved the following shares of common stock for future issuance:

Exercise of outstanding stock options	2,152,641
Available for issuance under equity compensation plans	57,198
Exercise of outstanding stock warrants	11,041,332
Conversion of Series A Preferred Stock	1,028,262
Reserved for issuance pursuant to the Arena Purchase Agreement	4,228,064
Total shares of authorized common stock reserved for future issuance	18,507,497

Common Stock Purchase Agreement

On August 31, 2022, the Company entered into a purchase agreement (the "Arena Purchase Agreement") with Arena Business Solutions Global SPC II, Ltd. ("Arena"), pursuant to which Arena has committed to purchase up to $15.0 million (the "Commitment Amount") of the Company's common stock, subject to an increase, at the Company's option, to $30.0 million of the Company's common stock (the "Additional Commitment Amount"). Under the terms and subject to the conditions of the Arena Purchase Agreement, the Company has the right, but not the obligation, to sell to Arena, and Arena is obligated to purchase up to $15.0 million of the Company's common stock, subject to increase at the Company's option by the Additional Commitment Amount. Such sales of common stock by the Company will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the approximately 36-month period commencing on the date of the Purchase Agreement, provided that the registration statement (the "Registration Statement") covering the resale by Arena of the shares of the Company's common stock purchased under the Purchase Agreement remains effective, and the other conditions set forth in the Arena Purchase Agreement are satisfied. The purchase price of the shares of the Company's common stock will be equal to 96% of the simple average of the daily VWAP of the Company's common stock immediately preceding the time of sale as computed under the Arena Purchase Agreement.

The Company determined that its right to sell shares of the Company's common stock to Arena represents a freestanding put option under ASC 815, but has a fair value of zero, and therefore no additional accounting was required. The Company issued 296,181 shares of common stock (the "Commitment Shares") to Arena as a commitment fee in connection with entering into the Arena Purchase Agreement. The $650 thousand fair value of the Commitment Shares along with $379 thousand of other issuance costs related to the Arena Purchase Agreement were recognized as a loss within other expense, net.

As of December 31, 2022, the Company had sold 475,755 shares of common stock under the Arena Purchase Agreement at a weighted-average price of $1.74 per share, resulting in net proceeds of $0.8 million for the year ended December 31, 2022.

12. Stock-Based Compensation

All common stock share and per share amounts related to the Company's incentive plans have been retroactively adjusted to reflect the Transaction and reverse recapitalization as described in Note 3.

2014 Restricted Unit Plan

On March 4, 2014, Legacy Comera established the 2014 Restricted Unit Plan (the "2014 Plan"). A total of 2,500,000 incentive units were authorized as part of the 2014 Plan, under which participants would receive membership interests in Legacy Comera. The 2014 Plan was extinguished on April 30, 2021 as a result of the Reorganization.

2021 Stock Option and Grant Plan

On April 30, 2021, Legacy Comera established the 2021 Stock Option and Grant Plan (the "2021 Plan"), which provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, unrestricted stock awards and restricted stock units. In connection with the closing of the Transaction, option awards outstanding under the 2021 Plan were exchanged for options to purchase shares of CLS Holdings Common Stock (the "Exchanged Options"), with proportional adjustments to the number of shares underlying the options and the exercise price of the options approved by the compensation committee and board of directors of Legacy Comera. Other than with respect to the exercise price and the number of shares of CLS Holdings Common Stock underlying the Exchanged Options, the Exchanged Options remain subject to the terms and conditions of the Legacy Comera option awards issued pursuant to the 2021 Plan. The Exchanged Options are outstanding under and count against the number of shares reserved for issuance pursuant to the 2022 Equity and Incentive Plan (the "2022 Plan"). Following the closing of the Transaction, no additional awards may be granted under the 2021 Plan.

As of December 31, 2022, there are 1,168,441 Exchanged Options outstanding, included in the 2,152,641 shares per the table in Note 11, which are potentially exercisable for 1,168,441 shares of CLS Holdings Common Stock at a weighted-average exercise price of $0.59 per share.

2022 Equity and Incentive Plan

On May 10, 2022, the Company established the 2022 Plan, which provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, unrestricted stock awards, restricted stock units, stock appreciation rights, cash awards and dividend equivalent rights. Incentive stock options may be granted only to the Company's employees, including officers. Non-statutory options, restricted stock awards, unrestricted stock awards, restricted stock units, stock appreciation rights, cash awards and dividend equivalent rights may be granted to employees, directors, consultants and key persons of the Company.

The total number of common shares authorized to be issued under the 2022 Plan was 2,059,839. The share pool will automatically increase on January 1 of each year by four percent of the number of shares of Stock outstanding on the immediately preceding December 31, or such lesser number of shares as approved by the board of directors. As of December 31, 2022, there were 2,152,641 options outstanding with a weighted-average exercise price of $1.67 and 57,198 shares available for future grants under the 2022 Plan.

Shares underlying awards that are forfeited, cancelled, reacquired by the Company prior to vesting, satisfied without the issuance of common stock, or are otherwise terminated under the 2022 Plan without having been fully exercised (including the Exchanged Options) will be available for future awards.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted were as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2022	2021
Expected option life (years)	6.1	5.6
Risk-free interest rate	3.37%	0.90%
Expected volatility	64.20%	62.84%
Expected dividend yield	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity for the year ended December 31, 2022:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	2,689,935	$ 0.59		$ 767
Granted	984,200	2.96		
Exercised	(1,385,310)	0.59		
Cancelled or forfeited	(136,184)	0.59		
Outstanding as of December 31, 2022	2,152,641	$ 1.67	9.1	$ 748
Exercisable as of December 31, 2022	484,444	$ 0.59	8.5	$ 310

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock.

The weighted-average grant-date fair value of the Company's stock options granted during the years ended December 31, 2022 and 2021 was $1.79 and $0.41, respectively.

As of December 31, 2022, total unrecognized compensation cost related to the unvested stock options was $1.9 million, which is expected to be recognized over a weighted-average period of 3.3 years.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Year Ended December 31,	
	2022	2021
Cost of revenue	$ 1,776	$ 19,876
Research and development	11,608	414,322
General and administrative	362,406	680,458
Total stock-based compensation	$ 375,790	$ 1,114,656

13. Common Stock Warrants

During the year ended December 31, 2022, there were 100 Public Warrants exercised, resulting in proceeds of $1,150. There were no warrants issued or expired during the same period.

The warrants were assumed as part of the Transaction and the following represents a summary of the warrants outstanding and exercisable at December 31, 2022:

					Number of Shares Underlying Warrants	
Description	Issue Date	Classification	Exercise Price	Expiration Date	Outstanding Shares	Exercisable Shares
Private Placement Warrants	Nov 17, 2020	Liability	$ 11.50	May 19, 2027	5,817,757	5,817,757
Public Warrants	Nov 17, 2020	Equity	$ 11.50	May 19, 2027	5,223,575	5,223,575
					11,041,332	11,041,332

Public Warrants

Public Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants were assumed in connection with the Transaction and became exercisable on June 19, 2022.

The Public Warrants are redeemable at the option of the Company, in whole and not in part, at a price of $0.01 per underlying share, provided that the last reported sales price of the Company's common stock has been at least $18.00 per share (subject to adjustment), on each of twenty (20) trading days within the thirty (30) trading-day period ending on the third trading day prior to the date on which notice of the redemption is given.

Private Placement Warrants

The Private Placement Warrants are identical to the Public Warrants, except that (i) the Private Placement Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees and (ii) the Private Placement Warrants and the common stock issuable upon exercise of the Private Placement Warrants will be entitled to registration rights. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company on the same basis as the Public Warrants.

14. Concentrations of Risk

The Company has certain customers whose revenue individually represented 10% or more of the Company’s total revenue or whose accounts receivable balances individually represented 10% or more of the Company’s total accounts receivable.

For the years ended December 31, 2022 and 2021, three and two customers, respectively, accounted for 100% of revenue recognized in the period.

As of December 31, 2022 one customer accounted for 100% of accounts receivable. There were no customer concentrations in the prior year, as there was no accounts receivable as of December 31, 2021.

15. Income Tax

From inception through April 30, 2021, the Company was a Delaware limited liability company for federal and state tax purposes and, therefore, all items of income or loss through April 30, 2021 flowed through to the members of the limited liability company. Accordingly, the Company did not record deferred tax assets or liabilities or have net operating loss carryforwards. Effective April 30, 2021, the Company converted from an LLC to a C corporation (the “Reorganization”) for federal and state income tax purposes.

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2022 and 2021.

The effective income tax rate differed from the amount computed by applying the federal statutory rate to the Company’s loss before income taxes as follows:

	Year Ended December 31,			
	2022		2021	
Tax effected at statutory rate	21.0	%	21.0	%
State taxes	4.7	%	5.3	%
Stock compensation	0.4	%	(0.9)	%
Non-Deductible Expenses	(8.9)	%	(3.3)	%
Warrant Revaluation	2.3	%	—	%
Federal research and development credits	0.7	%	0.9	%
Change in valuation allowance	(20.2)	%	(23.0)	%
Effective income tax rate	—	%	—	%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following:

	December 31,	
	2022	2021
Total deferred tax assets:		
Federal net operating loss carryforward	$ 4,103,247	$ 885,617
R&D credit carryforward	239,905	63,406
Capitalized R&D	299,449	—
Accruals and reserves	215,975	176,231
Lease liability	87,284	88,259
Stock-based compensation	10,864	173,069
Total deferred tax assets	4,956,724	1,386,582
Valuation allowance	(4,858,529)	(1,235,082)
	98,195	151,500
Total deferred tax liabilities:		
Property and equipment and right-of-use asset	(98,195)	(151,500)
Total net deferred tax assets	$ —	$ —

The Company has had no income tax expense due to operating losses incurred since inception. ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on this, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the deferred tax assets is not determined to be more likely than not. During 2022, the valuation allowance increased by $3.6 million primarily due to the increase in the Company's book loss reported in the period.

Beginning in 2022, Tax Cuts and Jobs Act (TCJA) amended Section 174 and now requires U.S.-based and non-U.S-based research and experimental (R&E) expenditures to be capitalized and amortized over a period of five or 15 years, respectively, for amounts paid in tax years starting after December 31, 2021. Prior to the TCJA amendment, Section 174 allowed taxpayers to immediately deduct R&E expenditures in the year paid or incurred. The Company has applied this required change in accounting method beginning in 2022 and the computation may be adjusted pending future IRS guidance.

As of December 31, 2022, the Company had approximately $15.0 million and $15.0 million of Federal & State operating loss carryforwards respectively. The Federal net operating losses are not subject to expiration and the state net operating losses begin to expire in 2041. These loss carryforwards are available to reduce future federal taxable income, if any. As of December 31, 2022, the Company also has federal and state research and development tax credit carryforwards of approximately $0.2 million and $0.1 million respectively, to offset future income taxes, which will begin to expire beginning in December 2036. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The amount of loss carryforwards that may be utilized in any future period may be limited based upon changes in the ownership of the company's ultimate parent.

The Company follows the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*, which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. As of December 31, 2022, and 2021, the Company has not recorded tax reserves associated with any unrecognized tax benefits. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its consolidated statements of operations and comprehensive loss. As of December 31, 2022, and 2021, the Company had no reserves for uncertain tax positions. For the years ended December 31, 2022 and 2021, no estimated interest or penalties were recognized on uncertain tax positions.

The Company has not conducted a study of its research and development credit carryforwards. This study may result in an adjustment to 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 sheets or consolidated statements of operations and comprehensive loss if an adjustment were required.

The Company's federal and Massachusetts income tax returns for the years ended December 31, 2021 to December 31, 2022 remain open and are subject to examination by the Internal Revenue Service and state taxing authorities.

16. Net Loss per Share or Unit – Basic and Diluted

For the years ended December 31, 2022 and 2021, basic net loss per share or unit was computed by dividing the net loss attributable to common stockholders or unit holders by the weighted average number of common shares or units outstanding. Prior to April 30, 2021, undistributed losses were allocated equally to each class of member units, including vested incentive units, since they shared equally in the residual net assets of Legacy Comera upon liquidation, subject to their different distribution participation rights. Subsequent to April 30, 2021, undistributed losses were allocated entirely to common stockholders since neither the convertible preferred stock nor the contingently returnable Earn-Out Shares are required to share in the losses of the Company.

As the Transaction has been accounted for as a reverse recapitalization, as described in Note 3, the net loss per share or unit information prior to the Transaction, has been retroactively adjusted to amounts reflecting the Exchange Ratio established in the Transaction.

For the years ended December 31, 2022 and 2021, diluted net loss per share or unit is the same as basic net loss per share or unit since the effect of considering unvested incentive units, stock options, and convertible preferred stock in the calculation would be anti-dilutive.

The following potentially dilutive common stock or member unit equivalents, presented based on amounts outstanding at each year end, were excluded from the computation of diluted net loss per share or unit because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2022	2021
Options to purchase common stock	2,152,641	2,689,935
Earn-Out Shares	3,150,000	—
Convertible preferred stock (as converted to common stock)	342,754	10,643,403
Warrants to purchase common stock	11,041,332	—

The following table sets forth the calculation of basic and diluted net loss per share or unit:

	Year Ended December 31,	
	2022	2021
Net loss available to common stockholders or members — basic and diluted	$ (18,377,954)	$ (5,451,778)
Weighted-average number of common shares or units used in computing net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	10,452,697	3,012,603
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (1.76)	$ (1.81)

17. Commitments and Contingencies

Leases

On March 8, 2018, the Company entered into a non-cancelable operating lease agreement for office and laboratory space in Woburn, Massachusetts. The lease agreement required monthly lease payments as well as payment of a proportional share of operating costs. On March 10, 2021, the Company extended the lease agreement through June 30, 2024 at a monthly lease rate of $12 thousand, subject to annual increases in January based on changes in the consumer price index. On March 4, 2022, the Company executed the first amendment to the Woburn Lease (the "Amendment") which increased the size of the leased office and laboratory space with an aggregate monthly lease payment to $18 thousand, subject to annual increases beginning in November 2022 based on the consumer price index, in addition to payment of a proportional share of operating costs.

The maturities and balance sheet presentation under all non-cancelable operating leases as of December 31, 2022, are as follows:

	Operating Leases
Maturity of lease liabilities	
2023	$ 217,545
2024	123,077
Total lease liabilities	340,622
Less: imputed interest	(21,136)
Present value of operating lease liability as of December 31, 2022	$ 319,486
Reported as of December 31, 2022	
Lease liabilities — current	$ 199,184
Lease liabilities — noncurrent	120,302
	$ 319,486

As the Company's leases do not provide an implicit rate, the Company estimated its incremental borrowing rate based on the information available at each lease commencement date in determining the present value of the lease payments. The weighted-average discount rate used for leases as of December 31, 2022 is 8.0%. The weighted-average lease term as of December 31, 2022 is 1.5 years. During the years ended December 31, 2022 and 2021 operating cash flows used for operating leases was $196 thousand and $136 thousand, respectively. During the years ended December 31, 2022 and 2021, lease cost was $201 thousand and $139 thousand, respectively.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2022 and 2021, and, to the best of the Company's knowledge, no material legal proceedings are currently pending or threatened.

Indemnification Agreements

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company agrees to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third-party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Through December 31, 2022, the Company had not experienced any losses related to these indemnification agreements and no material claims were outstanding.

Other Matters

In February 2022, the Company determined it was affected by a business email compromise fraud which resulted in a diversion of the Company's capital to unknown parties. This incident led to a loss of $136 thousand of cash for the year ended December 31, 2021, and an additional $590 thousand in the year ended December 31, 2022 which was recorded as other expense, net in the Company's consolidated statements of operations and comprehensive loss. The Company has insurance related to this event which fully offset the loss recorded during the year ended December 31, 2021, and partially offset the loss recorded during the year ended December 31, 2022, resulting in a net loss of $426 thousand. The Company implemented a variety of measures to further enhance its cybersecurity protections and minimize the impact of any future cyber incidents.

18. Subsequent Events

The Company has completed an evaluation of all subsequent events after the consolidated balance sheet date of December 31, 2022 through March 17, 2023, the date the financial statements were issued, to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2022 and events which occurred subsequently but were not recognized in the consolidated financial statements. The Company has concluded that no subsequent events have occurred that require disclosure, except as disclosed within the consolidated financial statements, as follows:

January 2023 PIPE Financing

On January 2, 2023, the Company entered into the Securities Purchase Agreement (the "2023 PIPE Purchase Agreement," and the transactions contemplated thereby, the "January 2023 PIPE Financing") with the purchasers party thereto ("the Purchasers"), pursuant to which we agreed to issue and sell to the Purchasers in the January 2023 PIPE Financing an aggregate of 2,406,242 units (the "Units," and each, a "Unit"), each consisting of (i) one share of the Company's common stock and (ii) one warrant (the "2023 PIPE Warrants") to purchase two shares of the Company's common stock (the "Warrant Shares") at an exercise price of $1.23 per Warrant Share, for an aggregate purchase price of approximately $3.6 million, consisting of $1.48 per Unit, inclusive of $0.25 per 2023 Private Placement Warrant. The Company received $1.5 million of advanced deposits in December, prior to the execution of the January 2023 PIPE Financing, and incurred $90 thousand of deferred issuance costs. The $1.5 million of advanced deposits are classified as current restricted cash, with a corresponding liability classified as deposit liability.

The 2023 PIPE Warrants are immediately exercisable and will expire five (5) years from the date of issuance. The closing of the January 2023 PIPE Financing was subject to customary representations and warranties and closing conditions and took place on January 4, 2023. The Company intends to use the proceeds from the January 2023 PIPE Financing for working capital and general corporate purposes.

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**.**

COMERA LIFE SCIENCES HOLDINGS, INC.

Date: March 17, 2023

By: /s/ Jeffrey S. Hackman
Jeffrey S. Hackman
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report 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/ Jeffrey S. Hackman Jeffrey S. Hackman	Chairman, President, Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2023
/s/ Michael Campbell Michael Campbell	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 17, 2023
/s/ Sirshendu Roopom Banerjee Sirshendu Roopom Banerjee	Director	March 17, 2023
/s/ Kirsten Flowers Kirsten Flowers	Director	March 17, 2023
/s/ Stuart Randle Stuart Randle	Director	March 17, 2023
/s/ James Sherblom James Sherblom	Director	March 17, 2023
/s/ Edward Sullivan Edward Sullivan	Director	March 17, 2023
/s/ William A. Wexler William A. Wexler	Director	March 17, 2023

Management Team

Jeffrey S. Hackman
Chairman, President, Chief Executive Officer and Director

Neal Muni, M.D.
Executive Vice President and Chief Operating Officer

Dr. Robert Mahoney
Chief Scientific Officer

Michael G. Campbell
Executive Vice President and Chief Financial Officer

Janice McCourt
Chief Business Officer

Board of Directors

Roopom Banerjee

Kirsten Flowers

Jeffrey S. Hackman

Stuart Randle

Rev. Dr. James Sherblom

Edward Sullivan

William A. Wexler

CORPORATE AND STOCKHOLDER INFORMATION

Corporate Headquarters
Comera Life Sciences Holdings, Inc.
12 Gill Street, Suite 4650
Woburn, MA 01801
www.Comerals.com

Common Stock Listing
Our common stock is traded on the Nasdaq Capital Market under the symbol "CMRA."

Independent Registered Public Accounting Firm
Baker Tilly US LLP
1 Highwood Drive
Tewksbury, MA 01876

Transfer Agent
Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004-1561

Investor Inquiries
The 2022 Annual Report, Form 10-K and other investor information are available free of charge at *https://ir.comeralifesciences.com/financial-information/sec-filings*

Legal Counsel
Foley Hoag LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210