Table of Contents

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-269564

Prospectus

Comera Life Sciences Holdings, Inc.

7,218,726 Shares of Common Stock

This prospectus relates to the offer and resale from time to time by the Selling Stockholders named in this prospectus (the "Selling Stockholders") or their permitted transferees of up to 7,218,726 shares of common stock, $0.0001 par value per share (the "Holdco Common Stock") of Comera Life Sciences Holdings, Inc. ("Holdco," "we," "us," "our" or the "Company"). On January 2, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement," and the transactions contemplated thereby, the "Private Placement") with the Selling Stockholders, pursuant to which, on January 4, 2023, the company sold an aggregate of 2,406,242 units (the "Units," and each, a "Unit"), at a purchase price of $1.48 per Unit, with each Unit consisting of one share of Holdco Common Stock and one warrant (the "Private Placement Warrants") to purchase two shares of Holdco Common Stock (the "Warrant Shares") at an exercise price of $1.23 per Warrant Share (the "Warrant Exercise Price"). The shares of Holdco Common Stock included in this prospectus consist of 2,406,242 shares of Holdco Common Stock and 4,812,484 Warrant Shares issuable upon exercise of the Private Placement Warrants that we have issued, or, in the case of the Warrant Shares, are issuable, pursuant to the terms of the Private Placement Warrants. See the section titled "*Selling Stockholders*" for additional information regarding the Selling Stockholders.

We are not selling any shares of Holdco Common Stock being offered by this prospectus and will not receive any of the proceeds from the sale of such shares by the Selling Stockholders. However, we may receive up to approximately $5.9 million in aggregate gross proceeds upon the exercise of the Private Placement Warrants, if any.

The Selling Stockholders may sell or otherwise dispose of the shares of Holdco Common Stock included in this prospectus in a number of different ways and at varying prices. See the section titled "*Plan of Distribution*" for more information about how the Selling Stockholders may sell or otherwise dispose of the Holdco Common Stock being offered in this prospectus.

The Holdco Common Stock and warrants to purchase Holdco Common Stock (the "Holdco Warrants") are listed on the Nasdaq Capital Market ("Nasdaq") under the symbols "CMRA" and "CMRAW," respectively. On February 9, 2023, the last reported sales price of Holdco Common Stock, as reported by Nasdaq, was $1.30 per share, and the last reported sales price of the Holdco Warrants on Nasdaq was $0.0432 per warrant.

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in Holdco Common Stock is highly speculative and involves a high degree of risk. You should review carefully the risks and uncertainties described in the section titled "*Risk Factors*" beginning on page 7 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of the Holdco Common Stock or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 10, 2023

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-1 that we filed with the SEC. The Selling Stockholders may, from time to time, sell up to 7,218,726 shares of Holdco Common Stock, as described in this prospectus. We will not receive any proceeds from the sale by the Selling Stockholders of the securities described in this prospectus. However, we may receive up to approximately $5.9 million in aggregate gross proceeds upon the exercise of the Private Placement Warrants, if any.

You should rely only on the information contained in this prospectus, any supplement to this prospectus or in any free writing prospectus, filed with the SEC. Neither we nor the Selling Stockholders have authorized anyone to provide you with additional information or information different from that contained in this prospectus, or any applicable prospectus supplement or any free writing prospectuses prepared by us or on our behalf and filed with the SEC. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the Selling Stockholders will make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, any post-effective amendment and any applicable prospectus supplement to this prospectus is accurate only as of the date on its respective cover, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

We may also file a prospectus supplement or post-effective amendment to the registration statement of which this prospectus forms a part that may contain material information relating to these offerings. The prospectus supplement or post-effective amendment, as the case may be, may add, update or change information contained in this prospectus with respect to such offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement or post-effective amendment, you should rely on the prospectus supplement or post-effective amendment, as applicable. Before purchasing any Holdco Common Stock, you should carefully read this prospectus and any prospectus supplement and/or post-effective amendment, as applicable, together with the additional information described under "*Where You Can Find More Information*."

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

This document includes trademarks, tradenames and service marks, certain of which belong to Holdco and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this document appear without the ®, TM and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that Holdco will not assert its rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. Holdco does not intend its use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of Holdco by, these other parties.

On May 19, 2022, we consummated the 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 Merger 1 Corp., CLS Sub Merger 2 Corp. and Comera Life Sciences, Inc. ("Comera"). Pursuant to the Business Combination Agreement, CLS Merger 1 Corp. merged with and into Comera and CLS Merger 2 Corp. merged with and into OTR resulting in Comera and OTR becoming wholly owned subsidiaries of Holdco. Collectively, we refer herein to these transactions as the "Transaction."

Unless the context indicates otherwise, references in this prospectus to the “Company,” “Holdco,” “Combined Company,” “we,” “us,” “our” and similar terms refer to Comera Life Sciences Holdings, Inc., and its consolidated subsidiaries.

MARKET AND INDUSTRY DATA

This prospectus 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*."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This registration statement, of which this prospectus forms a part, 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:

- our ability to maintain the listing of our securities on the Nasdaq Capital Market (“Nasdaq”);
- the effect of the COVID-19 pandemic on our business;
- the price of our securities may be volatile due to a variety of factors, including volatility in the capital markets generally, 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 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 will need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at all;
- 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;
- general economic conditions; and
- other risks and uncertainties described in this prospectus, 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.

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before you decide to invest in Holdco Common Stock, you should read the entire prospectus carefully, including the section titled "Risk Factors" and our financial statements and related notes thereto included elsewhere in this prospectus.

Overview

Comera Life Sciences Holdings, Inc. was incorporated in Delaware on January 25, 2022 as a wholly owned subsidiary of Comera for the purpose of effectuating the Transaction. Effective May 19, 2022, as a result of the transactions contemplated by the Business Combination Agreement, Holdco became the parent of both Comera and OTR. Comera, our operating subsidiary, was formed in the State of Delaware on January 2, 2014 as ReForm Biologics, LLC. On April 30, 2021, we completed a corporate reorganization of Reform Biologics, LLC and changed its name to ReForm Biologics, Inc. On January 7, 2022, we changed Reform Biologics, Inc.'s name to Comera Life Sciences, Inc.

We are a pre-clinical 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 to subcutaneous forms. Although our product candidates are at the pre-clinical stage and none have been approved for commercial sale, our internal portfolio of proprietary techniques known as the 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. 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, 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. To accomplish this, we are developing an internal portfolio of proprietary therapeutic product candidates using our innovative proprietary formulation platform, SQore™. We also collaborate with pharmaceutical and biotechnology companies, applying the SQore™ platform to our partners' biologic medicines to deliver enhanced SQ formulations. Holdco Common Stock and Holdco Warrants are listed on Nasdaq under the symbols "CMRA" and "CMRAW," respectively.

The address of our principal executive office is 12 Gill Street, Suite 4650, Woburn, Massachusetts 01801. Our telephone number is (617) 871-2101. Our website address is www.comeralifesciences.com. Information contained on our website or connected thereto does not constitute part of, and is not incorporated by reference into, this prospectus.

The 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 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, 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 Comera was effected through the merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly owned subsidiary of Holdco, and through the merger of Comera Merger Sub with and into Comera, with Comera surviving the merger as a wholly-owned subsidiary of Holdco.

The Transaction was accounted for as a reverse recapitalization because 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.

The Private Placement

On January 2, 2023, we entered into the Purchase Agreement with the Selling Stockholders, pursuant to which we agreed to issue and sell to the Selling Stockholders in a private placement (the "Private Placement") an aggregate of 2,406,242 Units, with each Unit consisting of (i) one share of Holdco Common Stock and (ii) one Private Placement Warrant to purchase two 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 Private Placement Warrants are immediately exercisable and will expire five (5) years from the date of issuance and will be subject to customary adjustments. The Private Placement Warrants also contain beneficial ownership limitations that may be waived at the option of each holder upon 61 days' notice to the Company but in no event may such beneficial ownership limitation exceed 19.99% of the number of shares of Holdco Common Stock outstanding (the "Cap"). We have agreed to consult with Nasdaq to determine whether approval of our stockholders is required to eliminate or increase the Cap. To the extent Nasdaq indicates that stockholder approval is required to eliminate or increase the Cap, we have agreed to submit a resolution to eliminate or increase the Cap to our stockholders as promptly as practical at an annual or special meeting of stockholders, but not later than July 31, 2023. The closing of the Private Placement was subject to customary representations and warranties and closing conditions and took place on January 4, 2023. No placement agent was retained, and no placement agent fees are payable in connection with the Private Placement. The Company intends to use the proceeds from the Private Placement for working capital and general corporate purposes.

The Selling Stockholders consist of a select group of existing stockholders who are 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 the Company's board of directors and Barbara Finck, a former member of the Company's board of directors, who participated on the same terms and subject to the same conditions as all other Selling Stockholders.

Pursuant to a registration rights agreement entered into with the Selling Stockholders on January 4, 2023 (the "Registration Rights Agreement"), we agreed to file a registration statement with the SEC covering resales by the Selling Stockholders of the shares of Holdco Common Stock issued pursuant to the Private Placement and Warrant Shares issuable pursuant to the Warrant., no later than sixty (60) calendar days following the date of the Closing, and to use our best efforts to have such registration statement declared effective as promptly as possible thereafter. This registration statement, of which this prospectus forms a part, is being filed to fulfill our obligations under the Registration Rights Agreement. We will bear all expenses of such registration of the resale of the shares of Holdco Common Stock issued pursuant to the Private Placement and Warrant Shares issuable pursuant to the Warrant.

RISK FACTOR SUMMARY

This summary briefly states the principal risks and uncertainties facing our business that could affect Holdco Common Stock, 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 Holdco Common Stock.

- 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 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 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 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 its 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, supply chain and interest rate pressures, foreign currency exchange rate fluctuations, the ongoing conflict between Russia and Ukraine 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 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 certain of 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 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 current product candidates or any future product candidates for clinical trials or 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 it might not receive such designation, and even if it does, 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.
- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

- We are subject to cybersecurity risks and experienced a diversion of funds through a business email compromise fraud, resulting in a total loss of $726 thousand before we became aware of the matter in February 2022, of which $300 thousand was recovered by insurance proceeds.
- 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 Purchase Agreement, and these sales and issuances could dilute the interest of our stockholders and cause the price of our securities to fall.

THE OFFERING	
Issuer	Comera Life Sciences Holdings, Inc.
Shares of Holdco Common Stock offered by the Selling Stockholders	Up to 7,218,726 shares of Holdco Common Stock,
Use of proceeds	We will not receive any proceeds from the resale of shares of Holdco Common Stock included in this prospectus by the Selling Stockholders. However, we may receive up to $5.9 million in aggregate gross proceeds upon the exercise of the Private Placement Warrants, if any. For more information see the section herein titled "*Use of Proceeds*."
Risk Factors	See the section herein titled "*Risk Factors*" and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our securities.
Nasdaq Capital Market trading symbol	"CMRA"

RISK FACTORS

You should carefully review and consider the following risk factors and the other information contained in this prospectus, including the financial statements and notes to the financial statements included herein, in evaluating an investment in Holdco Common Stock. The risks discussed below may not prove to be exhaustive and are based on certain assumptions made by Holdco that later may prove to be incorrect or incomplete. Holdco may face additional risks and uncertainties that are not presently known, or that are currently deemed immaterial, which may also impair the business or financial condition of Holdco.

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 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 U.S. Food and Drug Administration (“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 September 30, 2022, we had 11 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 and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund our operations and capital expenditure requirements for the next twelve months from the date the condensed consolidated financial statements are issued. 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 prospectus.

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.

As of September 30, 2022, we had cash and cash equivalents of $2.7 million. 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, including the trading price of common stock, resulting from the ongoing COVID-19 pandemic. 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, 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, which may exacerbate the magnitude of the factors discussed above.

Although we entered into the Purchase Agreement with Arena in August 2022, the number of shares of Holdco Common Stock we decide to sell to Arena under the 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 Holdco Common Stock that may be available to us to sell to Arena pursuant to the 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 Holdco Common Stock to decrease. Because the purchase price per share to be paid by Arena for the shares of Holdco 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 Purchase Agreement, if any, it is not possible for us to predict prior to any such sales the number of shares of Holdco Common Stock that will ultimately sell to Arena under the Purchase Agreement, the purchase price per share that Arena will pay for the shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases from Arena under the 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.

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 Coronavirus Aid, Relief, and Economic Security Act (“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.

The U.S. Department of the Treasury has announced that it will conduct audits for PPP Loans that exceed $2,000 for a period of six years after forgiveness. Should we be audited or reviewed by the U.S. Department of the Treasury or the SBA, such audit or review could result in the diversion of management's time and attention and cause us to incur significant costs. 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, the ongoing military conflict between Russia and Ukraine 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. The ongoing military conflict between Russia and Ukraine 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.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. 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 global capital markets deteriorate, including as a result of political unrest or war, it may make any necessary financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If economic

conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. 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, 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, the institutional review boards ("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 investigational new drug applications ("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 clinical research organizations ("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 Biologics License Application (“BLA”) or New Drug Application (“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 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 or the COVID-19 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 does 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, 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 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 coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally 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 COVID-19 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 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 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.

Our reliance on third parties heightens the risks we face.

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where the third parties that we may come to rely on do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

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, 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. 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 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 Good Clinical Practices ("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 current Good Manufacturing Practice ("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, 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 contract manufacturing organization (“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 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any current or future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

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.

We also could be required to seek funds through arrangements with additional collaborators. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves, any of which may have a material adverse effect on our business, operating results 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. At the federal level, Congressional leadership and the Biden administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. 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. 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 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 U.S. Department of Health and Human Services ("HHS") to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states

to build and submit importation plans for drugs from Canada. On September 25, 2020, the HHS's Centers for Medicare & Medicaid Services ("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 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Further, implementation of these changes and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. The effect of these legislative and executive activities on our business model and operations is currently unclear.

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 ("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, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("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, 204, 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.

Our internal computer systems, or those used by our contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations ("CROs") and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

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 (FBI) 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 TCG Technologies 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 (PEN test) of our network, enacted multi-factor authorization (MFA) 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.

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. As a public company, we are subject to the reporting requirements of 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 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 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")of the Holdco Common Stock 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:

- 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.

If we fail to maintain effective internal controls over financial reporting, the price of our securities may be adversely affected.

We are required to maintain appropriate internal controls over financial reporting. Failure to maintain those controls could adversely affect our public disclosures regarding our business, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting, or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal controls over financial reporting, or disclosure of management's assessment of our internal controls over financial reporting, may have an adverse impact on the price of our securities.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) ("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 of the Sarbanes-Oxley Act. The standards required for a public company under Section 404(a) are significantly more stringent than those that were required of 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 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 warrants may never develop or, if developed, it may not be sustained. In addition, the price of our common stock and 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 warrants could decline.

The trading market for our common stock and 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 warrant 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 warrants adversely, or provide more favorable relative recommendations about the Company's competitors, the price of our common stock and 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 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 $1.07 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 common stock and warrants less attractive because it relies on these exemptions. If some investors find our common stock or warrants less attractive as a result, there may be a less active trading market and share price for our common stock or 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.

We may issue additional shares of Holdco Common Stock or shares of preferred stock under our amended and restated certificate of incorporation, which would dilute the interest of our stockholders.

Our amended and restated certificate of incorporation authorizes the issuance of 150,000,000 shares of Holdco Common Stock, and 1,000,000 shares of preferred stock, in each case, par value $0.0001 per share,

which includes shares of Holdco Common Stock issuable under an employee incentive plan. The issuance of additional common stock or preferred stock:

- may significantly dilute the equity interest of current stockholders, who will not have preemption rights in respect of such an issuance;
- could cause a change in control if a substantial number of shares of Holdco Common Stock are issued, which may affect, among other things, our ability to use our net operating loss carry forwards, if any, and could result in the resignation or removal of our present officers and directors; and
- may adversely affect prevailing market prices for our common stock and/or warrants.

Additionally, pursuant to the Purchase Agreement entered into with Arena in August 2022, Arena has committed to purchase up to $15.0 million of our common stock, subject to increase to $30.0 million at our option. Depending on market liquidity at the time of such sales, if any, resales of those shares by Arena may cause the public trading price of our common stock to decrease and could cause additional substantial dilution to our stockholders.

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 Holdco 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 its 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 its directors. Our staggered board of directors can discourage proxy contests for the election of its directors and purchases of substantial blocks of its shares by making it more difficult for a potential acquirer to gain control of its 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 Articles 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 Articles.

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 may have the effect of heightening many of the other risks described in this "Risk Factors" section, such as the demand for our products, its ability to achieve or maintain profitability and its ability to raise additional capital in the future. In addition, natural disasters, 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 its 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.

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 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 (FBI) 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 TCG Technologies 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 (PEN test) of our network, enacted multi-factor authorization (MFA) protocols, implemented an employee education program, and implementing improvements to current network.

The techniques used by cyber attackers change frequently and may be difficult to detect for long periods of time. Although we maintain information technology measures designed to protect itself against intellectual property theft, data breaches and other cyber incidents, such measures will require updates and improvements, and we cannot guarantee that such measures will be adequate to detect, prevent or mitigate cyber incidents. The implementation, maintenance, segregation and improvement of these systems requires significant management time, support and cost. Moreover, there are inherent risks associated with developing, improving, expanding and updating current systems, including the disruption of our data management, procurement, production execution, finance, supply chain and sales and service processes. These risks may affect our ability to manage our data and inventory, procure parts or supplies or produce, sell, deliver and service our products, adequately protect intellectual property or achieve and maintain compliance with, or realize available benefits under, applicable laws, regulations and contracts. We cannot be sure that the systems upon which we rely, including those of its third-party vendors or suppliers, will be effectively implemented, maintained or expanded as planned. If we do not successfully implement, maintain or expand these systems as planned, its operations may be disrupted, its ability to accurately and timely report its financial results could be impaired, and deficiencies may arise in its internal control over financial reporting, which may impact our ability to certify our financial results. Moreover, our proprietary information or intellectual property could be compromised or misappropriated and its reputation may be adversely affected. If these systems do not operate as we expect them to, we may be required to expend significant resources to make corrections or find alternative sources for performing these functions.

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.

USE OF PROCEEDS

This prospectus relates to shares of Holdco Common Stock that may be offered and sold from time to time by the Selling Stockholders. All of the Holdco Common Stock offered by the Selling Stockholders pursuant to this prospectus will be sold by the Selling Stockholders for their own account. We will not receive any of the proceeds from these sales. We cannot currently determine the price or prices at which shares of Holdco Common Stock may be sold by the Selling Stockholders under this prospectus. For information about the selling stockholders, see "Selling Stockholders."

We may receive up to approximately $5.9 million in aggregate gross proceeds upon the exercise of the Private Placement Warrants, if any. See the section titled "*Plan of Distribution*" elsewhere in this prospectus for more information.

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

Unless the context otherwise requires, all references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Holdco," "Company," "we," "us," and "our" refer to Comera Life Sciences Holdings, Inc., and its subsidiaries at and after consummation of the Transaction (the "Closing"). All references to "CLS Holdings", "Comera" and "OTR" refer to Comera Life Sciences Holdings, Inc., Comera Life Sciences, Inc. and OTR Acquisition Corp., respectively, prior to the Closing. You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward- looking statements that involve risks, uncertainties and assumptions. You should read the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus 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.

Overview

We are a pre-clinical 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 to subcutaneous forms. Although our product candidates are at the pre-clinical stage and none have been approved for commercial sale, our internal portfolio of proprietary techniques known as the 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. 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, 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. To accomplish this, we are developing an internal portfolio of proprietary therapeutic product candidates using our innovative proprietary formulation platform, SQore™. We also collaborate with pharmaceutical and biotechnology companies, applying the SQore™ platform to our partners' biologic medicines to deliver enhanced SQ formulations.

Business

We are a preclinical stage life sciences 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 IV to 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 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 January 7, 2022, we changed ReForm Biologics, Inc.’s name to Comera Life Sciences, Inc. to emphasize our vision of a compassionate new era in medicine.

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

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 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 us apart from our peers in the years ahead.

The Transaction

On May 19, 2022 (the “Closing Date”), Holdco consummated the acquisition of all of the issued and outstanding shares of OTR and Comera (the “Transaction”), in accordance with the Business Combination

Agreement. Pursuant to the terms of the Business Combination Agreement, a transaction between OTR and Comera was effected through the merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly-owned subsidiary of CLS Holdings, and through the merger of Comera Merger Sub with and into Comera, with Comera surviving the merger as a wholly-owned subsidiary of CLS Holdings.

The Transaction was accounted for as a reverse recapitalization because 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.

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 September 30, 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 losses were $5.5 million and $2.1 million for the years ended December 31, 2021 and 2020, respectively, and $15.0 million for the nine months ended September 30, 2022. As of September 30, 2022 and December 31, 2021, we had an accumulated deficit of $31.9 million and $16.9 million, respectively. 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 September 30, 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.

In addition, in connection with the vote on the Transaction, OTR experienced a significant number of redemptions of its Class A Common Stock. As a result, in connection with the closing of the Transaction, the net inflow of cash to the Company was $3.3 million which included $1,000,000 received from the private placement of Holdco Common Stock immediately prior to the Transaction (the “Maxim Private Placement”). We expect to continue to require additional sources of liquidity post-Transaction. Our ability to issue additional shares of Holdco Common Stock will be limited by the market price for our securities and the number of shares that are sold pursuant to this registration statement.

We will receive up to an aggregate of $127.0 million if all of the outstanding Holdco Warrants are exercised to the extent such warrants are exercised for cash. However, we will only receive such proceeds if and when the warrant holders exercise the Holdco Warrants, and we believe the likelihood that warrant holders will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the market price of Holdco Common Stock. The closing price of Holdco Common stock on Nasdaq on September 30, 2022 was $1.61, which is $9.89 below the exercise price of all of the Holdco Warrants and Private Placement Warrants. If the market price for Holdco Common Stock does not increase from the current level, it is unlikely that any of the Holdco Warrants or Private Placement 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 through equity or debt financings 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.

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact Holdco's business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict.

The Company plans to continue to closely monitor the ongoing impact of the COVID-19 pandemic on the Company's employees and other business operations. In an effort to provide a safe work environment for the Company's employees, the Company has, among other things, limited employees in the Company's office and lab facilities to those where on-site presence is needed for their job activities, implemented various social distancing measures in the Company's offices and labs and are providing personal protective equipment for the Company's employees present in the Company's office and lab facilities, as needed. The Company is continuing to monitor the impact and effects of the COVID-19 pandemic and the Company's response to it, and the Company expects to continue to take actions as may be required or recommended by government authorities or that are determined to be in the best interests of the Company's employees and other business partners in light of the pandemic.

Recent Developments

On January 2, 2023, the Company entered into a securities purchase agreement with certain purchasers, pursuant to which the Company agreed to issue and sell to the purchasers in a private placement an aggregate of 2,406,242 units, each unit consisting of (i) one share of the Company's common stock and (ii) one warrant to purchase two shares of Holdco Common Stock at an exercise price of $1.23 per 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.

On August 31, 2022, the Company entered into a purchase agreement with Arena Business Solutions Global SPC II, Ltd. ("Arena"), pursuant to which Arena has committed to purchase up to $15.0 million 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 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.

On July 28, 2022, in connection with the consummation of the Transaction, the audit committee of the board of directors of the Company approved the engagement of Baker Tilly US, LLP as the Company's principal

independent registered public accounting firm and dismissed WithumSmith+Brown, PC who had previously served as the independent registered public accounting firm of OTR prior to the consummation of the Transaction. For more information see the section herein titled "*Changes in Registrant's Certifying Accountant*."

On June 13, 2022, we entered into an employment letter agreement with Michael Campbell and, effective as of June 15, 2022, appointed Mr. Campbell as the Executive Vice President, Chief Financial Officer, principal financial officer and principal accounting officer of the Company. For more information see the section herein titled "*Executive Compensation — Employment Offer Letters*."

On May 19, 2022, we consummated the transactions contemplated by the Business Combination Agreement. For more information related to the Transaction, see the section herein titled "*Prospectus Summary — The Transaction*."

Financial Overview

Revenue

Through September 30, 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.

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 margins 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 professional fees for legal, consulting, accounting and audit services. In addition, for the nine months ended September 30, 2022, 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.

Other Income (Expense), Net

Nine months Ended September 30, 2022

For the nine months ended September 30, 2022, total other expense, net was primarily comprised of a $6.6 million expense related to stock issuance costs which exceeded gross proceeds received from the Transaction and Maxim Private Placement and a $1.0 million expense related to issuance costs associated with the Purchase Agreement, as well as 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 nine months ended September 30, 2021, total other income, net 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.

Year ended December 31, 2021

For the year ended December 31, 2021, other income, net is primarily comprised of change in fair value of convertible notes, gain on debt extinguishment and interest income from bank deposits. Interest income has not historically been material. On January 14, 2021, we entered into convertible promissory note agreements for aggregate cash receipts of $750 thousand. These notes bore interest at a rate of 6.5% per annum. On May 26,
2021, the outstanding convertible promissory notes and accrued, unpaid interest were converted into 403,287 shares of Comera Series B-2 Preferred Stock. On April 24, 2020, we entered into a promissory note for aggregate cash proceeds of $161 thousand. These notes bore interest at a rate of 1.0% per annum. On January 7, 2021, the outstanding principal and accrued, unpaid interest was forgiven.

Comparison of Financial Condition and Results of Operations for the Years Ended December 31, 2021 and 2020

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		Change	
	2021	2020	Dollar	Percent
Revenue	$ 319,832	$ 442,919	$ (123,087)	(28%)
Cost of revenue	161,008	104,407	56,601	54%
Operating expenses				
Research and development	1,752,669	1,261,747	490,922	39%
General and administrative	3,941,783	1,204,285	2,737,498	227%
Total operating expenses	5,694,452	2,466,032	3,228,420	131%
Loss from operations	(5,535,628)	(2,127,520)	(3,408,108)	(160%)
Other income, net	83,850	2,033	81,817	**
Net loss and comprehensive loss	$(5,451,778)	$(2,125,487)	$(3,326,291)	(156%)

** Not meaningful.

Revenue

Revenue was $320 thousand for the year ended December 31, 2021, compared to $443 thousand for the year ended December 31, 2020. The decrease of $123 thousand was primarily due to a decrease in research activities performed under customer contracts during the year ended December 31, 2021.

Cost of Revenue

Cost of revenue was $161 thousand for the year ended December 31, 2021, compared to $104 thousand for the year ended December 31, 2020. The increase of $57 thousand is primarily due to higher direct labor costs incurred during the year ended December 31, 2021.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		Change	
	2021	2020	Dollar	Percent
Employee related	$1,257,232	$ 736,776	$520,456	71%
Occupancy and facility related	250,622	252,205	(1,583)	(1%)
Lab supplies and materials	153,608	134,603	19,005	14%
Other	91,207	138,163	(46,956)	(34%)
Total research and development expense	$1,752,669	$1,261,747	$490,922	39%

Research and development expenses were $1.8 million for the year ended December 31, 2021, compared to $1.3 million for the year ended December 31, 2020. The increase of $491 thousand is primarily due to higher employee related expenses, specifically an increase of $380 thousand in stock-based compensation expense, and other personnel related costs due to expanding research activities in the year ended December 31, 2021.

General and Administrative Expenses

For the year ended December 31, 2021, general and administrative expenses were $3.9 million compared to $1.2 million for the year ended December 31, 2020. The increase of $2.7 million is primarily due to an increase in administrative costs to support the Company's planned growth, including salaries and stock-based compensation expense of $1,034 thousand, consulting fees of $920 thousand, patent costs of $300 thousand, recruiting expenses of $153 thousand, and accounting related expenses of $137 thousand.

Other Income, Net

Other income, net for the year ended December 31, 2021 primarily relates to forgiveness of a note payable under the Paycheck Protection Program administered by the U.S. Small Business Administration of $161 thousand and partially offset by the change in fair value of convertible promissory notes of $77 thousand.

On April 24, 2020, the Company entered into a loan transaction pursuant to which it received $161 thousand under the Paycheck Protection Program administered by the U.S. Small Business Administration. On January 7, 2021, the Company received notice that forgiveness of all principal and accrued interest was approved and the Company recorded the amounts as other income. On January 14, 2021, the Company entered into convertible promissory note agreements for aggregate cash receipt of $750 thousand and were accounted for at fair value. On May 26, 2021, the outstanding convertible notes and accrued, unpaid interest were converted into 403,287 shares of Comera Series B-2 Preferred Stock.

Other income, net for the year ended December 31, 2020 was not material and consists primarily of interest income on bank deposits.

Liquidity and Capital Resources

Since our inception, we have not generated sufficient revenue to support our operations and have incurred significant operating losses and negative cash flows from our operations. We have historically funded our operations primarily with proceeds from the issuance of capital units, convertible notes, and preferred stock.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (3,757,949)	$ (1,804,104)
Net cash used in investing activities	(142,013)	(12,366)
Net cash provided by financing activities	10,279,675	1,552,330
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 6,379,713	$ (264,140)

Operating Activities

During the year ended December 31, 2021, operating activities used $3.8 million of cash and cash equivalents, primarily due to funding our net loss of $5.5 million and partially offset by non-cash stock-based compensation expense of $1.1 million and $0.6 million in net cash inflows associated with changes in operating assets and liabilities. The net cash outflows associated with changes in operating assets and liabilities were primarily due to increases of $400 thousand in accrued expenses and other current liabilities and $319 thousand in accounts payable, partially offset by inflows of $231 thousand in prepaid expenses and other current assets.

During the year ended December 31, 2020, operating activities used $1.8 million of cash and cash equivalents, primarily due to funding our net loss of $2.1 million and partially offset by non-cash expenses related to stock-based compensation expense of $101 thousand and consulting expense of $171 thousand.

Investing Activities

Investing activities in both years presented relates to purchases of property and equipment. We purchased property and equipment for $142 thousand and $12 thousand in the years ended December 31, 2021 and 2020, respectively.

Financing Activities

Financing activities during the year ended December 31, 2021 relates to $9.3 million for the issuance of convertible preferred stock, $750 thousand related to the issuance of convertible notes, and $180 thousand from the exercise of stock options.

Financing activities during the year ended December 31, 2020 relates to $1.4 million for the issuance of capital units and $161 thousand of proceeds from a Payment Protection Program loan.

Comparison of Financial Condition and Results of Operations for the Nine months Ended September 30, 2022 and 2021

Results of Operations

The following table sets forth our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Revenue	$ 476,982	$ 246,498	$ 230,484	94%
Cost of revenue	160,030	122,073	37,957	31%
Operating expenses:				
Research and development	1,250,570	1,262,329	(11,759)	(1)%
General and administrative	8,027,316	2,373,621	5,653,695	238%
Total operating expenses	9,277,886	3,635,950	5,641,936	155%
Loss from operations	(8,960,934)	(3,511,525)	(5,449,409)	155%
Other (expense) income, net	(6,080,570)	83,850	(6,164,420)	**
Net loss and comprehensive loss	$(15,041,504)	$(3,427,675)	$(11,613,829)	339%

** Not meaningful

Revenue

Revenue was $477 thousand for the nine months ended September 30, 2022, compared to $246 thousand for the nine months ended September 30, 2021. The increase of $230 thousand is primarily related to an increase in research activities performed under customer contracts during the nine months ended September 30, 2022.

Cost of Revenue

Cost of revenue was $160 thousand for the nine months ended September 30, 2022, compared to $122 thousand for the nine months ended September 30, 2021. The increase of $38 thousand is primarily related to higher direct labor costs incurred during the nine months ended September 30, 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 nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Employee related	$ 687,464	$ 934,711	$(247,247)	(26)%
Lab supplies and materials	322,251	143,011	179,240	125%
Occupancy and facility related	121,220	119,479	1,741	1%
Other	119,635	65,128	54,507	84%
Total research and development expense	$1,250,570	$1,262,329	$ (11,759)	(1)%

Research and development expenses were $1.3 million for the nine months ended September 30, 2022, compared to $1.3 million for the nine months ended September 30, 2021. The overall decrease of $12 thousand and the decrease in employee related expenses of $247 thousand is primarily related to a stock compensation

expense charge of $383 thousand recorded in the prior period related to the vested awards in connection with the Reorganization. The overall decrease is partially offset by an increase in lab supplies and materials of $179 thousand and the employee related decrease is partially offset by an increase in salaries and related benefits of $148 thousand. The increase in lab supplies and materials is primarily associated with an increase in research activities in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 as the Company continues to develop its platform.

General and Administrative Expenses

General and administrative expenses were $8.0 million for the nine months ended September 30, 2022, compared to $2.4 million for the nine months ended September 30, 2021. The increase of $5.7 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 costs associated with transitioning to a public company. These increases include $797 thousand of consulting fees, $616 thousand of legal fees, $559 thousand of accounting fees, $488 thousand of salaries and benefits, and $126 thousand of patent fees. In addition, there was an increase related to directors and officers liability insurance of $1.3 million, including $634 thousand associated with a tail policy related to the Transaction.

Other Income (Expense), Net

For the nine months ended September 30, 2022, total other expense, net was primarily comprised of a $6.6 million expense related to stock issuance costs which exceeded gross proceeds received from the Transaction and Maxim Private Placement and a $1.0 million expense related to issuance costs associated with the Purchase Agreement, as well as 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 nine months ended September 30, 2021, total other income, net 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.

Three Months Ended September 30, 2022 Compared with Three Months Ended September 30, 2021

The following table sets forth our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Revenue	$ 234,922	$ 87,767	$ 147,155	168%
Cost of revenue	60,963	48,364	12,599	26%
Operating expenses:				
Research and development	394,800	263,620	131,180	50%
General and administrative	2,314,554	689,483	1,625,071	236%
Total operating expenses	2,709,354	953,103	1,756,251	184%
Loss from operations	(2,535,395)	(913,700)	(1,621,695)	177%
Other (expense) income, net	(541,446)	—	(541,446)	100%
Net loss and comprehensive loss	$(3,076,841)	$(913,700)	$(2,163,141)	237%

Revenue

Revenue was $235 thousand for the three months ended September 30, 2022, compared to $88 thousand for the three months ended September 30, 2021. The increase of $147 thousand is primarily related to research activities performed under customer contracts.

Cost of Revenue

Cost of revenue was $61 thousand for the three months ended September 30, 2022, compared to $48 thousand for the three months ended September 30, 2021. The increase of $13 thousand is primarily related to higher direct labor costs incurred during the three months ended September 30, 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 three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Employee related	$233,848	$169,016	$ 64,832	38%
Occupancy and facility related	44,132	41,128	3,004	7%
Lab supplies and materials	42,951	46,436	(3,485)	(8)%
Other	73,869	7,040	66,829	949%
Total research and development expense	$394,800	$263,620	$131,180	50%

Research and development expenses were $395 thousand for the three months ended September 30, 2022, compared to $264 thousand for the three months ended September 30, 2021. The overall increase of $131 thousand is primarily related to expansion of research and development activities and higher employee related expenses, including salaries and benefits, of $65 thousand and other miscellaneous expenses, including consulting expenses of $62 thousand.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the three months ended September 30, 2022, compared to $689 thousand for the three months ended September 30, 2021. The increase of $1.6 million is primarily related to increases in expenses in connection with the Company's growth and costs associated with transitioning to a public company. These increases include $530 thousand of salaries and benefits, $364 thousand of accounting fees, and $193 thousand of legal fees. In addition, there was an increase related to directors and officers liability insurance of $371 thousand. These increases were partially offset by a decrease in recruiting fees of $114 thousand.

Other Income (Expense), Net

For the three months ended September 30, 2022, total other expense, net is primarily comprised of a $1.0 million loss related to issuance costs associated with the Purchase Agreement. This expense was partially offset by a $500 thousand decrease in fair value of the Company's derivative warrant liabilities which were assumed in the Transaction.

There was no other income (expense), net for the three months ended September 30, 2021.

Cash Flows

The following table sets forth the sources and uses of cash, cash equivalents, and restricted cash for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$(7,924,004)	$ (2,154,408)
Net cash used in investing activities	(28,607)	(11,464)
Net cash provided by financing activities	4,111,825	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	$(3,840,786)	$ 8,113,803

Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was $8.5 million which consisted of a $15.0 million net loss, partially offset by $5.6 million of adjustments to reconcile net loss to cash used in operating activities and $939 thousand of changes in operating assets and liabilities. Our adjustments to reconcile net loss to cash used in operating activities were primarily comprised of $6.6 million related to issuance costs which exceeded gross proceeds received from the Transaction and Maxim Private Placement and $650 thousand related to noncash Purchase Agreement issuance costs, 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 $1.0 million in accounts payable and $380 thousand in accrued expenses and other current liabilities, partially offset by increases of $294 thousand in accounts receivable and $157 thousand in prepaid expenses and other current assets.

During the nine months ended September 30, 2021, net cash used in operating activities was $2.2 million which consisted of a $3.4 million net loss and partially offset by $1.1 million of adjustments to reconcile net loss to cash used in operating activities and $220 thousand of changes in operating assets and liabilities. Our adjustments to reconcile net loss to cash used in operating activities were primarily comprised of $1.1 million of stock-based compensation 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 $130 thousand in accounts payable and decrease of $110 thousand in accounts receivable.

Investing Activities

The cash outflows from investing activities for the nine months ended September 30, 2022 and 2021 related to the purchase of property and equipment.

Financing Activities

Financing activities during the nine months ended September 30, 2022 related to $3.3 million of net proceeds received from the Transaction and Maxim Private Placement, $749 thousand of proceeds from the Purchase Agreement, and $660 thousand of proceeds from the exercise of stock options, and partially offset by $605 thousand of repayments under our insurance premium financing arrangement.

Financing activities during the nine months ended September 30, 2021 related to $9.3 million of 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.

Funding Requirements

We do not believe the cash and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund our operations for the next twelve months from the date the condensed consolidated financial statements are issued. 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.

Contractual Obligations and Commitments

We have entered into a noncancelable operating lease agreement for office and laboratory space in Woburn, Massachusetts. We executed an extension to the lease on March 10, 2021, which extended the lease through June 2024. On March 4, 2022, we executed the first amendment to the lease agreement which granted us additional leased space. As of September 30, 2022, the Company has not yet taken possession of the additional leased space, as it is occupied by another tenant. Once the Company has taken possession of the space, the monthly rent will be approximately $18 thousand. Until such time, monthly rent continues to be $12 thousand.

We enter into contracts in the normal course of business with contract research organizations, contract manufacturing organizations and other third parties for clinical trials, testing and manufacturing services. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. The amount and timing of such payments are not known.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in Note 2 of the audited financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation*. We measure stock options and other equity-based awards granted based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued equity-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method.

Prior to April 30, 2021, we were organized as a limited liability company and issued incentive units. On April 30, 2021, we completed a series of reorganizational transactions. As part of the transactions each previously outstanding

incentive unit of Reform Biologics LLC was cancelled and options to purchase common stock of Reform Biologics, Inc. were issued. If outstanding incentive units were subject to vesting at the time of the reorganization, then the options issued by Reform Biologics, Inc. were subject to continued vesting pursuant to the same terms.

We estimate the fair value of each incentive unit utilizing an option pricing model and stock option grant using the Black-Scholes option-pricing model, which uses as inputs the estimated fair value the underlying equity and assumptions we make for the volatility of our equity, the expected term of our equity awards, the risk-free interest rate for a period that approximates the expected term of our equity awards and our expected dividend yield.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

- Fair Value of Our Equity. Our equity was not publicly traded, and therefore we estimated the fair value of our equity, as discussed in "Determination of the Fair Value of Common Stock" below.
- Expected Term. The expected term represents the period that the awards are expected to be outstanding. The expected term of awards granted has been determined using the simplified method, which uses the midpoint between the vesting date and the contractual term.
- Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately
- equal to the equity-based award's expected term.
- Expected Volatility. Because we do not have a trading history of our equity, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the awards.
- Dividend Rate. The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Determination of the Fair Value of Common Stock

As there was no public market for Comera's equity prior to the closing of the Transaction, the estimated fair value of its equity was determined by its board of directors as of the date of each option grant, with input from management, considering third-party valuations of Comera Common Stock as well as its board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Following the closing of the Transaction and the commencement of trading of Holdco Common Stock on Nasdaq, it is not necessary for our board of directors to estimate the fair market value of Holdco Common Stock in connection with our accounting for granted equity awards.

For financial reporting purposes, we performed valuations, with the assistance of a third-party specialist, at various dates. In conducting the valuations, the Comera board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the capital units or preferred stock relative to our incentive units or Comera Common Stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our pipeline programs;

- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our equity;
- the likelihood of achieving a liquidity event or a sale of our company in light of prevailing market conditions; and
- the analysis the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

The dates of our valuations have not always coincided with the dates of our stock option grants. In determining the fair value of the shares underlying options set forth in the table above, we considered, among other things, the most recent contemporaneous valuations of our ordinary shares and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of development and commercialization and our business strategy, our operating and financial performance and current business conditions.

Our valuations were prepared using the option-pricing method, or OPM, which treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The future value of the common stock is discounted back to the valuation date at an appropriate risk- adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Risk

As of September 30, 2022, we had cash, cash equivalents, and restricted cash of $2.7 million. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material impact on our cash, cash equivalents, and restricted cash, financial position or results of operations.

Foreign Currency Exchange Risk

We are not exposed to significant foreign exchange rate risk. Our headquarters are located in the United States, where the majority of our general and administrative expenses and research and development costs are incurred in U.S. dollars. A limited amount of our contracts may be denominated in foreign currencies. We believe that a 10% change in the foreign currency exchange rates would not have a material impact on our financial position or results of operations.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 of the audited financial statements included elsewhere in this prospectus.

DESCRIPTION OF BUSINESS

Overview

We are a preclinical stage life sciences 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 the Transaction, contemplated by the Business Combination Agreement, pursuant to which Comera Merger Sub merged with and into Comera and OTR Merger Sub merged with and into OTR resulting in Comera and OTR becoming wholly owned subsidiaries of Holdco.

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 a subcutaneous (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 with Arena Business Solutions Global SPC II, Ltd. (Arena) for up to $15 million of the Company's common stock, 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. Comera has the right to sell to Arena up to $15 million worth of shares, in its sole discretion, over a 36-month period subject to certain limitations

The Market

According to BCC Research, LLC, the global market for biologic therapeutic drugs (or biotherapeutics), which are drugs produced from living organisms, was approximately $286 billion in 2020, and is estimated to grow to approximately $422 billion in 2025, representing an 8.4% CAGR over the next five years. 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, or 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 so 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

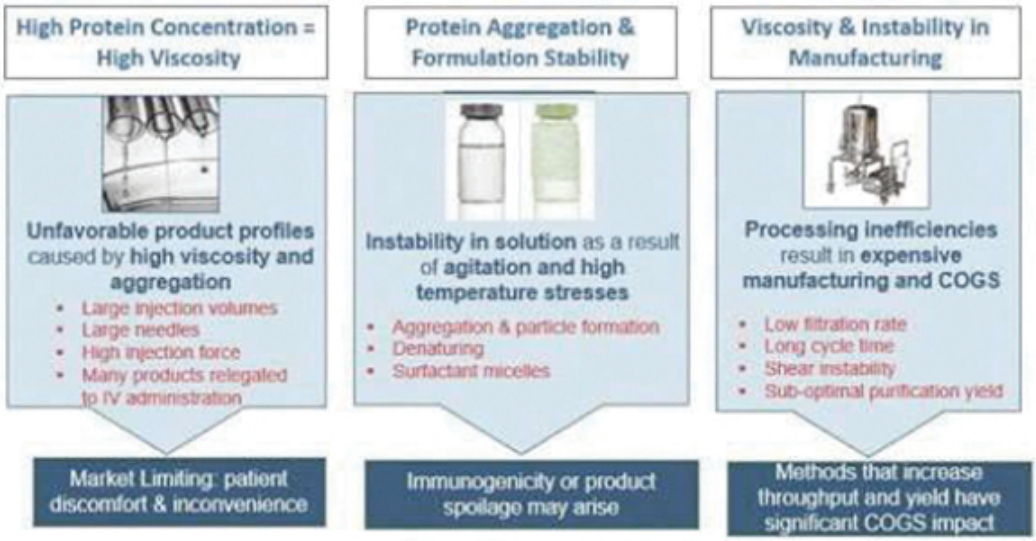
There has been little technology advancement for therapeutic protein product formulation in the industry over the past decade. Currently there are three major problems that our technologies and formulations are designed to address:

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 R&D group of one of the largest multinational chemical companies. In addition to the surfactants, we have has 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, increases the time required, increases costs, and shear instability, and decreases purification yield. The 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 continues 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 versions. 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 on our excipient library to mine the data for the selection of the best excipient for each specific biologic protein.

Our library of over 200 excipients has been created, validated by our proprietary testing methods, and patent applications have been filed disclosing or claiming the excipients or their use. Our patent portfolio includes 7 issued U.S. patents, plus patents in Canada, Japan, and China with over 35 other pending applications. We believe our technology meets 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 also allows 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 addresses 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 unless a new excipient can be identified. 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 Comera's 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 IP portfolio and can only be accessed through licenses granted by Comera.

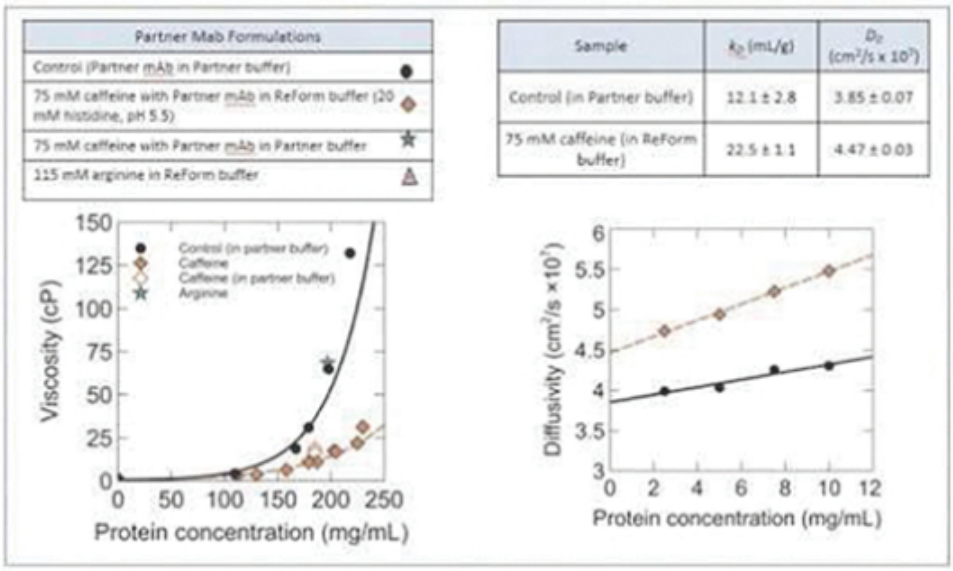
Lower Viscosity: Our viscosity reduction technologies are being developed to significantly lower the viscosity of highly concentrated drug products. Highly viscous products tend to be thick and therefore cannot be delivered by a syringe. Instead, they must often be administered by intravenous infusion. 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 10 top-tier pharma companies on high concentration formulations of antibodies. The viscosity reductions were confirmed by each of the pharma 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 pharma companies, based on 2020 revenues. We have state-of-the-art analytical equipment that can characterize the protein formulations of excipient candidates, plus 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 US Pats. No 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 world-wide, our method of using caffeine in this way has significantly reduced viscosity for highly concentrated formulations for antibodies. 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 NaCl, which are typically used in the industry 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. 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. 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.

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 about 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 FDA approved products administered parenterally, as well as orally, with a well-established, known safety and usage profile. Comera filed a Type IV Drug Master File (DMF) for caffeine 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 we may file. We would need to develop substantial additional information to support any such applications.

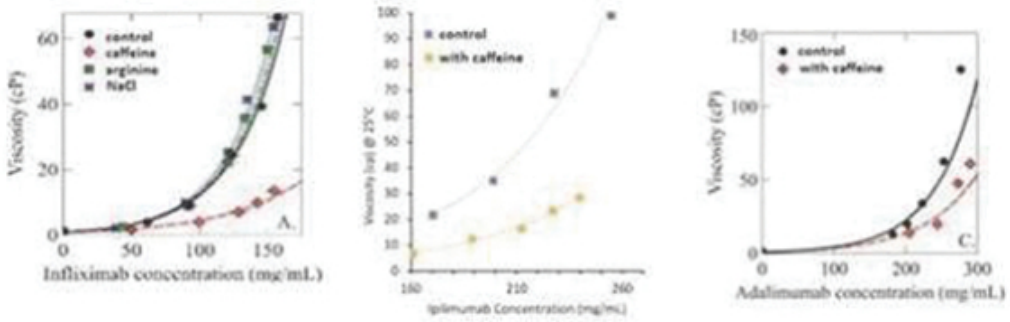
Our advances in caffeine use prompted our research & development team to publish a peer-reviewed article in the November 2021 edition of the Journal of Pharmaceutical Sciences (volume 110, pages 3594-3604), a peer- reviewed journal for breakthrough drug formulation research. It documents the potential 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, sodium chloride, or NaCl, and arginine did not reduce infliximab viscosity, caffeine reduced viscosity 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 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-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 SQoreTM 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, serum concentrations of the mAb to generate a PK profile, and 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 study confirmed the findings of the first study, with no evidence of local or systemic toxicity demonstrated, no interference with monoclonal antibody absorption, and no significant differences in AUC between groups administered a caffeine-containing formulation vs. control formulation. Based on the results of the February study, a follow-on study has been commissioned with WuXi with 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 R&D 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, offering 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 their assets into SQ formulations 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 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 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 readying for commercialization when existing third-party therapeutics go off-patent.

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

CLS – 001 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 (CDMO) organizations for key aspects of our development and commercialization plans, including production of monoclonal antibody 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 monoclonal antibody drug formulations, most commonly intravenous formulations for which the partner seeks to develop a subcutaneous formulation. Other potential customers include pharmaceutical and biotechnology companies who have existing subcutaneous monoclonal antibody 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 subcutaneous 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 five issued US patents shown below. We also received notice of allowance for a Japanese patent on caffeine for viscosity reduction and a third U.S. patent on our surfactant replacement. A summary of our active intellectual property portfolio is shown below.

Title	U.S. Application Number	U.S. Patent Number	U.S. 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)]	14/966,549	9,605,051	formulation
	15/434,379	9,867,881	formulation
	16/284,583	pending	pending
Excipient Compounds for Biopolymer Formulations	15/331,197	10,478,498	formulation
	16/659,046	pending	pending
Excipient Compounds for Biopolymer Formulations	63/280,080	pending provisional	pending
Excipient Compounds for Protein Processing	15/896,374	pending	pending
Excipient Compounds for Protein Formulations	17/011,014	pending	pending
	17/332,521	pending	pending
	17/175,162	pending	pending
	17/471,518	pending	pending
Stabilizing Excipients for Therapeutic Protein Formulations [Foreign counterparts: issued CA 3030422; pending in KR, EP (PCT/ US2017/041691)]	15/647,669		
	15/676,168		

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 FD&C Act, and biologics under the FD&C Act and the Public Health Service Act, or PHSA, as amended, 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 approve pending applications, issuance of clinical holds for ongoing studies, suspension or 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 or 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, FDA must approve a New Drug Application, or NDA. For biologic product candidates regulated under the FD&C Act and PHSA, FDA must approve a Biologics License Application, or BLA. The process 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 Practices, 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 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 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;
- 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 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 automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed at any time after a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

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 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 efficacy 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 test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, or the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. FDA must approve an NDA or BLA before a 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, 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 PDUFA, as amended, 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, or PREA, as amended, 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, PREA does not apply to a drug or biologic for an indication for which orphan designation has been granted, except that 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 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, 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 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 & 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: (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 the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. 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 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 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;
- 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 Affordable Care Act, or 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 30, 2020, the OIG, published modifications to the federal Anti-Kickback Statute. The rule removes 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. These modifications were originally set to take effect on January 1, 2022. However, in response to a lawsuit, the Biden administration delayed the effective date of the November rule until January 1, 2023. Further, implementation of this rule is currently under review by the Biden administration and the rule may be amended or repealed. If the rule is enacted in its current form, 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. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, 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, 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. Further, 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 December 31, 2021 due to the COVID-19 pandemic. 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. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

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, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven- year period beginning January 1, 2021, and ending December 31, 2027. The MFN is currently subject to ongoing litigation. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs.

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 September 30, 2022, we had 11 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.

Properties

We lease our corporate headquarters, which includes office and laboratory space, in Woburn, Massachusetts pursuant to a lease that expires in June 2024. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

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

MANAGEMENT

Management and Board of Directors

The following table sets forth the persons who serve as executive officers and directors of Holdco as of January 31, 2023.

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	58	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 the board of directors of each of Comera and Holdco since September 2021 and May 2022, respectively. 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., finishing as action CEO of its parent company, Novelion Therapeutics Inc. (NVLNF). Under his leadership, Novelion reached profitability. He joined Novelion from Shire Inc., 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, following two years leading US commercial operations for Sigma Tau. 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, has served as Executive Vice President and Chief Operating Officer of each of Comera and Holdco since September 2021 and May 2022, respectively. From July 2014 to January 2020, he was the CEO of Azurity Pharmaceuticals, a privately-held pharmaceutical company focusing on patients with underserved conditions. Under Dr. Muni's tenure at Azurity, he led two successful private equity transactions including a 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 INDs filings. Dr. Muni's notable other experience includes over 20 years of ongoing affiliation with the Brigham and Women's Hospital and Harvard Medical School as Associate Physician and Instructor in Medicine, and his prior appointment to the FDA as a Medical Officer in the Division of Cardiovascular Devices. Dr. Muni is well-qualified to serve as our Executive Vice President and Chief Operating Officer due to his extensive industry and regulatory experience.

Dr. Robert Mahoney has served as the Chief Scientific Officer of each of Comera and Holdco since October 2021 and May 2022, respectively, as a member of Comera's 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. 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 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. 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. Dr. Mahoney is well-qualified to serve as our Chief Scientific Officer due to his deep experience in research and development to develop and commercialize new products.

Michael G. Campbell, CPA has served as Chief Financial Officer of each of Comera and Holdco since June 2022 and served as Interim Chief Financial Officer prior to that since April 2022. Previously, he served as a consultant through Monomoy Advisors LLC. Previously, Mr. Campbell filled several senior finance leadership roles at Ortho Clinical Diagnostics (OCDX) 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), 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. Mr. Campbell received a B.S. degree in Accountancy from Bentley University and is a Certified Public Accountant. Mr. Campbell is qualified to act in the capacity of Chief Financial Officer of the company due to his professional qualifications, prior leadership positions and 30 plus years' experience in business finance and accounting across the medical device and medical diagnostics industries.

Janice Marie McCourt has served as the Chief Business Officer of Holdco since November 2022. Prior to joining Holdco, Ms. McCourt was the Chief Business and Corporate Development Officer at Lyvgen Biopharma Co., 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 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.) (NYSEAmerican: 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 joined Comera as Executive Chairman and Director in January 2021 to lead our corporate reorganization, Series B fundraising effort, reposition our mission and vision, recruit a new senior management team, build out a diverse and inclusive board of directors, and seek future funding and served as Executive Chairman of Comera until February 2022. 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 in Boston, London, and Munich. From 1984 to 1989 he served as Senior Vice President and Chief Financial Officer of Genzyme Corporation (Nasdaq: GENZ) 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) 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. producing and distributing hermetic post- harvest solutions addressing hunger and extreme poverty in the developing world; Connected Homecare utilizing proprietary software and smart phones to monitor and provide better care for patients at home; and Comera Life Sciences utilizing proprietary technology to help develop and lead a new era in compassionate medicine. Dr. Sherblom holds a BA 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 Comera's board of directors since June 2021 and as a member of the Holdco Board since May 2022. 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 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. 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 BS 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 Comera's board of directors since September 2021 and as a member of the Holdco Board since May 2022. Mr. Sullivan began his career with KPMG 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 Comera's board of directors since September 2021 and as a member of the Holdco Board since May 2022. 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 since 2017, a Senior Advisor to Bain Capital, since 2020 and an Operating Partner at CRG Investments since 2018. Previously, Mr. Banerjee was President and CEO of Raindance Technologies from 2010 to 2016 which pioneered the first liquid biopsy blood tests for noninvasive cancer detection, Director of Investment Banking at Leerink Swann from 2005 to 2009, a Management Consultant at McKinsey 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 MIT, 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 Comera's board of directors since August 2021 and as a member of the Holdco Board since May 2022. Since January 2020, Ms. Flowers has served as the Chief Commercial Officer of Kura Oncology, Inc. (Nasdaq: Kura), 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) 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) 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 BS 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 Comera's strategic advisory board since November 17, 2020 and as a member of Holdco's board 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 US 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
- we have implemented a range of other corporate governance best practices, including implementing a robust director education program.

Composition of Our Board

Our business and affairs are managed under the direction of the Holdco Board. The Holdco Board 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 2024 for Class III directors. Our Class I directors consists of Rev. Dr. Jim Sherblom and Stuart Randle; our class II directors consists of Jeffrey S. Hackman and Edward Sullivan; and our Class III directors consists of Roopom Banerjee, MPP, Kirsten Flowers and William A. Wexler.

Director Independence

Under Nasdaq listing standards, a majority of the members of the Holdco Board must qualify as "independent," as affirmatively determined by the Holdco Board. 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 the Holdco Board, other than Jeffrey S. Hackman, qualifies as an independent director under Nasdaq listing standards.

Board Committees

The Holdco Board 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 the Holdco Board when necessary to address specific issues.

Audit Committee

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

The primary purpose of the audit committee is to discharge the responsibilities of the Holdco Board 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. The Holdco Board 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 Code. The primary purpose of the compensation committee is to discharge the responsibilities of the Holdco Board to oversee its compensation policies, plans and programs and to review and determine the compensation to be paid to its executive officers, directors and other senior management, as appropriate.

Specific responsibilities of the compensation committee includes:

- reviewing and approving, or recommending that our Board approve, the compensation of our executive officers;
- reviewing and recommending to the Holdco Board the compensation of our directors;
- reviewing and approving, or recommending that the Holdco Board 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 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. The Holdco Board has determined 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 the Holdco Board approve, nominees for election to our Board;

- evaluating the performance of the Holdco Board and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans; and
- developing and making recommendations to the Holdco Board 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 the Holdco Board as a whole, as well as through various standing committees that address risks inherent in their respective areas of oversight. The Holdco Board 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. The Holdco Board believes its administration of its risk oversight function has not negatively affected the Holdco Board 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. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

EXECUTIVE COMPENSATION

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	—	88,250	—	—	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 to our financials statements for the years ended December 31, 2021 and 2020 "*Basis of Presentation and Significant Accounting Policies — Stock-Based Compensation Expense*" found elsewhere in this registration statement, of which this prospectus forms a part.

(2) Non-equity incentive plan compensation for fiscal 2022 have not yet been determined. We will report the finally determined non-equity incentive compensation for 2022 in a Current Report on Form 8-K once a final determination of achievement of the qualitative and quantitative performance objectives for 2022 are made.

(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 executives officers were:

Name	2022 Annual Base Salary ($)
Jeffrey Hackman	400,000
Michael Campbell	375,000
Neal Muni, MD	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. The Company will report fiscal 2022 non-equity incentive compensation determinations, if any, in a Current Report on Form 8-K. Those decisions are expected to be made in the second half of 2023.

Equity Compensation

Comera grants stock options to its employees, including our named executive officers, as the long-term incentive component of its compensation program pursuant to the Comera Life Sciences Holdings, Inc. 2022 Equity and Incentive Plan, or 2022 Plan. The 2022 Plan is administered by the Holdco Board or a committee appointed by it to administer the 2022 Plan. Typically, these options 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. The Company's 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 Holdco Common Stock on the date of grant. The number of securities reflected in the table below represent shares of Holdco 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.

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 Holdco 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 Holdco Common Stock.

		Option Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities 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	8/09/2032
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) Issued pursuant to the 2021 Plan.
(3) Issued pursuant to the 2022 Plan.

Executive Officer Letters

Each of the current named executive officers has entered into an offer letter agreement with Comera. 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 Comera 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 Comera. 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 the compensation committee. For more information related to the offer letter agreements see the section herein titled "*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 the 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 the offer letter) in all respects.

The 2022 Plan

Prior to the consummation of the Transaction, Comera maintained the Comera Life Sciences, Inc. 2021 Stock Option and Grant Plan, or 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 Equity and Incentive Plan (the "2022 Plan"), which is described in more detail below.

The 2022 Plan allows Holdco to make equity and equity-based incentive awards, as well as cash awards, to employees, directors and consultants. The Holdco Board anticipates that providing such persons with a direct stake in Holdco will assure a closer alignment of the interests of such individuals with those of Holdco and its stockholders, thereby stimulating their efforts on Holdco's behalf and strengthening their desire to remain with Holdco. The purposes of the 2022 Plan is to attract and retain personnel for positions with Holdco or any subsidiary of Holdco; to provide additional incentive to employees, directors, and consultants; and to promote the success of Holdco's business. These incentives are provided through the grant of stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock units, dividend equivalent rights, and cash awards as the administrator of the 2022 Plan may determine.

Key Plan Provisions

- The 2022 Plan will continue until the tenth anniversary of the effective date of the 2022 Plan unless earlier terminated by the Holdco Board or Holdco's compensation committee.
- The 2022 Plan provides for the grant of stock options, both incentive stock options and nonstatutory stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock units, dividend equivalent rights, and cash awards.
- 2,059,839 shares of Holdco Common Stock are authorized for issuance pursuant to awards under the 2022 Plan.
- The 2022 Plan provides for an automatic share reserve increase feature, whereby the share reserve will be increased automatically on the first day of each fiscal year beginning with the 2023 fiscal year, in an amount equal to 4% of the total number of shares of Holdco Common Stock outstanding on the last day of the

immediately preceding fiscal year, or a lesser number of shares as determined by the administrator. The automatic share reserve feature will cease immediately after the increase on the first day of the 2032 fiscal year.

- The 2022 Plan is administered by the compensation committee of the Holdco Board, as designated by the Holdco Board.

Summary of the 2022 Plan

This section summarizes certain principal features of the 2022 Plan. The summary is qualified in its entirety by reference to the complete text of the 2022 Plan, which is attached as an exhibit to this registration statement of which this prospectus forms a part.

Eligibility

All officers, employees, non-employee directors and consultants are eligible to receive awards under the 2022 Plan.

No awards may be granted under the 2022 Plan after the date that is ten years from the effective date of the plan, and awards of incentive stock options may not be granted after the date that is ten years from the date the 2022 Plan was approved by the Holdco Board.

Authorized Shares

There are currently 2,059,839 shares of Holdco Common Stock (the "Initial Limit") reserved for issuance under the 2022 Plan, and shares subject to the Rollover Options count against this limit. The 2022 Plan provides that the number of shares of Holdco Common Stock reserved and available for issuance under the 2022 Plan will automatically increase each January 1, beginning on January 1, 2023 and on each January 1 thereafter, by 4% of the outstanding number of shares of Holdco Common Stock on the immediately preceding December 31, or such lesser amount as determined by the plan administrator (the "Annual Increase"). This limit is subject to adjustment in the event of a reorganization, recapitalization, reclassification, stock split, stock dividend, reverse stock split or other similar change in Holdco's capitalization. The maximum aggregate number of shares of Holdco Common Stock that may be issued upon exercise of incentive stock options under the 2022 Plan may not exceed the Initial Limit cumulatively increased on January 1, 2023 and on each January 1 thereafter by the lesser of the Annual Increase or a number of shares of Holdco Common Stock equal to twice the Initial Limit. Shares underlying any awards under the 2022 Plan that are forfeited, cancelled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by Holdco prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) will be added back to the shares available for issuance under the 2022 Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, the shares may be issued as incentive stock options. In addition, to the extent consistent with the requirements of Section 422 of the Code, awards granted or stock issued upon assumption of, or in substitution or exchange for, awards previously granted by an entity that Holdco acquires or merges with or into, shall not reduce the shares available for issuance under the 2022 Plan , nor will the shares underlying such awards be added back to the shares available for issuance under the 2022 Plan in the event of any forfeiture, cancelation, reacquisition, expiration, termination, cash settlement or non-issuance of such shares.

The 2022 Plan contains a limitation whereby the value of all awards under the 2022 Plan and all other cash compensation paid by Holdco to any non-employee director may not exceed $750,000 in any calendar year, except that the limit will be $1,000,000 for the first calendar year a non-employee director is initially appointed to the Holdco Board. The foregoing limitation will be calculated without regard to amounts paid to any non-employee director (including retirement benefits and severance payments) in respect of any services provided in any capacity (including employee or consultant) other than as a non-employee director. The Holdco Board may make exceptions to this limit for a non-executive chair of the Holdco Board with the approval of a majority of the disinterested directors.

The 2022 Plan also requires that all awards under the 2022 Plan be granted with a vesting schedule or restriction period of at least one year, except that awards for shares equal to an aggregate amount of up to five percent of the shares authorized for issuance under the 2022 Plan may be granted without meeting this requirement.

Plan Administration

The 2022 Plan is administered by the compensation committee of the Holdco Board, the Holdco Board or another board committee pursuant to the terms of the 2022 Plan. The plan administrator, which is currently the compensation committee of the Holdco Board, has full power to select from among the individuals eligible for awards, the individuals to whom awards will be granted, to make awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2022 Plan. The 2022 Plan prohibits the plan administrator, without the approval of Holdco's stockholders, from repricing any stock options or stock appreciation rights. The plan administrator's determinations under the 2022 Plan need not be uniform. The plan administrator may delegate to one or more officers the authority to grant stock options and other awards to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act, subject to certain limitations and guidelines. Persons eligible to participate in the 2022 Plan will be the directors, officers, employees and consultants of Holdco and its affiliates as selected from time to time by the plan administrator in its discretion.

The 2022 Plan requires the plan administrator to make appropriate adjustments to the number of shares of Holdco Common Stock that are subject to the 2022 Plan, to certain limits in the 2022 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

Stock Options

The 2022 Plan permits the granting of both options to purchase shares of Holdco Common Stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. Options granted under the 2022 Plan will be non-qualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of Holdco and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive awards under the 2022 Plan. The option exercise price of each option will be determined by the plan administrator but generally may not be less than 100% of the fair market value of Holdco Common Stock on the date of grant or, in the case of an incentive stock option granted to a ten percent stockholder, 110% of such share's fair market value on the date of grant. The term of each option will be fixed by the plan administrator and may not exceed ten years from the date of grant, subject to limited exceptions as described in the 2022 Plan. The plan administrator will determine at what time or times each option may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of an option, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the plan administrator or by delivery (or attestation to the ownership) of shares of Holdco Common Stock that are beneficially owned by the optionee free of restrictions or were purchased in the open market. The exercise price may also be delivered by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the plan administrator may permit options to be exercised using a "net exercise" arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with a fair market value that does not exceed the aggregate exercise price.

Stock Appreciation Rights

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to receive shares of Holdco Common Stock, or cash to the extent provided for in an award agreement, equal to the value of the appreciation in Holdco Common

Stock price over the exercise price. The exercise price generally may not be less than 100% of the fair market value of Holdco Common Stock on the date of grant. The term of each stock appreciation right will be fixed by the plan administrator and may not exceed ten years from the date of grant, subject to limited exceptions as described in the 2022 Plan. The plan administrator will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock, Restricted Stock Units, Unrestricted Stock, Dividend Equivalent Rights

The plan administrator may award restricted shares of Holdco Common Stock and restricted stock units subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment through a specified vesting period. The plan administrator may also grant shares of Holdco Common Stock that are free from any restrictions under the 2022 Plan. Unrestricted stock may be granted or sold to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant. The plan administrator may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would have been paid if the recipient had held a specified number of shares of Holdco Common Stock.

Cash Awards

The plan administrator may grant cash-based awards under the 2022 Plan to participants, subject to such vesting and other terms and conditions as the plan administrator may determine.

Payments by Participants

Participants in the 2022 Plan are responsible for the payment of any federal, state, local or foreign taxes that Holdco or its subsidiaries are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any tax withholding obligation of Holdco or its subsidiaries to be satisfied, in whole or in part, by the applicable entity withholding from shares of Holdco Common Stock to be issued pursuant to an award a number of shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any tax withholding obligation of Holdco or its subsidiaries to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to Holdco or its subsidiaries in an amount that would satisfy the withholding amount due.

Non-Transferability of Awards

The 2022 Plan generally does not allow for the transfer or assignment of awards, other than by will or by the laws of descent and distribution or pursuant to a domestic relations order; however, the plan administrator may permit the transfer of nonstatutory stock options by option holders by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners.

Form S-8

On August 12, 2022, Holdco filed a Registration Statement on Form S-8 to register the securities issuable pursuant to the 2022 Plan, including the Rollover Options.

Merger or Change in Control

The 2022 Plan provides that upon the effectiveness of a “change in control transaction,” as defined in the 2022 Plan, an acquirer or successor entity (or parent thereof) may assume, continue or substitute for the outstanding awards under the 2022 Plan. To the extent that awards granted under the 2022 Plan are not assumed,

continued or substituted by the successor entity, all awards granted under the 2022 Plan shall terminate and, in such case, the plan administrator in its discretion may take one or more of the following actions with respect to outstanding awards at any time prior to the closing: (i) provide for the acceleration of any time period relating to the exercise or payment of the award; (ii) provide for payment to the holder of the award of cash or other property with a fair market value equal to the amount that would have been received upon the exercise or payment of the award had the award been exercised or paid upon the change in control transaction in exchange for cancellation of the award; (iii) adjust the terms of the award in a manner determined by the plan administrator to reflect the change in control transaction or (iv) make such other provision as the plan administrator may consider equitable to the holders of awards and in the best interests of Holdco.

Amendment or Termination

The plan administrator may establish subplans and modify exercise procedures and other terms and procedures in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States.

All awards will be subject to any Holdco clawback policy as set forth in such clawback policy or the applicable award agreement.

The Holdco Board may amend or discontinue the 2022 Plan and the plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. Certain amendments to the 2022 Plan will require the approval of Holdco's stockholders.

Director Compensation

During 2022, Comera's 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 to our financials statements for the years ended December 31, 2021 and 2020 "*Basis of Presentation and Significant Accounting Policies—Stock-Based Compensation Expense*" found elsewhere in this registration statement, of which this prospectus forms a part.

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 Holdco 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 Holdco 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.

PRINCIPAL STOCKHOLDERS

The following table shows the beneficial ownership of Holdco Common Stock as of January 20, 2023 by:

- each person who is known by Holdco to be the beneficial owner of more than 5% of issued and outstanding shares of Holdco Common Stock on an as-converted to Holdco 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 Holdco Common Stock beneficially owned by them. Unless otherwise indicated below, we have based our calculation of the percentage of beneficial ownership on 22,265,463 shares of Holdco Common Stock and 4,305 shares of Holdco 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 22,608,217 total votes as of January 20, 2023.

	Common Stock		% of Total Voting Power
Name of Beneficial Owner[1]	Shares	Percent	
Named Executive Officers and Directors			
Rev. Dr. James Sherblom[2]	708,333	3.2%	3.1%
Jeffrey S. Hackman[3]	151,699	*	*
Neal Muni, MD[4]	78,074	*	*
Michael G. Campbell, CPA	25,000	*	*
Stuart Randle[5]	163,205	*	*
Edward Sullivan, CPA[6]	55,081	*	*
Roopom Banerjee, MPP[7]	82,954	*	*
Kirsten Flowers[8]	62,683	*	*
William A. Wexler[9]	61,062	*	*
All executive officers and directors as a group (11 persons)	1,528,806	6.7%	6.6%
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	7.0%	6.9%
Cherington et al.[15]	4,434,410	18.7%	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 Holdco Common Stock, (b) 162,162 shares of Holdco Common Stock subject to warrants exercisable for $1.23 per share, (c) 12,080 shares of Holdco Common Stock subject to

stock options exercisable for $0.59 per share within 60 days of January 20, 2023, and (d) 81,847 Earn-Out Shares.

(3) Consists of (a) 47,600 shares of Holdco Common Stock and (b) 104,099 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023.

(4) Consists of 78,074 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023.

(5) Consists of (a) 42,469 shares of Holdco Common Stock, 67,566 shares of Holdco Common Stock subject to warrants exercisable for $1.23 per share and 120,119 Earn-Out Shares held directly by Stuart Randle, (b) 11,245 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023 held directly by Stuart Randle, and (c) 31,647 shares of Holdco Common Stock and 39,712 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 Holdco Common Stock held by the Randle Trust.

(6) Consists of (a) 19,665 shares of Holdco Common Stock, (b) 21,958 shares of Holdco Common Stock subject to warrants exercisable for $1.23 per share, (c) 11,245 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023, and (c) 2,213 Earn-Out Shares.

(7) Consists of (a) 28,956 shares of Holdco Common Stock, (b) 40,540 shares of Holdco Common Stock subject to warrants exercisable for $1.23 per share, (c) 11,245 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023, and (d) 2,213 Earn-Out Shares.

(8) Consists of (a) 22,199 shares of Holdco Common Stock, (b) 27,026 shares of Holdco Common Stock subject to warrants exercisable for $1.23 per share, (c) 11,245 shares of Holdco Common Stock subject to stock options exercisable for $0.59 per share within 60 days of January 20, 2023, and (d) 2,213 Earn-Out Shares.

(9) Consists of (a) 11,062 shares of Holdco Common Stock and (b) 50,000 shares of Holdco Common Stock subject to warrants exercisable for $11.50 per share.

(10) Consists of (a) 470,007 shares of Holdco Common Stock held by David Soane, (b) 2,673,274 shares of Holdco Common Stock, 135,134 shares of Holdco 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 Holdco Common Stock, 135,134 shares of Holdco 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 Holdco 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, Miam, 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 Holdco 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 Holdco 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 1221 Brickell Avenue, Suite 2660, Miami, Florida 33131.

(13) Consists of (a) 421,759 shares of Holdco Common Stock and (b) 762,634 shares subject to warrants to purchase Holdco Common Stock at an exercise price of $11.50 per share.

(14) Consists of (a) 245,000 shares of Holdco Common Stock and (b) 1,400,000 shares of Holdco 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 Holdco Common Stock, 1,486,486 shares of Holdco 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 Holdco Common Stock and 257,672 Earn-Out Shares held by Cherington Holdings LLC, (c) 75,968 shares of Holdco 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 Holdco 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 Holdco 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 Holdco Common Stock, (b) 1,033,782 shares of Holdco 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 Holdco Common Stock, (b) 743,242 shares of Holdco 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.

CERTAIN COMERA RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Indemnification Agreements

Comera has entered into contractual indemnification agreements with certain of its directors and officers in addition to the indemnification provided for in the certificate of incorporation of Comera (as amended, the "Comera Charter"). These agreements, among other things, require 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 Comera; and (b) subject to certain limitations, attorneys' fees and certain expenses incurred by these individuals in any proceedings by or in the right of Comera.

Similarly, Holdco has entered into separate indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in Holdco's Amended and Restated Certificate of Incorporation (the "Holdco Charter") and the Amended and Restated Bylaws of Holdco (the "Holdco 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 the Holdco Charter and the Holdco 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 Holdco and its 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

The Private Placement

On January 2, 2023, we entered into the Purchase Agreement with the Selling Stockholders, pursuant to which we agreed to issue and sell to the Selling Stockholders in the Private Placement an aggregate of 2,406,242 Units, each Unit consisting of (i) one share of Holdco Common Stock and (ii) one Private Placement Warrant to purchase two 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. As part of the Private Placement, Holdco also entered into the Registration Rights Agreement with the Selling Stockholders

The Selling Stockholders consist of a select group of existing stockholders who are 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 the Company's board of directors and Barbara Finck, a former member of the Company's board of directors, who participated on the same terms and subject to the same conditions as all other Selling Stockholders.

The participating investors also included certain existing stockholders of Holdco who beneficially own in excess of 10% of Holdco's outstanding shares of Holdco Common Stock, 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 the Holdco Common Stock currently issued and outstanding, and (ii) Charles Cherington, a former director of Comera. See the section titled "*Selling Stockholders*" for additional information regarding the Selling Stockholders.

Series B Preferred Stock Financing

From May 26, 2021 through July 15, 2021, Comera sold an aggregate of 3,970,465 shares of 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 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, 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 grants registration rights, certain financial information rights and the right to examine the books and records of Comera. The agreement also grants to Phoenix Venture Partners LP and Cherington Holdings LLC the right to send a representative to attend meetings of the Comera Board of Directors in a nonvoting observer capacity; and
- a voting rights agreement which provides 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 grants 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 issuances of Comera Series B Preferred Stock by related persons and their affiliated entities. None of Comera's executive officers were issued shares of 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	$ 255,415.10
The Soane Family Trust[3]	210,971	134,429	$ 755,416.37
Cherington et al[4]	210,971	134,429	$ 755,416.37
The Stuart A. Randle Trust of 1998[5]	42,194	—	$ 99,999.78

(1) The purchase price for each investor includes $250,000 plus accrued interest associated with convertible notes that were settled for shares of Comera Series B-2 Preferred Stock.
(2) Zachariah Jonasson is a former member of the 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 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 Comera.
(5) Stuart Randle is a member of the Comera Board of Directors and is affiliated with The Stuart A. Randle Trust of 1998.

Conversion from LLC to Corporation

On April 30, 2021, 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 Comera Series A Preferred Stock. Each Incentive Unit issued and outstanding was cancelled upon the conversion.

The following table summarizes the converted 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 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 Comera Series A-1 Preferred Stock, Comera Series A-2 Preferred Stock, Comera Series A-3 Preferred Stock, Comera Series A-4 Preferred Stock, Comera Series A-5 Preferred Stock, and 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 Comera Series A-1 Preferred Stock, Comera Series A-3 Preferred Stock, Comera Series A-4 Preferred Stock, Comera Series A-5 Preferred Stock, and Comera Series A-6 Preferred Stock, respectively, held by The Soane Family Trust, (b) 22,485 shares of Comera Series A-3 Preferred Stock held by The Alexander V. Soane 2019 Irrevocable Trust, and (c) 22,485 shares of 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 Comera. The shares of Series A Preferred Stock include (a) 933,334, 73,421, 29,477, 147,834, and 29,567 shares of Comera Series A-2 Preferred Stock, Comera Series A-3 Preferred Stock, Comera Series A-4 Preferred Stock, Comera Series A-5 Preferred Stock, and Comera Series A-6 Preferred Stock, respectively, held by Cherington Holdings LLC, (b) 101,286 shares of Comera Series A-4 Preferred Stock held by Ashley S. Pettus 2012 Irrevocable Trust FBO Benjamin P. Cherington, (c) 101,285 shares of Comera Series A-4 Preferred Stock held by Ashley S. Pettus 2012 Irrevocable Trust FBO Cyrus B. Cherington, and (d) 101,286 shares of 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, 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, 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 Comera Series B-2 Preferred Stock.

Class B1 Capital Unit Financing

From February 19, 2020 to August 4, 2020, 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, 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 Comera Class B1 Capital Units by related persons and their affiliated entities. None of Comera's executive officers purchased Comera Class B1 Capital Units, nor were they issued Comera Class B1-A Capital Units.

Unit Holder	Class B1 Capital Units	Class B1-A Capital Units	Total Purchase Price
Phoenix Venture Partners, LP[(1)]	147,834	29,567	$413,935.20
The Soane Family Trust[(2)]	89,287	17,857	$250,003.60
Cherington, et al[(3)]	147,834	29,567	$413,935.20

(1) Zachariah Jonasson was a member of the 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 cofounder of Comera and a holder of more than 5% of the outstanding shares of Holdco 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 Holdco Common Stock.

Comera Stockholder Agreements

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 "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 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 Comera Stockholder Agreements, certain holders of 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 Comera. The Comera Stockholder Agreements also provided the parties thereto with certain registration rights, pre-emptive rights, information and inspection rights, drag-along rights, right of first refusal and co-sale rights, among other rights. The 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, the Holdco 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 "*Executive Compensation — Employment Offer Letters*."

Transactions with Board Members and Major Investors

In 2021, Comera granted stock options to its directors and certain investors to purchase shares of 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 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 Holdco 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

The Company obtains 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, the 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, the Company recognized $8,000 and $21,000, respectively, as a reduction to general and administrative expense related to these contracts.

Policies and Procedures for Related Party 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.

DESCRIPTION OF HOLDCO'S SECURITIES

The following summary of the capital stock of Holdco is subject in all respects to the applicable provisions of the Delaware General Corporation Law, or DGCL, and the Holdco Charter. In connection with the closing of the Transaction, Holdco adopted the Holdco Charter and Holdco Bylaws. The following discussion is a summary of the Holdco Charter and Holdco Bylaws and is qualified by reference to the actual documents which are exhibits to the registration statement of which this prospectus is a part. We urge you to read each of them in their entirety for a complete description of the capital stock of Holdco.

General

The total number of authorized shares of capital stock of Holdco consists of 150 million shares of common stock, par value of $0.0001 per share (the "Holdco Common Stock"), and 1 million shares of preferred stock, par value of $0.0001 per share (the "Preferred Stock").

Common Stock

Common stockholders of record are entitled to one vote for each share held on all matters to be voted on by stockholders. Holders of Holdco Common Stock will vote together as a single class on all matters submitted to a vote of stockholders, except as required by law. Unless specified in the Holdco Charter or Holdco Bylaws, or as required by applicable law or applicable stock exchange rules, the affirmative vote of a majority of the shares of Holdco Common Stock that are voted is required to approve any such matter voted on by Holdco stockholders. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Holdco's stockholders are entitled to receive ratable dividends when, as and if declared by the board of directors of Holdco (the "Board") out of funds legally available therefor.

Holders of Holdco Common Stock will not be entitled to vote on any amendment to the Holdco Charter (including any preferred stock designation) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of that affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other series of Preferred Stock, to vote thereon by law or pursuant to the Holdco Charter (including any preferred stock designation). The number of authorized shares of Holdco Common Stock may be increased or decreased (but not below the number of shares of Holdco Common Stock then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then- outstanding shares of capital stock of Holdco entitled to vote thereon, without a separate class vote of the holders of Holdco Common Stock.

On liquidation, dissolution, sale or winding up of Holdco, holders of Holdco Common Stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights.

In connection with the closing of the Transaction, Holdco entered into a registration rights and lock-up agreement (the "Registration Rights and Lock-Up Agreement") with certain stockholders with respect to the shares of Holdco Common Stock they received in the Transaction. The Registration Rights and Lock-Up Agreement required Holdco to, among other things, file a resale shelf registration statement on behalf of the stockholders no later than 30 days from the Closing. The Registration Rights and Lock-Up Agreement also provides certain demand registration rights and piggyback registration rights to the stockholders, subject to underwriter cutbacks and issuer blackout periods. Holdco also agreed to pay certain fees and expenses relating to registrations under the Registration Rights and Lock-Up Agreement.

Subject to certain exceptions, the Registration Rights and Lock-Up Agreement further provides for the Holdco Common Stock held by the signatories to be locked-up until the earlier of (i) one year following the Closing and (ii) the date on which the sale price of the Holdco Common Stock equals or exceeds $12.00 per share for any 20 trading days within any 30-day trading period commencing 150 days after the Closing.

Preferred Stock

The Board is authorized, subject to any limitations prescribed by law, to provide by resolution for the issuance of authorized and unissued shares of Preferred Stock in one or more series, and by filing a certificate pursuant to the applicable law of the State of Delaware, referred to as a "preferred stock designation," to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights, including voting rights and rights upon any liquidation of Holdco, of the shares of each such series and any qualifications, limitations or restrictions thereof. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares of Preferred Stock then outstanding) by the Board, without a separate class vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any preferred stock designation. Except as otherwise provided in any preferred stock designation: (a) any new series of Preferred Stock may be designated, fixed and determined as provided herein by the Board without approval of the holders of the Holdco Common Stock or the holders of Preferred Stock, or any series thereof, and (b) any such new series may have powers, preferences and rights, including, without limitation, voting rights, dividend rights, liquidation rights, redemption rights and conversion rights, senior to, junior to or pari passu with the rights of the shares of Holdco Common Stock, existing series of Preferred Stock or any future class or series of Preferred Stock or Holdco Common Stock.

Series A Convertible Perpetual Preferred Stock

There Board has designate 4,305 shares of Preferred Stock as Series A Preferred Stock. The Series A Preferred Stock is senior to the Holdco Common Stock and any other series or class of Preferred Stock.

Liquidation Rights

In the event of any liquidation, dissolution or winding up of Holdco, the holders of Series A Preferred Stock shall be entitled to receive, out of the assets of Holdco available for distribution to Holdco's stockholders, before any distribution to the holders of any other securities of Holdco, an amount per share equal to $1,000 per share (as may be adjusted for stock splits, dilutive issuances and the like, the "Series A Original Purchase Price") plus the aggregate amount of dividends then accrued on such share of Series A Preferred Stock. If there are insufficient assets to make such distribution, then such distribution shall be made ratably among the holders of outstanding shares of Series A Preferred Stock in proportion to the full preferential amount to which each such holder is otherwise entitled to receive.

Merger or Sale Resulting in a Change of Control

In the event of a merger or consolidation as a result of which 50% or more of the equity interest or voting power (or similar equity interest) of the surviving entity is held by persons other than holders of 50% or more of the equity interests or voting power (or similar equity interest) of Holdco prior to the merger or consolidation, the holders of Series A Preferred Stock shall be entitled to receive, out of the aggregate consideration to which the holders of all capital stock of the Corporation are entitled to receive in connection with the merger or consolidation, before any distribution to the holders of any other securities of Holdco, an amount per share equal to the Series A Original Purchase Price. If there is insufficient consideration to make such distribution, then such distribution shall be made ratably among the holders of outstanding shares of Series A Preferred Stock in proportion to the full preferential amount to which each such holder is otherwise entitled to receive.

Sale of Assets

In the event of any sale, lease or exchange of all or substantially all of the property and assets of the Corporation, including its goodwill and its corporate franchises, the holders of outstanding shares of Series A Preferred Stock shall be entitled to be paid, out of the aggregate consideration payable to Holdco (the

"Qualifying Sale Consideration"), prior and in preference to the payment, out of the Qualifying Sale Consideration, to holders of any other currently-outstanding capital stock, consideration in an amount per share equal to the Series A Original Purchase Price. If the Qualifying Sale Consideration is insufficient to permit the payment to such holders of the full preferential amounts to which they are entitled to receive, then the entire Qualifying Sale Consideration shall be distributed ratably among the holders of outstanding shares of Series A Preferred Stock in proportion to the full preferential amount to which each such holder is otherwise entitled to receive.

Voting Rights

Holders of Series A Preferred Stock, as such, shall be entitled to cast the number of votes equal to the number of shares of Holdco Common Stock into which such share of Series A Preferred Stock could be converted, but not more than 19.99% of the total voting power of Holdco Common Stock.

Preferential Dividends

The holders of Series A Preferred Stock shall be entitled to receive, out of assets of the Corporation legally available therefor, 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, payable quarterly on January 1, April 1, July 1 and October 1 of each calendar year (provided, however, that if such date is not a business day, the relevant quarterly dividend shall be payable on the first business day following such date) (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 such Series A Dividend Rate shall increase by 2% per annum from and after each successive Series A Quarterly Dividend Payment Date, up to a maximum of 18%.

Optional Right to Convert

Each outstanding share of Series A Preferred Stock may be converted into such number of fully paid and nonassessable shares of Holdco Common Stock as determined by dividing the Series A Original Purchase Price by $12.56 (as may be adjusted for stock splits, dilutive issuances and the like, the "Series A Conversion Price") at any time by the holder; provided, however, in no event shall outstanding shares of Series A Preferred Stock be converted into more than 19.99% of the outstanding shares of Holdco Common Stock.

In order to convert Series A Preferred Stock into shares of Holdco Common Stock, a holder must give notice to Holdco and surrender the original certificate or certificates therefor. Thereupon, Holdco shall, as soon as practicable, and in no event later than three trading days afterwards, issue and deliver to such holder of Series A Preferred Stock, or the nominee or nominees of such holder, a certificate or certificates representing the number of whole shares of Holdco Common Stock to which such holder shall be entitled. The conversion shall be deemed to have been made, and the resulting shares of Holdco Common Stock shall be deemed to have been issued, immediately prior to the close of business on the date of such notice and tender of the shares of Series A Preferred Stock.

Subject to the Protective Provisions (as defined below), in the event that, at any time or from time to time after Holdco first issues the Series A Preferred Stock: (1) a record date is fixed for the effectuation of a split or subdivision of outstanding shares of Holdco Common Stock, then, as of such record date, the Series A Conversion Price shall be appropriately decreased so that the number of shares of Holdco Common Stock issuable on conversion of each share of Series A Preferred Stock shall be increased in proportion to such increase of the aggregate number of shares of Holdco Common Stock outstanding; (2) a record date is fixed for the effectuation of a combination of outstanding shares of Holdco Common Stock, then, as of such record date, the Series A Conversion Price shall be appropriately increased so that the number of shares of Holdco Common Stock issuable on conversion of each share of Series A Preferred Stock shall be decreased in proportion to such

decrease in outstanding shares of Holdco Common Stock; and (3) there shall be a reclassification or recapitalization of outstanding shares of Holdco Common Stock (other than a split or subdivision provided for above, a liquidation, dissolution or winding up, certain qualifying mergers sales), provision shall be made so that the holders of Series A Preferred Stock shall thereafter be entitled to receive upon conversion of Series A Preferred Stock the number of shares of stock or other securities or property of Holdco or otherwise, to which a holder of shares of Holdco Common Stock deliverable upon conversion would have been entitled on such reclassification or recapitalization, and appropriate adjustment shall be made with respect to the rights of the holders of Series A Preferred Stock after the reclassification or recapitalization to the end that the foregoing shall be applicable after that event as nearly equivalently as may be practicable.

Reservation of Stock Issuable Upon Conversion

Holdco shall at all times reserve and keep available out of its authorized but unissued shares of Holdco Common Stock, solely for the purpose of effecting the conversion of outstanding shares of Series A Preferred Stock, such number of shares of Holdco Common Stock as shall from time to time be sufficient to effect the conversion of three hundred percent (300%) of all shares of Series A Preferred Stock then outstanding.

Protective Provisions

Holdco shall not, directly or indirectly, by amendment, merger, consolidation or otherwise, without (in addition to any other vote required by the Holdco Charter or applicable law) the prior vote or consent of the holders of at least 90% of the then outstanding shares of Series A Preferred Stock, voting or consenting separately as a single class: (1) amend, alter or repeal any provision of the Holdco Charter or the preferred stock designation with respect to the Series A Preferred Stock, if such action would adversely alter the powers, preferences, or special rights of the Series A Preferred Stock; (2) create, or authorize the creation of, or issue any series of Preferred Stock, or reclassify any class or series of capital stock into any series of Preferred Stock; (3) purchase or redeem, or permit any subsidiary to purchase or redeem, any shares of stock junior to the Series A Preferred Stock other than repurchases of shares of such capital stock from former directors, officers, employees, consultants or other persons performing services for Holdco or any subsidiary of Holdco in connection with the cessation of employment or service and for a purchase price per share of such capital stock not exceeding the original purchase price thereof; (4) incur, or permit Holdco's subsidiaries to incur, or issue, or permit Holdco's subsidiaries to issue, any indebtedness for borrowed money, including obligations (whether or not contingent), under guaranties, or loans or debt securities, including equity-linked or convertible debt securities; (5) declare or pay any dividend on any stock junior to the Series A Preferred Stock; or (6) enter into, or permit Holdco's subsidiaries to enter into, any agreement, arrangement or understanding providing for any of the actions described in the aforesaid items (1) — (5).

Redemption

Holdco, at the option of the Board, may at any time or from time to time upon not less than 10 business days' notice, redeem the whole or any part of the outstanding Series A Preferred Stock at a per share price of $1,000, subject to adjustment, plus all accumulated and unpaid dividends (the "Series A Redemption Price").

If Holdco closes on the issuance or sale of Holdco 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 Holdco in excess of $5 million, each holder of Series A Preferred Stock shall have the right to cause Holdco to apply up to 30% of the aggregate net proceeds from such issuance or sale, to the redemption of any or all of such holder's Series A Preferred Stock at the Series A Redemption Price.

Reissuance

No share or shares of Series A Preferred Stock acquired by Holdco by reason of conversion, redemption, repurchase or otherwise shall be reissued as Series A Preferred Stock, and all such shares thereafter shall be retired and cancelled and shall become authorized but unissued and undesignated Preferred Stock.

Provisions that Have or May Have the Effect of Delaying or Prohibiting a Change in Control

Classified Board

The Holdco Charter divides the Board into three classes with three directors being elected in each year and each class (except for those directors initially appointed as Class I and Class II directors) serving a three-year term. The initial Class I directors' term will expire at the annual general meeting for the fiscal year ended in 2023, the initial Class II directors' term will expire at the annual general meeting for the fiscal year ended in 2024, and the initial Class III directors' term will expire at the annual general meeting for the fiscal year ended in 2025.

Removal of Directors

The Holdco Charter provides that a director may be removed from office only for cause and by the affirmative vote of a majority of the total voting power of the outstanding shares of capital stock of Holdco entitled to vote generally in the election of directors, voting together as a single class. Subject to applicable law, however, if the Board were to establish a series of Preferred Stock and provide that series with the right to elect a director in the preferred stock designation, that director could be removed only by the holders of a majority of the shares of that series of Preferred Stock.

Exclusive Forum for Certain Lawsuits

The Holdco Charter provides that unless Holdco consents 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 Holdco, (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 Holdco to Holdco or its stockholders, (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL"), the Holdco Charter and the Holdco Bylaws, 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). The Holdco Charter also provides that, unless Holdco consents 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.

Special Meeting of Stockholders

Subject to the special rights, if any, of the holders of any series of Preferred Stock, a special meeting of the stockholders may be called only by or at the direction of the Board, the Chairperson of the Board or the Chief Executive Officer, and not by any other person or persons.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

The Holdco Bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors at an annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice will need to be received by Holdco secretary at Holdco's principal executive offices not later than the close of business on the 90th day, nor earlier than the opening of business on the 120th day, prior to the anniversary date of the immediately preceding annual meeting of stockholders. Pursuant to Rule 14a-8 of the Exchange Act, proposals seeking inclusion in Holdco's annual proxy statement must comply with the notice periods contained therein. The Holdco Bylaws

also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders.

Action by Written Consent

The Holdco Charter provides that any action required or permitted to be taken by the stockholders must be effected at a duly called annual or special meeting and may not be taken by written consent except that any preferred stock designation may provide that holders of the designated series of Preferred Stock may act by written consent.

Authorized but Unissued Shares of Holdco Common Stock and Preferred Stock

Holdco's authorized but unissued Holdco Common Stock and Preferred Stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Holdco Common Stock and Preferred Stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Limitation on Liability and Indemnification of Directors and Officers

The Holdco Charter provides that no director will be personally liable to Holdco or its stockholders, to the fullest extent permitted by the DGCL, for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to further eliminate or limit the liability of directors, then the liability of Holdco's directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. Any repeal or modification of this provision of the Holdco Charter will be prospective only and not adversely affect any right or protection of a director with respect to events occurring prior to the time of such repeal or modification.

The Holdco Bylaws also permit Holdco to secure insurance on behalf of any officer, director or employee for any liability arising out of his or her actions, regardless of whether Delaware law would permit indemnification. Holdco has or will purchase a policy of directors' and officers' liability insurance that insures Holdco's directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances and insures Holdco against its obligations to indemnify the directors and officers.

These provisions may discourage stockholders from bringing a lawsuit against Holdco's directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit Holdco and its stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent Holdco pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Holdco believes that these provisions, the insurance and the indemnity agreements are necessary to attract and retain talented and experienced directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Holdco pursuant to the foregoing provisions, or otherwise, Holdco has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Rule 144

Pursuant to Rule 144 under the Securities Act ("Rule 144"), a person who has beneficially owned restricted Holdco Common Stock or restricted Holdco Warrants for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been our affiliate at the time of, or at any time

during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and has filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as it was required to file reports) preceding the sale.

Persons who have beneficially owned restricted Holdco Common Stock or restricted Holdco Warrants for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of Holdco Common Stock then outstanding; or
- the average weekly reported trading volume of Holdco Common Stock or Warrants, as applicable, during the four calendar weeks preceding the date on which notice of the sale if filed with the SEC.

Sales by affiliates of Holdco Common Stock or Holdco Warrants under Rule 144 are also limited by manner of sale provisions and notice requirements and by the availability of current public information about Holdco.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business- combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials) other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10-type information with the SEC reflecting its status as an entity that is not a shell company.

We are no longer a shell company, and so, once the conditions listed above are satisfied, Rule 144 will become available for the resale of the above-noted restricted securities.

Transfer Agent and Warrant Agent

Continental Stock Transfer & Trust Company is the transfer agent for the Holdco Common Stock and the warrant agent for the Holdco Warrants.

Trading Symbol and Market

Holdco Common Stock and Holdco Warrants are listed on Nasdaq under the symbols “CMRA” and “CMRAW,” respectively.

Holders

As of January 20, 2023, there were 68 holders of record of shares of Holdco Common Stock. The number of holders of record does not include a potentially substantially greater number of “street name” holders or beneficial holders whose shares of Holdco Common Stock and Holdco Warrants are held of record by banks, brokers and other financial institutions.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of shares of Holdco Common Stock (the "Holdco Securities"). This discussion is limited to certain U.S. federal income tax considerations to beneficial owners of Holdco Securities who are initial purchasers of such Holdco Securities pursuant to this offering and hold the Holdco Securities as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"). This discussion assumes that any distributions made by us on Holdco Securities and any consideration received by a holder in consideration for the sale or other disposition of Holdco Securities will be in U.S. dollars.

This summary is based upon U.S. federal income tax laws as of the date of this prospectus, which is subject to change or differing interpretations, possibly with retroactive effect. This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors, including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own five percent or more (by vote or value) of Holdco Common Stock;
- persons that acquired Holdco Common Stock pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to Holdco Securities;
- persons holding Holdco Securities as part of a "straddle," constructive sale, hedge, conversion or other integrated or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships (or entities or arrangements classified as partnerships or other pass-through entities for U.S. federal income tax purposes) and any beneficial owners of such partnerships;
- tax-exempt entities;
- controlled foreign corporations; and
- passive foreign investment companies.

If a partnership (including an entity or arrangement treated as a partnership or other pass-thru entity for U.S. federal income tax purposes) holds Holdco Securities, the tax treatment of a partner, member or other beneficial owner in such partnership will generally depend upon the status of the partner, member or other beneficial owner, the activities of the partnership and certain determinations made at the partner, member or other beneficial owner level. If you are a partner, member or other beneficial owner of a partnership holding Holdco Securities, you are urged to consult your tax advisor regarding the tax consequences of the acquisition, ownership and disposition of Holdco Securities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and do not expect to seek, a ruling from the U.S. Internal Revenue Service (the "IRS") as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF HOLDCO SECURITIES. EACH PROSPECTIVE INVESTOR IN HOLDCO SECURITIES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF HOLDCO SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL NON-INCOME, STATE, LOCAL, AND NON-U.S. TAX LAWS.

U.S. Holders

This section applies to you if you are a "U.S. holder." A U.S. holder is a beneficial owner Holdco Securities who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a United States person.

Taxation of Distributions.

If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of Holdco Common Stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in Holdco Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the Holdco Common Stock and will be treated as described under "*U.S. Holders — Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Holdco Securities*" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited

to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividend income" that will be subject to tax at preferential long-term capital gains rates. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate U.S. holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Holdco Securities.

Upon a sale or other taxable disposition of Holdco Securities, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the Common Stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the Common Stock so disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. holders may be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its Holdco Securities so disposed of. A U.S. holder's adjusted tax basis in its Holdco Securities generally will equal the U.S. holder's acquisition cost less any prior distributions treated as a return of capital.

Information Reporting and Backup Withholding.

In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of Holdco Securities, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS.

Non-U.S. Holders

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of Holdco Securities who or that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the United States subject to U.S. tax as expatriates);
- a foreign corporation; or
- an estate or trust that is not a U.S. holder;

but generally does not include an individual who is present in the United States for 183 days or more in the taxable year of the disposition of Holdco Securities. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of Holdco Securities.

Taxation of Distributions.

In general, any distributions we make to a Non-U.S. holder of shares of Holdco Securities, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles),

will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of Holdco Common Stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the Holdco Common Stock, which will be treated as described under "*Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Holdco Securities*" below. In addition, if we determine that we are likely to be classified as a "United States real property holding corporation" (see "*Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Holdco Securities*" below), we generally will withhold 15% of any distribution that exceeds our current and accumulated earnings and profits.

The withholding tax generally does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. federal income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A corporate Non-U.S. holder receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower applicable treaty rate).

Gain on Sale, Taxable Exchange or Other Taxable Disposition of Holdco Securities.

A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain realized on a sale, taxable exchange or other taxable disposition of Holdco Securities unless:

- the gain is effectively connected with the conduct by the Non-U.S. holder of a trade or business within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held Holdco Common Stock, and, in the case where shares of Holdco Common Stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of Holdco Securities at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of Holdco Common Stock. There can be no assurance that Holdco Common Stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" imposed at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of Holdco Securities will be subject to tax at generally applicable U.S. federal income tax rates. In addition, a buyer of Holdco Securities from such holder may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized upon such disposition. We will be classified as a United States real property holding corporation if the fair market value of our "United States real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes.

Information Reporting and Backup Withholding.

Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of shares of Holdco Securities. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty generally will satisfy the certification requirements necessary to avoid the backup withholding as well.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes

Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred as the "Foreign Account Tax Compliance Act" or "FATCA") generally impose withholding at a rate of 30% in certain circumstances on dividends in respect of Holdco Securities which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (1) enters into, and complies with, an agreement with the IRS to report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (2) if required under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which will exchange such information with the U.S. authorities. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the entity through which Holdco Securities are held will affect the determination of whether such withholding is required. Similarly, dividends in respect of Holdco Securities held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (1) certifies to us or the applicable withholding agent that such entity does not have any "substantial United States owners" or (2) provides certain information regarding the entity's "substantial United States owners," which will in turn be provided to the U.S. Department of Treasury. Under certain circumstances, a Non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a Non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits.

Thirty percent withholding under FATCA was scheduled to apply to payments of gross proceeds from the sale or other disposition of property that produces U.S.-source interest or dividends beginning on January 1, 2019, but on December 13, 2018, the IRS released proposed regulations that, if finalized in their proposed form, would eliminate the obligation to withhold on gross proceeds. Such proposed regulations also delayed withholding on certain other payments received from other foreign financial institutions that are allocable, as provided for under final Treasury Regulations, to payments of U.S.-source dividends, and other fixed or determinable annual or periodic income.

Although these proposed Treasury Regulations are not final, taxpayers generally may rely on them until final Treasury Regulations are issued. All prospective investors should consult their tax advisors regarding the possible implications of FATCA on their investment in our securities.

SELLING STOCKHOLDERS

This prospectus relates to the offer and sale by the Selling Stockholders of up to 7,218,726 shares of Holdco Common Stock, including 2,406,242 shares of Holdco Common Stock already issued to the Selling Stockholders and 4,812,484 shares of Holdco Common Stock issuable upon exercise of the Private Placement Warrants, if any. We are registering the shares of Holdco Common Stock included in this prospectus pursuant to the Purchase Agreement and Registration Rights Agreement, in order to permit the Selling Stockholders to offer the shares included in this prospectus for resale from time to time. When we refer to the "Selling Stockholders" in this prospectus, we refer to the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors and other permitted transferees that hold any of the Selling Stockholders' interests in the shares of Holdco Common Stock after the date of this prospectus.

The table below presents information regarding the Selling Stockholders and the shares of Holdco Common Stock that may be resold by the Selling Stockholders from time to time under this prospectus. This table is prepared based on information supplied to us by the Selling Stockholders, and reflects holdings as of January 20, 2023. The number of shares in the column "Maximum Number of Shares of Holdco Common Stock to be Offered Pursuant to this Prospectus" represents all of the shares of Holdco Common Stock being offered for resale by the Selling Stockholders under this prospectus. The Selling Stockholders may sell some, all or none of the shares being offered for resale in this offering. We do not know how long the Selling Stockholders will hold the shares before selling them. Except as set forth in the section titled "*Plan of Distribution*" in this prospectus, we are not aware of any existing arrangements between the Selling Stockholders and any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares of Holdco Common Stock being offered for resale by this prospectus.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act, and includes shares of Holdco Common Stock with respect to which the Selling Stockholder has sole or shared voting and investment power. The percentage of shares of Holdco Common Stock beneficially owned by the Selling Stockholders prior to the offering shown in the table below is based on an aggregate of 22,265,463 shares of Holdco Common Stock outstanding on January 20, 2023. The fourth column assumes the resale by the Selling Stockholder of all of the shares of Holdco Common Stock being offered for resale pursuant to this prospectus.

Please see the section entitled "*Plan of Distribution*" for further information regarding the Selling Securityholders' methods of distributing these securities. For information regarding transactions between us and the Selling Securityholders, see the section entitled "*Certain Relationships and Related Party Transactions*."

Name of Selling Stockholder	Number of Shares of Holdco Common Stock Owned Prior to Offering (#)	(%)	Maximum Number of Shares of Holdco Common Stock to be Offered[1]	Number of Shares of Holdco Common Stock Owned After Offering (#)	(%)
The Soane Family Trust[2]	3,471,696	15.50%	202,701	3,268,995	14.59%
Charles Cherington[3]	2,879,666	12.12%	2,229,729	649,937	2.74%
IAF, LLC[4]	2,170,180	9.31%	1,550,673	619,507	2.66%
Freebird Partners LP [5]	1,313,423	5.71%	1,114,863	198,560	*
Denny Family Partners II LLC[6]	1,005,226	4.43%	608,106	397,120	1.75%
John Halpern[7]	924,575	4.08%	608,106	316,469	1.40%
James Sherblom[8]	708,333	3.16%	608,106	100,227	*
The Alexander V. Soane 2019 Irrevocable Trust[9]	223,863	1.00%	202,701	21,162	*
The Nicholas V. Soane 2019 Irrevocable Trust[10]	223,863	1.00%	202,701	21,162	*
Stuart Randle[8]	123,493	*	101,349	22,144	*
Roopom Banerjee[8]	82,954	*	60,810	22,144	*
Kirsten Flowers[8]	62,683	*	40,539	22,144	*
Edward Sullivan[8]	55,081	*	32,937	22,144	*
Barbara Finck[11]	51,938	*	20,268	31,670	*

* Represents beneficial ownership of less than 1% of the outstanding shares of Holdco Common Stock.

(1) Represents shares of Holdco Common Stock and shares of Holdco Common Stock issuable upon exercise of the Private Placement Warrants acquired pursuant to the Private Placement.

(2) Does not include (a) 589,786 shares of Holdco Common Stock held by David Soane, or (b) 223,863 shares of Holdco Common Stock 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 beneficially own the shares of Holdco Common Stock held thereby. The principal business address of the Selling Stockholder is c/o Soane Labs, LLC, 380 NE 72nd Terrace, Miam, Florida 33138.

(3) Does not include (a) 1,268,761 shares of Holdco Common Stock held by Cherington Holdings LLC, (b) 95,328 shares of Holdco Common Stock held by each of The Ashley S. Pettus 2012 Irrevocable Trust FBO Bejamin P. Cherington and The Ashley S. Pettus 2012 Irrevocable Trust FBO Henry S. Cherington, or (c) 95,327 shares of Holdco Common Stock 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 Holdco 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.

(4) David W. Laughlin is the Sole Manager of IAF, LLC and may be deemed to share beneficial ownership of the securities held thereby. The principal business address of the Selling Stockholder is 15 Church Street, Charleston, South Carolina 29401.

(5) 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 principal business address of the Selling Stockholder is 2800 Post Oak Blvd, Suite 2000.

(6) George Denny is the Manager of Denny Family Partners II LLC and may be deemed to share beneficial ownership of the securities held thereby. The principal business address of the Selling Stockholder is 14 Grayvik Dr., Key Largo, Florida 33037.

(7) The principal business address of the Selling Stockholder is 260 Palmetto Lane, West Palm Beach, Florida 33405.

(8) The Selling Stockholder is a current member of Holdco Board. The principal business address of the Selling Stockholder is c/o Comera Life Sciences Holdings, Inc., 12 Gill Street, Suite 4650, Woburn, Massachusetts 01801.

(9) Does not include (a) 589,786 shares of Holdco Common Stock held by David Soane, (b) 223,863 shares of Holdco Common Stock held by The Nicholas V. Soane 2019 Irrevocable Trust or (c) 3,471,696 shares of Holdco Common Stock held by The Soane Family Trust. David Soane is the trustee of each of the Soane Trusts and may therefore be deemed to beneficially own the shares of Holdco Common Stock held thereby. The principal business address of the Selling Stockholder is c/o Soane Labs, LLC, 380 NE 72nd Terrace, Miam, Florida 33138.

(10) Does not include (a) 589,786 shares of Holdco Common Stock held by David Soane, (b) 223,863 shares of Holdco Common Stock held by The Alexander V. Soane 2019 Irrevocable Trust or (c) 3,471,696 shares of Holdco Common Stock held by The Soane Family Trust. David Soane is the trustee of each of the Soane Trusts and may therefore be deemed to beneficially own the shares of Holdco Common Stock held thereby. The principal business address of the Selling Stockholder is c/o Soane Labs, LLC, 380 NE 72nd Terrace, Miam, Florida 33138.

(11) The Selling Stockholder is a former member of the Holdco Board (resigned January 4, 2023). The principal business address of the Selling Stockholder is c/o Comera Life Sciences Holdings, Inc., 12 Gill Street, Suite 4650, Woburn, Massachusetts 01801.

PLAN OF DISTRIBUTION

Each Selling Stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market for such securities or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- in market transactions, including transactions on a national securities exchange or quotations service or in the over-the-counter market;
- block trades in which the broker-dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an exchange distribution in accordance with the rules of the exchange;
- through trading plans entered into by a Selling Stockholder pursuant to Rule 10b5-1 under the Exchange Act that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- settlement of short sales entered into after the date of this prospectus;
- agreements with broker-dealers to sell a specified number of the securities at a stipulated price per share;
- directly to purchasers, including through a specific bidding, auction or other process or in privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- transfers pursuant to a loan, pledge or similar arrangement;
- through a combination of any of the above methods of sale; or
- any other method permitted pursuant to applicable law.

In addition, a Selling Stockholder that is an entity may elect to make a *pro rata* in-kind distribution of securities to its members, partners or stockholders pursuant to the registration statement of which this prospectus is a part by delivering a prospectus with a plan of distribution. Such members, partners or stockholders would thereby receive freely tradeable securities pursuant to the distribution through a registration statement. To the extent a distributee is an affiliate of ours (or to the extent otherwise required by law), we may file a prospectus supplement in order to permit the distributees to use the prospectus to resell the securities acquired in the distribution.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

The Selling Stockholders also may transfer the securities in other circumstances, in which case the transferees, donees, pledgees or other successors-in-interest will be the selling beneficial owners for purposes of this prospectus. Upon being notified by a Selling Stockholder that a transferee, donee, pledgee or other successor-in-interest intends to sell our securities, we will, to the extent required, promptly file a supplement to this prospectus to name specifically such person as a selling Stockholder.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by such Selling Stockholder. The Selling Stockholder may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities upon default. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or the Exchange Act in connection with the securities being registered pursuant to this prospectus.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

EXPERTS

The financial statements of Comera as of December 31, 2021 and 2020, and for each of the years then ended, included in this prospectus, have been audited by Baker Tilly US, LLP, an independent registered public accounting firm, as stated in their report appearing elsewhere herein, which contains an explanatory paragraph regarding Comera’s ability to continue as a going concern. Such financial statements have been included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

CHANGES IN REGISTRANT'S CERTIFYING ACCOUNTANT

(a) Dismissal of independent registered public accounting firm

On July 28, 2022, the audit committee (the "Audit Committee") of the board of directors of Holdco (the "Board") approved the engagement of Baker Tilly US, LLP ("Baker Tilly") as Holdco's principal independent registered public accounting firm and dismissed WithumSmith+Brown, PC ("Withum"), who had previously served as the independent registered public accounting firm of OTR prior to the consummation of the Transaction.

The report of Withum on OTR's balance sheets as of December 31, 2021 and 2020, and the related statements of operations, changes in stockholders' deficit and cash flows for the year ended December 31, 2021 and the period from July 23, 2020 (inception) to December 31, 2020, and the related notes to the financial statements, did not contain an adverse opinion or a disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles, other than the restatement of OTR's financial statements for the annual period ended December 31, 2020 as reflected in OTR's filing on Form 10-K/A completed on March 8, 2022 and the emphasis of matters regarding OTR's ability to continue as a going concern. In addition, OTR restated its interim financial statements for the quarterly periods ended March 31, 2021, June 30, 2021 and September 30, 2021 as reflected in OTR's filing on Form 10-Q/A filed on December 13, 2021.

During the period from July 23, 2020 (inception) to December 31, 2021, and the subsequent interim period through July 27, 2022, there were no "disagreements" (as such term is defined in Item 304(a)(1)(iv) of Regulation S-K under the Exchange Act) between OTR and Withum on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Withum, would have caused it to make reference to the subject matter of the disagreements in its reports on OTR's financial statements.

During the period from July 23, 2020 (inception) to December 31, 2021, and the subsequent interim period through July 27, 2022, there were no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K under the Exchange Act), other than the occurrence of material weaknesses in internal control over financial reporting for the year ended December 31, 2021, the period from July 23, 2020 (inception) to December 31, 2020 (and all interim periods with such periods) and the quarterly period ended March 31, 2022 as a result of OTR's disclosure controls not being effective for such periods (and no assessment was rendered by Withum for the quarter ended June 30, 2022 following the closing of the business combination on May 19, 2022).

(b) Disclosures regarding the new independent auditor

Baker Tilly served as the independent registered public accounting firm of Comera prior to the Transaction. During the period from January 24, 2022 (inception) through July 27, 2022, the Company did not consult with Baker Tilly with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Baker Tilly concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any other matter that was the subject of a disagreement or a reportable event (as defined above).

LEGAL MATTERS

Foley Hoag LLP, Boston, Massachusetts, will pass upon the validity of the securities offered hereby.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the Holdco Common Stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to Holdco we refer you to the registration statement, including the exhibits filed as a part of the registration statement.

Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement is this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

INDEX TO FINANCIAL STATEMENTS

COMERA LIFE SCIENCES, INC.

Index to Financial Statements as of December 31, 2021 and 2020 and for the Years Then Ended

Unaudited Condensed Financial Statements as of September 30, 2022 and December 31, 2021 and for the Nine Months Ended September 30, 2022 and September 30, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Comera Life Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Comera Life Sciences, Inc. (the "Company") as of December 31, 2021 and 2020, the related 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, 2021 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses since inception, and has an accumulated deficit as of December 31, 2021. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Baker Tilly US, LLP

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

Tewksbury, Massachusetts
March 8, 2022,
Except for the effects of the reverse recapitalization described in Note 1, as to which the date is September 2, 2022.

COMERA LIFE SCIENCES, INC.
BALANCE SHEETS

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 6,510,140	$ 155,427
Accounts receivable	—	109,868
Due from related parties	286	5,400
Prepaid expenses and other current assets	270,648	39,693
Total current assets	6,781,074	310,388
Restricted cash	50,000	25,000
Property and equipment, net	234,167	178,290
Right of use asset	320,373	—
Security deposit	32,200	32,200
Total assets	$ 7,417,814	$ 545,878
Liabilities, Convertible Preferred Stock, Stockholders' Deficit and Members' Equity		
Current liabilities:		
Accounts payable	$ 416,941	$ 97,616
Accrued expenses and other current liabilities	506,611	106,810
Deferred revenue	—	28,949
Lease liability—current	121,552	—
Total current liabilities	1,045,104	233,375
Note payable	—	160,588
Lease liability—noncurrent	201,504	—
Total liabilities	1,246,608	393,963
Commitments and contingencies (Note 17)		
Convertible preferred stock (Note 9)	20,857,453	—
Stockholders' deficit and members' equity[(1)]:		
Capital units	—	10,681,040
Common stock, $0.0001 par value; 150,000,000 shares authorized; 308,443 and no shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	31	—
Additional paid-in capital	2,213,547	918,922
Accumulated deficit	(16,899,825)	(11,448,047)
Total stockholders' deficit and members' equity	(14,686,247)	151,915
Total liabilities, convertible preferred stock, stockholders' deficit and members' equity	$ 7,417,814	$ 545,878

(1) Retroactively adjusted for the reverse recapitalization as described in Note 1.

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

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

	Year Ended December 31,	
	2021	2020
Revenue	$ 319,832	$ 442,919
Cost of revenue	161,008	104,407
Operating expenses:		
Research and development	1,752,669	1,261,747
General and administrative	3,941,783	1,204,285
Total operating expenses	5,694,452	2,466,032
Loss from operations	(5,535,628)	(2,127,520)
Other income (expense), net:		
Gain on debt extinguishment	160,588	—
Change in fair value of convertible notes	(76,738)	—
Other income, net	—	2,033
Total other income, net	83,850	2,033
Net loss and comprehensive loss	$ (5,451,778)	$ (2,125,487)
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted[1]	$ (1.81)	$ (0.25)
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[1]	3,012,603	8,521,250

(1) Retroactively adjusted for the reverse recapitalization as described in Note 1.

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

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

	Convertible Preferred Stock		Capital Units		Incentive Units		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit or Members' Equity
	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount			
Balance as of January 1, 2020	—	$ —	8,748,276	$ 9,118,198	1,823,017	$ —	—	$ —	$ 817,882	$ (9,322,560)	$ 613,520
Issuance of capital units, net of issuance costs of $50,068	—	—	680,730	1,562,842	—	—	—	—	—	—	1,562,842
Vesting of incentive units	—	—	—	—	164,457	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	101,040	—	101,040
Net loss	—	—	—	—	—	—	—	—	—	(2,125,487)	(2,125,487)
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	—	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options[1]	—	—	—	—	—	—	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)

(1) Retroactively adjusted for the reverse recapitalization as described in Note 1.

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

COMERA LIFE SCIENCES, INC.
STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2021	2020
Cash flows from operating activities:		
Net loss	$ (5,451,778)	$ (2,125,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,114,656	101,040
Depreciation expense	86,136	89,749
Loss on disposal of equipment	—	1,392
Noncash consulting expense	—	171,100
Noncash lease expense	2,683	—
Gain on debt extinguishment	(160,588)	—
Change in fair value of convertible notes	76,738	—
Changes in operating assets and liabilities:		
Accounts receivable	109,868	(113,068)
Prepaid expenses and other current assets	(230,955)	(583)
Due from related parties	5,114	(5,400)
Accounts payable	319,325	20,981
Accrued expenses and other current liabilities	399,801	82,223
Deferred revenue	(28,949)	(26,051)
Net cash used in operating activities	(3,757,949)	(1,804,104)
Cash flows from investing activities:		
Purchases of property and equipment	(142,013)	(12,366)
Net cash used in investing activities	(142,013)	(12,366)
Cash flows from financing activities:		
Proceeds from issuance of capital units, net of issuance costs	—	1,391,742
Proceeds from issuance of convertible preferred stock, net of issuance costs	9,349,675	—
Proceeds from issuance of promissory note	—	160,588
Proceeds from issuance of convertible notes	750,000	—
Proceeds from exercise of stock options	180,000	—
Net cash provided by financing activities	10,279,675	1,552,330
Net increase (decrease) in cash, cash equivalents and restricted cash	6,379,713	(264,140)
Cash, cash equivalents and restricted cash at beginning of year	180,427	444,567
Cash, cash equivalents, and restricted cash at end of year	$ 6,560,140	$ 180,427
Supplemental disclosures of noncash activities:		
Issuance of capital units in exchange for services	$ —	$ 171,100
Conversion of capital units into convertible preferred stock	$ 10,681,040	$ —
Settlement of convertible notes for convertible preferred stock	$ 826,738	$ —

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

COMERA LIFE SCIENCES, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization

Formation and Organization

Comera Life Sciences, Inc. ("Comera" or "Company") was formed in the state of Delaware on January 2, 2014 as ReForm Biologics, LLC. On April 30, 2021, the Company 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 the Company as of the date of the Reorganization was exchanged for shares of convertible preferred stock and previously outstanding incentive units of the Company were cancelled. On January 7, 2022, the Company changed its name to Comera Life Sciences, Inc. to emphasize the Company's vision of a compassionate new era in medicine.

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 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 while simultaneously lowering healthcare costs. To accomplish this, Comera is developing an internal portfolio of proprietary therapeutics that incorporate the Company's innovative proprietary formulation platform, SQore™. Comera also collaborates with pharmaceutical and biotechnology companies, applying the SQore™ platform to the Company's partners' biologic medicines to deliver enhanced formulations that facilitate self-injectable care.

Reverse Recapitalization

Comera Life Sciences Holdings, Inc. ("CLS Holdings") was incorporated in Delaware on January 25, 2022 as a wholly-owned subsidiary of Comera Life Sciences, Inc. for the purpose of effecting the Transaction (as defined below). On May 19, 2022 (the "Closing Date"), CLS Holdings consummated the acquisition of all the issued and outstanding shares of OTR Acquisition Corp. ("OTR") and Comera (the "Transaction"), in accordance with the Business Combination Agreement dated January 31, 2022 (as amended May 19, 2022, the "Business Combination Agreement") by and among CLS Holdings, 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 Comera was effected through the merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly-owned subsidiary of CLS Holdings, and through a merger of Comera Merger Sub with and into Comera, with Comera 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.

The Transaction was accounted for as a reverse recapitalization, with OTR being treated as the "acquired" company and Comera being treated as the "acquirer" for accounting purposes based upon the pre-merger shareholders of Comera holding the majority of the voting interests of CLS Holdings, Comera's existing management team serving as the initial management team of CLS Holdings, Comera's appointment of the majority of the initial board of directors of CLS Holdings, and Comera's operations comprising the ongoing operations of the combined company.

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 common stock instruments, prior to the Transaction, have been retroactively adjusted to share amounts reflecting the capital structure of CLS Holdings

following the Transaction, including adjustments based on the exchange ratio (the "Exchange Ratio"). Accordingly, certain amounts have been retroactively adjusted to reflect the reverse recapitalization pursuant to the Transaction for all periods presented within the balance sheets and statements of convertible preferred stock, stockholders' deficit and members' capital. Additionally, the net loss per share or unit and weighted-average number of common shares or units used in computing net loss per share or unit attributable to common stockholders or unit holders, prior to the Transaction, have been retroactively adjusted to amounts reflecting the Exchange Ratio established in the Transaction.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("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, 2021, the Company has funded its operations primarily with proceeds from the issuance of capital units, convertible notes, and preferred stock. The Company has incurred recurring losses since its inception, including net losses of $5.5 million and $2.1 million for the years ended December 31, 2021 and 2020, respectively. In addition, as of December 31, 2021, the Company had an accumulated deficit of $16.9 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 and cash equivalents on hand as of December 31, 2021 of $6.5 million will be sufficient to fund its operations and capital expenditure requirements for the next twelve months from the date the financial statements are issued. The Company 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 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 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.

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict.

The Company plans to continue to closely monitor the ongoing impact of the COVID-19 pandemic on the Company's employees and other business operations. In an effort to provide a safe work environment for the Company's employees, the Company has, among other things, limited employees in the Company's office and lab facilities to those where on-site presence is needed for their job activities, implemented various social distancing measures in the Company's offices and labs including replacing all in-person meetings with virtual interactions, and are providing personal protective equipment for the Company's employees present in the Company's office and lab facilities. The Company is continuing to monitor the impact and effects of the COVID-19 pandemic and the Company's response to it, and the Company expects to continue to take actions as may be required or recommended by government authorities or that are determined to be in the best interests of the Company's employees and other business partners in light of the pandemic.

Use of Estimates

The preparation of 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 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 financial statements include, but are not limited to, the valuation of the Company's common stock, capital and incentive units and stock-based compensation. 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 accounts receivable, due from related parties, accounts payable, and

accrued expenses. The fair value of long-term debt approximates its carrying value and has been estimated based on interest rates being offered for similar debt having the same or similar remaining maturities and terms of repayment.

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 potentially uncollectible 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. 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, 2021 and 2020, there was no allowance for credit losses or bad debt, respectively

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, 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, 2021 and 2020.

Leases

Effective January 1, 2021, the Company adopted ASU 2016-02, *Leases* (Topic 842). 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 income, net in the 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.

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*. The convertible preferred stock is only redeemable upon the occurrence of certain deemed liquidation events. As the preferred stock is considered to be contingently redeemable, the preferred stock has been classified outside of permanent equity. The preferred stock will be accreted to its redemption value if the deemed liquidation events are considered probable of occurring.

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 Topic 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 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, 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 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

Effective January 1, 2019 and January 1, 2021, the Company adopted FASB ASU No. 2014-09 (Topic 606), *Revenue from Contracts with Customers*, and its related amendments (collectively known as "ASC 606") and ASU No. 2018-18, *Clarifying the Interaction between Topic 808 (Collaborative Arrangements) and Topic 606 (Revenue from Contracts with Customers)*, respectively. The Company's principal sources of revenue during the years ended December 31, 2021 and 2020, were derived from research and development service agreements with customers.

At inception, management determines whether contracts are within the scope of 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. Amounts received prior to revenue recognition are recorded as deferred revenue. 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 consolidated 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. 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 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 the Company's equity, the Company and the board of directors were required to estimate the fair value of the Company'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 the Company'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, 2021 and 2020, 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, to 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.

Subsequent Event Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the date the financial statements are issued to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The guidance in ASU 2016-02 supersedes the prior leasing guidance, which requires lessees to recognize right-of use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. The Company adopted ASU 2016-02, as amended, as of January 1, 2021 by applying the modified retrospective approach for leases existing at, and entered into after, January 1, 2021. In addition, the standard allows for certain practical expedients in transition to ASU 2016-02, including the package of practical expedients. The Company utilized the package of practical expedients which allowed the Company to not reassess the following: (i) whether any expired or existing contracts contained leases; (ii) the lease classification for any expired or existing leases; and (iii) the treatment of initial direct costs for any existing leases. The adoption of this standard resulted in the recognition of a right of use asset and corresponding operating lease liability of $66 thousand upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments*, which has been subsequently amended ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company early adopted ASU 2016-13, as amended, as of January 1, 2021. The adoption of this standard did not have a material effect on the Company's financial statements upon adoption.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). ASU 2018-18 provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The Company early adopted this guidance as of January 1, 2021. The adoption of this standard did not have a material effect on the Company's financial statements upon adoption.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). This ASU simplifies the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exceptions for contracts in an entity's own equity. Under ASU 2020-06, certain features, including beneficial conversion features, are no longer required to be separately accounted for. The new guidance also requires the if-converted method to be applied for all convertible instruments and requires additional disclosures. The Company early adopted this standard as of January 1, 2021. The adoption of this standard did not have a material effect on the Company's financial statements upon adoption.

Recently Issued 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 financial statements and disclosures.

Reclassification of Prior Year Presentation

Certain immaterial prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

3. Fair Value of Financial Assets and Liabilities

As of December 31, 2021 and 2020, the Company did not hold any financial assets or liabilities that were measured at fair value on a recurring or nonrecurring basis. There were no assets or liabilities for which fair value was required to be disclosed. During the years ended December 31, 2021 and 2020, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of Convertible Notes

During the year ended December 31, 2021, the Company issued convertible notes to certain existing investors. The Company has elected to account for these instruments utilizing the fair value option as permitted under ASC 825. Management believes the fair value option more closely reflects the economics of the transaction from the perspective of the counterparties. At issuance the Notes were considered to have a fair value equal to the principal of the Notes and at settlement the Notes were considered to have a fair value equal to the fair value of the convertible preferred stock that was issued in settlement of the Notes. The fair value of the convertible preferred stock that was issued in settlement of the Notes was based on an option pricing model. The option pricing model utilized an enterprise value that was determined utilizing a backsolve method based on the issuance of a new class of preferred stock in an arms-length transaction. The enterprise value was then allocated to the various outstanding classes of equity. This model utilizes unobservable inputs. The change in fair value for the year ended December 31, 2021 was $77 thousand which was recorded as change in fair value of convertible notes in the Company's statements of operations and comprehensive loss.

The following table sets forth a summary of changes in the fair value of the Company's Notes for which fair value is determined by Level 3 inputs:

	Convertible Notes
Value as of December 31, 2020	$ —
Issuance of convertible notes	750,000
Change in fair value of convertible notes	76,738
Settlement into convertible preferred stock	(826,738)
Value as of December 31, 2021	$ —

4. Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheet and included in the statement of cash flows:

	December 31,	
	2021	2020
Cash and cash equivalents	$ 6,510,140	$ 155,427
Restricted cash	50,000	25,000
Cash, cash equivalents, and restricted cash	$ 6,560,140	$ 180,427

Amounts included in restricted cash as of December 31, 2021 and 2020 consist of cash held to collateralize a letter of credit issued as a security deposit in connection with the Company's lease on its corporate facility and for certain credit cards.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2021	2020
Contract assets	$ 85,018	$ —
Insurance recovery receivable	136,250	
Prepaid employee benefits	2,000	10,722
Prepaid rent	—	11,201
Other	47,380	17,770
Prepaid expenses and other current assets	$270,648	$39,693

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2021	2020
Lab equipment	$ 587,650	$ 463,817
Leasehold improvements	17,973	11,258
Computer equipment	21,747	10,282
Other equipment	9,411	9,411
	636,781	494,768
Less accumulated depreciation	(402,614)	(316,478)
Property and equipment, net	$ 234,167	$ 178,290

Depreciation expense for the years ended December 31, 2021 and 2020 was $86 thousand and $90 thousand, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2021	2020
Accrued bonus	$349,000	$ —
Professional fees	123,756	85,088
Accrued vacation	25,945	20,328
Other	7,910	1,394
Accrued expenses and other current liabilities	$506,611	$106,810

8. Members' Equity and Corporate Reorganization

On April 30, 2021, the Company completed the Reorganization. As part of the Reorganization each issued and outstanding capital unit of ReForm Biologics, LLC as of the date of the Reorganization was exchanged for shares of convertible preferred stock and previously outstanding incentive units of ReForm Biologics, LLC were cancelled. The financial statements as of and for the year ended December 31, 2021, reflect the exchange of capital units to convertible preferred stock.

The following summarizes the activity of Capital Units for the year ended December 31, 2021:

	Class A1 Capital Units		Class B1 Capital Units		Class B1-A Capital Units		Total Capital Units	
	Units	Amount	Units	Amount	Units	Amount	Units	Amount
Balance as of December 31, 2020	8,811,088	$ 9,289,298	514,932	$ 1,329,024	102,986	$ 62,718	9,429,006	$ 10,681,040
Conversion of capital units into convertible preferred stock	(8,811,088)	(9,289,298)	(514,932)	(1,329,024)	(102,986)	(62,718)	(9,429,006)	(10,681,040)
Balance as of December 31, 2021	—	$ —	—	$ —	—	$ —	—	$ —

The following summarizes the activity of Capital Units for the year ended December 31, 2020:

	Class A1 Capital Units		Class B1 Capital Units		Class B1-A Capital Units		Total Capital Units	
	Units	Amount	Units	Amount	Units	Amount	Units	Amount
Balance as of January 1, 2020	8,748,276	$ 9,118,198	—	$ —	—	$ —	8,748,276	$ 9,118,198
Issuance of capital units, net of issuance costs of $50,068	62,812	171,100	514,932	1,329,024	102,986	62,718	680,730	1,562,842
Balance as of December 31, 2020	8,811,088	$ 9,289,298	514,932	$ 1,329,024	102,986	$ 62,718	9,429,006	$ 10,681,040

During 2020, the Company issued an aggregate of 62,812 Class A Capital Units in exchange for services rendered in the amount of $171 thousand. Additionally, during 2020 the Company issued 514,932 Class B1 Capital Units and 102,986 Class B1-A Capital Units in exchange for gross cash proceeds of $1.4 million. The proceeds were allocated to the B1 and B1-A Capital Units utilizing a relative fair value basis.

9. Convertible Preferred Stock

As of December 31, 2021, the authorized capital stock of the Company included 14,051,702 shares of $0.001 par value preferred stock, of which 9,429,006 shares have been designated as series A convertible preferred stock (“Series A Preferred Stock”) and 4,622,696 shares have been designated as series B convertible preferred stock (“Series B Preferred Stock”).

Convertible preferred stock consisted of the following as of December 31, 2021:

	Par Value	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Convertible Preferred Stock	$0.001	6,000,000	6,000,000	$ 2,972,028	$ 18,000,000	6,000,000
Series A-2 Convertible Preferred Stock	$0.001	1,266,667	1,266,667	$ 1,865,374	$ 3,800,001	1,266,667
Series A-3 Convertible Preferred Stock	$0.001	527,752	527,752	$ 1,416,519	$ 1,583,256	527,752
Series A-4 Convertible Preferred Stock	$0.001	1,016,669	1,016,669	$ 3,035,377	$ 3,050,007	1,016,669
Series A-5 Convertible Preferred Stock	$0.001	514,932	514,932	$ 1,329,024	$ 2,162,714	514,932
Series A-6 Convertible Preferred Stock	$0.001	102,986	102,986	$ 62,718	$ 144,180	102,986
Series B-1 Convertible Preferred Stock	$0.001	4,219,409	3,970,465	$ 9,352,627	$ 9,410,002	3,970,465
Series B-2 Convertible Preferred Stock	$0.001	403,287	403,287	$ 823,786	$ 766,245	403,287
		14,051,702	13,802,758	$ 20,857,453	$ 38,916,405	13,802,758

The following summarizes the activity of the Series A convertible preferred stock for the year ended December 31, 2021:

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series A-3 Convertible Preferred Stock		Series A-4 Convertible Preferred Stock		Series A-5 Convertible Preferred Stock		Series A-6 Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance as of December 31, 2020	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —
Conversion of capital units into convertible preferred stock	6,000,000	2,972,028	1,266,667	1,865,374	527,752	1,416,519	1,016,669	3,035,377	514,932	1,329,024	102,986	62,718
Balance as of December 31, 2021	6,000,000	$ 2,972,028	1,266,667	$ 1,865,374	527,752	$ 1,416,519	1,016,669	$ 3,035,377	514,932	$ 1,329,024	102,986	$ 62,718

The following summarizes the activity of the Series B convertible preferred stock for the year ended December 31, 2021:

	Series B-1 Convertible Preferred Stock		Series B-2 Convertible Preferred Stock	
	Shares	Amount	Shares	Amount
Balance as of December 31, 2020	—	$ —	—	$ —
Issuance of convertible preferred stock, net of issuance costs of $60,327	3,970,465	9,352,627	403,287	823,786
Balance as of December 31, 2021	3,970,465	$ 9,352,627	403,287	$ 823,786

In April 2021, the Company 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 Series A Preferred Stock was issued in settlement of previously outstanding capital units of ReForm Biologics, LLC as part of the Reorganization.

In connection with the series B preferred stock purchase agreement dated May 26, 2021 (the “Series B Purchase Agreement”), the Company initially issued 2,240,507 shares of Series B-1 convertible preferred stock (the “Series B-1 Preferred Stock”) at an initial issuance price of $2.37 per share for total gross proceeds of $5.3 million. Concurrent with the issuance of these shares, the Company also issued 403,287 shares of Series B-2 preferred stock that were issued to settle the Notes. The Series B Purchase Agreement provided for the issuance of up to an additional 1,978,902 shares of Series B-1 Preferred Stock at the same terms to new investors. This provision does not create any enforceable rights or obligations related to the issuance of additional shares.

In a second closing associated with the Series B Purchase Agreement, during June 2021, the Company issued an additional 843,882 shares of Series B-1 Preferred Stock at an initial issuance price of $2.37 per share for total gross proceeds of $2.0 million. In a third closing associated with the Series B Purchase Agreement, during July 2021, the Company issued an additional 886,076 shares of Series B-1 Preferred Stock at an initial issuance price of $2.37 per share for total gross proceeds of $2.1 million.

As of December 31, 2021, 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 are entitled to receive dividends when, as and if declared by the Board. The Company may not pay any dividends on shares of common stock of the Company unless the holders of preferred stock also receive a corresponding dividend. As of December 31, 2021, no cash dividends have been declared or paid.

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 a deemed liquidation events, each holder of the then outstanding Series B Preferred Stock will be entitled to receive a preferential payment, prior and in preference to any distributions to the holders of the Series A Preferred Stock and common stock. After payments have been made in full to the holders of the Series B Preferred Stock, then, to the extent available, each holder of the then outstanding Series A Preferred Stock will be entitled to receive a preferential payment, prior and in preference to any distributions to the holders common stock. After payments have been made in full to the holders of the preferred stock, then, to the extent available, the remaining amounts will be distributed among the holders of the preferred stock and common stock, pro rata based on the number of shares 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, at the applicable conversion ratio then in effect for each series of preferred stock, initially set at the initial issuance price (i.e., one-for-one), and subject to adjustment in accordance with specified anti-dilution provisions. In addition, each share of preferred stock will be automatically converted into common stock at the applicable conversion ratio then in effect for each series of preferred stock upon the earlier of (i) a qualified initial public offering as defined, (ii) the closing of a business combination pursuant to which the Corporation is merged into, or otherwise combines with, a public company or a special purpose acquisition company listed on a “national securities exchange or (iii) upon a vote of the holders of a majority of the outstanding preferred stock.

The Company evaluated each series of its preferred stock and determined that each individual series 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 each

series of 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 of all series of preferred stock is considered to be clearly and closely related to the associated preferred stock host instrument. Accordingly, the conversion feature of all series of preferred stock is not considered an embedded derivative that requires bifurcation.

Redemption—

The preferred stock is only redeemable upon the occurrence of certain deemed liquidation events, as discussed above. As the preferred stock is considered to be contingently redeemable, the preferred stock has been classified outside of permanent equity. The preferred stock will be accreted to its redemption value if the deemed liquidation events are considered probable of occurring. Through December 31, 2021, the deemed liquidation events have not been considered probable of occurring, and therefore the preferred stock has not been accreted.

10. Common Stock

All common stock share amounts have been retroactively adjusted to reflect the Transaction and reverse recapitalization as described in Note 1.

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, 2021, no cash dividends have been declared or paid.

As of December 31 2021, the Company has reserved the following shares of common stock for future issuance:

Shares reserved for conversion of preferred stock	10,835,366
Shares reserved for exercise of outstanding stock options	2,689,935
Shares reserved for issuance under equity compensation plans	262,616
Total shares of authorized common stock reserved for future issuance	13,787,917

11. 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 1.

2014 Restricted Unit Plan

On March 4, 2014, the Company 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 the Company. Under the terms of the 2014 Plan, Incentive Units could be granted to a participant by the Company's board of directors. The strike price of the Incentive Units is determined by the Company's board of directors at the time of grant. The Company has certain repurchase rights for issued Incentive Units in the event of termination of the participant's employment or consulting relationship. As of December 31, 2020, there were 82,563 Incentive Units available for future grant. The plan was extinguished on April 30, 2021 as a result of the Reorganization.

2021 Stock Option and Grant Plan

On April 30, 2021, the Company established the 2021 Stock Option and Grant Plan (the "2021 Plan"), which provides for the Company to issue restricted stock awards, unrestricted stock awards and restricted stock units, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees, including officers. Restricted stock awards, unrestricted stock awards and restricted stock units and non-statutory stock options 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 2021 Plan was 3,260,994 shares as of December 31, 2021, of which 262,616 shares remained available for future grant.

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 2021 Plan without having been fully exercised will be available for future awards.

Incentive Unit Valuation

Each Incentive Unit represents a non-voting equity interest in the Company that entitles the holder to a percentage of the profits and appreciation in the Company's equity value arising after the date of grant and after such time as the strike price is met. Incentive Units are granted at no less than fair value on the date of grant as determined by the board of directors and typically vest over four years.

The Company measures and records the expense related to Incentive Units based on the fair value of those awards as determined on the date of grant. The Company used an option pricing model (OPM) to determine the total equity value of the Company at various dates and allocated that value to the outstanding Units, including Incentive Units. The OPM requires the use of subjective assumptions, which determine the fair value of equity-based awards, including the value of the Company's equity, volatility, time to liquidity and risk-free rate. Once the enterprise value has been allocated to each class of Unit, the value attributed to the Incentive Units is then discounted for a lack of marketability. The Company and the board of directors considers changes in facts and circumstances between valuation dates to determine the fair value of Incentive Units on each date of grant.

The following table summarizes the inputs used in the OPM:

	Year Ended December 31, 2020
Company equity value (in millions)	$3.6 - $10.7
Volatility	90.00%
Time to liquidity (years)	3.0
Risk-free rate	0.15% - 0.22%

Incentive Unit Activity

The following table summarizes the Company's Incentive Unit activity for the year ended December 31, 2021:

	Unvested Incentive Units	Weighted-Average Grant Date Fair Value Per Unit
Unvested as of December 31, 2020	429,963	$ 0.19
Vested	(32,939)	0.43
Forfeited	(4,428)	0.66
Cancelled	(392,596)	0.10
Unvested as of December 31, 2021	—	$ —

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, 2021
Expected option life (years)	5.6
Risk-free interest rate	0.90%
Expected volatility	62.84%
Expected dividend yield	— %

Stock Option Activity

The following table summarizes the Company's stock option activity for the year ended December 31, 2021:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	—	$ —		$ —
Granted	3,052,355	0.59		
Exercised	(308,443)	0.59		88
Cancelled or forfeited	(53,977)	0.59		
Outstanding as of December 31, 2021	2,689,935	$ 0.59	9.5	$ 767
Exercisable as of December 31, 2021	1,637,156	$ 0.59	9.4	$ 467

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 year ended December 31, 2021 was $0.53.

As of December 31, 2021, total unrecognized compensation cost related to the unvested stock options was $569 thousand, which is expected to be recognized over a weighted-average period of 3.5 years.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Year Ended December 31,	
	2021	2020
Cost of revenue	$ 19,876	$ 2,924
Research and development	414,322	36,961
General and administrative	680,458	61,155
Total stock-based compensation	$ 1,114,656	$ 101,040

12. Related Party Transactions

The Company provides administrative services to certain related parties that are affiliated entities through common equity ownership with financial and operational interests in the Company. During the years ended December 31, 2021 and 2020, the Company recognized $5 thousand and $21 thousand as a reduction to general and administrative expense related to these contracts, respectively. As of December 31, 2021, the Company had a minimal amount of receivables related to these arrangements. As of December 31, 2020, the Company had $5 thousand of receivables related to these arrangements.

13. 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, 2021 and 2020, two customers accounted for all revenue recognized in the period.

As of December 31, 2021, there were no customer concentrations in accounts receivable. As of December 31, 2020, one customer accounted for 97% of accounts receivable.

14. Note Payable

On April 24, 2020, the Company executed a promissory note pursuant to which it received proceeds of $161 thousand under the Paycheck Protection Program. The program was established as part of the Coronavirus Aid, Relief and Economic Security Act and is administered by the U.S. Small Business Administration.

The note had a two-year term, accrued interest at the rate of 1.0% per annum, and was prepayable at any time without payment of any premium. No payments of principal or interest were due during the six-month period beginning on the date of the note. The Paycheck Protection Program Flexibility Act of 2020 extended the deferral period for borrower payments of principal, interest, and fees on the note to the date of the U.S. Small Business Administration forgiveness.

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 the forgiveness had been approved and recorded a gain on debt extinguishment in the amount of $161 thousand.

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 for federal and state income tax purposes.

For the period from May 1, 2021 to December 31, 2021, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company. The Company's operations are based in the United States.

A reconciliation of income tax expense computed at the statutory federal income tax rate to the Company's effective tax rate as reflected in the financial statements is as follows:

	Year Ended December 31, 2021
Income tax at federal statutory tax rate	21.0%
State income taxes, net of federal benefit	5.3%
Income tax rate differential	(3.0)%
Stock-based compensation	(0.9)%
Permanent differences	(0.3)%
Research and development tax credits	0.9%
Change in valuation allowance	(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, 2021
Deferred tax assets:	
Net operating loss carryforwards	$ 885,617
R&D credit carryforwards	63,406
Lease liabilities	88,259
Stock-based compensation	173,069
Accrued expenses and other	176,231
	1,386,582
Valuation allowance	(1,235,082)
	151,500
Deferred tax liabilities:	
Property and equipment and right of use assets	(151,500)
Net deferred tax assets	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2021, based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2021. The valuation allowance increased $1.2 million during the year ended December 31, 2021 due primarily to net operating losses generated.

As of December 31, 2021, the Company had U.S. federal and state net operating loss carryforwards of $3.2 million, that may be available to offset future income tax liabilities. The U.S. federal tax operating loss

carryforwards are not subject to expiration and can be carried forward indefinitely while the state net operating loss carryforwards begin to expire in 2042.

As of December 31, 2021, the Company has federal and state research and development tax credit carryforwards of $48 thousand and $15 thousand, respectively. The Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percentage points, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

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, 2021, the Company has not recorded any amounts for uncertain tax positions. 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 statements of income. For the year ended December 31, 2021, no estimated interest or penalties were recognized on uncertain tax positions.

The Company's corporate tax returns for the year ended December 31, 2021 remain open and subject to examination by the Internal Revenue Service and state taxing authorities.

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

As the Transaction has been accounted for as a reverse recapitalization, as described in Note 1, 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, 2021 and 2020, 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 and member units outstanding. Prior to April 30, 2021, undistributed losses were allocated equally to each class of member units, including vested incentive units, since they share equally in the residual net assets of the Company upon liquidation, subject to their different distribution participation rights. Subsequent to April 30, 2021, the Company did not have any participating securities as the convertible preferred stock is not required to share in the losses of the Company.

For the years ended December 31, 2021 and 2020, 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,	
	2021	2020
Options to purchase common stock	2,689,935	—
Unvested incentive units	—	331,547
Convertible preferred stock (as converted to common stock)	10,643,403	—

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

	Year Ended December 31,	
	2021	2020
Net loss available to common stockholders or members — basic and diluted	$ (5,451,778)	$ (2,125,487)
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	3,012,603	8,521,250
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (1.81)	$ (0.25)

17. Commitments and Contingencies

Leases

On March 8, 2018, the Company entered into a noncancelable 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.

The maturities and balance sheet presentation under all non-cancelable operating leases as of December 31, 2021, are as follows:

	Operating Leases
Maturity of lease liabilities	
2022	$ 143,004
2023	143,004
2024	71,502
Total lease liabilities	357,510
Less: imputed interest	(34,454)
Present value of operating lease liability as of December 31, 2021	$ 323,056
Reported as of December 31, 2021	
Lease liabilities — current	$ 121,552
Lease liabilities — noncurrent	201,504
	$ 323,056

As of December 31, 2021, the Company maintained a Right-Of-Use asset with a corresponding operating lease liability of approximately $323 thousand, based on the present value of the minimum rental payments in accordance with ASC 842, *Leases*. As the Company's lease does not provide an implicit rate, the Company estimated its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. The weighted average discount rate used for leases as of December 31, 2021 is 8.0%. The weighted average lease term as of December 31, 2021 is 2.5 years. During the year ended December 31, 2021 operating cash flows used for operating leases was $136 thousand. During the year ended December 31, 2021, lease cost was $139 thousand. During the year ended December 31, 2020, rent expense incurred under this agreement was $134 thousand under previous accounting guidance.

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, 2021 and 2020, 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, 2021, 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 which was recorded within other income, net in the Company's statements of operations and comprehensive loss. Subsequent to December 31, 2021, an additional $590 thousand of cash was lost through the same incident. The Company implemented a variety of measures to further enhance its cybersecurity protections and minimize the impact of any future cyber incidents. The Company has insurance related to this event and expects to recover $300 thousand of losses in total. As of and for the year ended December 31, 2021, the Company recorded a $136 thousand insurance recovery receivable within prepaid expenses and other current assets in the Company's balance sheet and a corresponding recovery of losses which offset the loss within other income, net in the Company's statement of operations and comprehensive loss since the recovery of losses was considered probable. The remaining insurance recovery amount of $164 thousand relates to losses incurred subsequent to year end and will be recorded in the Company's financial statements for the year ending December 31, 2022.

18. Subsequent Events

The Company has completed an evaluation of all subsequent events after the balance sheet date of December 31, 2021 through March 8, 2022, the date the financial statements were issued, to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2021, and events which occurred subsequently but were not recognized in the financial statements.
The Company has concluded that no subsequent events have occurred that require disclosure, except as disclosed within the financial statements.

(a) Stock-based Compensation Activity

Through the date the financial statements were issued, the Company has issued 693,330 shares of common stock in connection with exercises of stock options for gross proceeds of $404 thousand.

(b) Business Combination Agreement

On January 31, 2022, Comera, OTR, CLS Holdings, Comera Merger Sub and OTR Merger Sub, entered into an agreement and plan of merger (the "Business Combination Agreement"), pursuant to which (i) Comera Merger Sub will be merged with and into Comera (the "Comera Merger"), with Comera surviving the Comera Merger as a direct wholly-owned subsidiary of CLS Holdings and (ii) immediately following the consummation of the Comera Merger, OTR Merger Sub will be merged with and into OTR (the "OTR Merger"), with OTR surviving the OTR Merger as a direct wholly-owned subsidiary of CLS Holdings. The Business Combination Agreement contains customary representations and warranties, covenants, closing conditions and other terms relating to the Comera Merger and OTR Merger and the other transactions contemplated thereby which are expected to close in May 2022, contingent upon approval of OTR stockholders.

Upon the closing of the Transaction (the "Closing"), by virtue of the Comera Merger, all shares of Comera common stock, par value $0.001 per share ("Comera Common Stock"), issued and outstanding immediately prior to the Closing (including shares of Comera Common Stock issued upon conversion of Comera preferred stock immediately prior to the Closing) will be 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 Comera unvested stock options and Comera vested incentive stock options will be converted into options to purchase shares of CLS Holdings Common Stock, all Comera vested in-the-money non-qualified stock options outstanding will be net exercised for shares of Comera Common Stock and, upon the Closing as described above, those shares of Comera Common Stock will be converted into the right to receive shares of CLS Holdings Common Stock.

In addition and as part of the overall consideration payable to the Company's stockholders, CLS Holdings shall place 3,150,000 shares of CLS Holdings Common Stock (the "Earn-Out Shares") into escrow. If, at any time prior to the second anniversary of the Closing, either (i) the volume-weighted-average-price of CLS Holdings Common Stock shall be equal to or greater than $12.50 for twenty trading days within a thirty-trading day period, or (ii) upon a change of control with aggregate consideration in excess of $12.50 per share, then the Earn-out Shares will be delivered to the Company's stockholders in accordance with the Business Combination Agreement.

COMERA LIFE SCIENCES HOLDINGS, INC.
BALANCE SHEETS
(unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 2,669,354	$ 6,510,140
Accounts receivable	293,821	—
Due from related parties	—	286
Prepaid expenses and other current assets	1,325,753	270,648
Total current assets	4,288,928	6,781,074
Restricted cash	50,000	50,000
Property and equipment, net	192,590	234,167
Right of use asset	362,401	320,373
Security deposit	43,200	32,200
Total assets	$ 4,937,119	$ 7,417,814
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,436,692	$ 416,941
Accrued expenses and other current liabilities	887,012	506,611
Insurance premium financing	911,124	—
Lease liability—current	195,253	121,552
Total current liabilities	3,430,081	1,045,104
Derivative warrant liabilities	331,612	—
Lease liability—noncurrent	171,596	201,504
Total liabilities	3,933,289	1,246,608
Commitments and contingencies (Note 17)		
Series A convertible preferred stock	4,431,838	—
Convertible preferred stock	—	20,857,453
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 150,000,000 shares authorized; 16,653,466 and 308,443 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1,665	31
Additional paid-in capital	28,511,656	2,213,547
Accumulated deficit	(31,941,329)	(16,899,825)
Total stockholders' deficit	(3,428,008)	(14,686,247)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 4,937,119	$ 7,417,814

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 234,922	$ 87,767	$ 476,982	$ 246,498
Cost of revenue	60,963	48,364	160,030	122,073
Operating expenses:				
Research and development	394,800	263,620	1,250,570	1,262,329
General and administrative	2,314,554	689,483	8,027,316	2,373,621
Total operating expenses	2,709,354	953,103	9,277,886	3,635,950
Loss from operations	(2,535,395)	(913,700)	(8,960,934)	(3,511,525)
Other income (expense), net:				
Change in fair value of derivative warrant liabilities	500,327	—	1,954,767	—
Reverse recapitalization issuance costs in excess of gross proceeds	—	—	(6,566,821)	—
Common stock purchase agreement issuance costs	(1,029,077)	—	(1,029,077)	—
Gain on debt extinguishment	—	—	—	160,588
Change in fair value of convertible notes	—	—	—	(76,738)
Interest expense	(12,696)	—	(12,773)	—
Other expense, net	—	—	(426,666)	—
Total other (expense) income, net	(541,446)	—	(6,080,570)	83,850
Net loss and comprehensive loss	(3,076,841)	(913,700)	(15,041,504)	(3,427,675)
Less: accretion of convertible preferred stock to redemption value	(86,816)	—	(287,984)	—
Net loss attributable to common stockholders or unit holders	$ (3,163,657)	$ (913,700)	$ (15,329,488)	$ (3,427,675)
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (0.20)	$ (6.34)	$ (1.85)	$ (0.87)
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	16,024,011	144,163	8,294,938	3,955,649

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' DEFICIT AND MEMBERS' CAPITAL
(unaudited)

	Series A Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Capital Units		Incentive Units		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit and Members' Capital
	Shares	Amount	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount			
Balance as of December 31, 2021, as originally stated	—	$ —	13,802,758	$ 20,857,453	400,000	$ 400	—	$ —	—	$ —	$ 2,213,178	$(16,899,825)	$(14,686,247)
Retroactive application of reverse recapitalization	—	—	—	—	(91,557)	(369)	—	—	—	—	369	—	—
Balance as of December 31, 2021, as adjusted	—	—	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	—	—	—	—	735,859	74	—	—	—	—	429,356	—	429,430
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	42,556	—	42,556
Net loss	—	—	—	—	—	—	—	—	—	—	—	(2,879,395)	(2,879,395)
Balance as of March 31, 2022	—	—	13,802,758	20,857,453	1,044,302	105	—	—	—	—	2,685,459	(19,779,220)	(17,093,656)
Issuance of common stock upon exercise of stock options, net of shares withheld to settle tax withholding requirements	—	—	—	—	679,265	68	—	—	—	—	230,003	—	230,071
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	—	—	—	—	—	—	—	—	—	—	—
Accretion of convertible preferred stock to redemption value	—	201,168	—	—	—	—	—	—	—	—	(201,168)	—	(201,168)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	56,739	—	56,739
Net loss	—	—	—	—	—	—	—	—	—	—	—	(9,085,268)	(9,085,268)
Balance as of June 30, 2022	4,305	4,345,022	—	—	15,937,185	1,594	—	—	—	—	27,070,815	(28,864,488)	(1,792,079)
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	—	—	—	—	420,000	42	—	—	—	—	748,846	—	748,888
Issuance of Commitment Shares	—	—	—	—	296,181	29	—	—	—	—	649,971	—	650,000
Accretion of convertible preferred stock to redemption value	—	86,816	—	—	—	—	—	—	—	—	(86,816)	—	(86,816)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	127,690	—	127,690
Net loss	—	—	—	—	—	—	—	—	—	—	—	(3,076,841)	(3,076,841)
Balance as of September 30, 2022	4,305	$4,431,838	—	$ —	16,653,466	$ 1,665	—	$ —	—	$ —	$28,511,656	$(31,941,329)	$ (3,428,008)

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' DEFICIT AND MEMBERS' CAPITAL (Continued)
(unaudited)

	Series A Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Capital Units		Incentive Units		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit and Members' Capital
	Shares	Amount	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount			
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	—	—	—	—	—	—	—	—	25,416	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	13,878	—	13,878
Net loss	—	—	—	—	—	—	—	—	—	—	—	(533,405)	(533,405)
Balance as of March 31, 2021	—	—	—	—	—	—	9,429,006	10,681,040	2,012,890	—	932,800	(11,981,452)	(367,612)
Vesting of incentive units	—	—	—	—	—	—	—	—	7,523	—	—	—	—
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	—	—	3,487,676	8,066,740	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,024,444	—	1,024,444
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,980,570)	(1,980,570)
Balance as of June 30, 2021	—	—	12,916,682	18,747,780	—	—	—	—	—	—	1,957,244	(13,962,022)	(12,004,778)
Issuance of convertible preferred stock, net of issuance costs of $60,327	—	—	886,076	2,109,673	—	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	308,443	31	—	—	—	—	179,969	—	180,000
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	34,288	—	34,288
Net loss	—	—	—	—	—	—	—	—	—	—	—	(913,700)	(913,700)
Balance as of September 30, 2021	—	$ —	13,802,758	$20,857,453	308,443	$ 31	—	$ —	—	$ —	$2,171,501	$(14,875,722)	$(13,660,316)

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (15,041,504)	$ (3,427,675)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	226,985	1,072,610
Depreciation expense	70,184	61,928
Noncash lease expense	1,765	2,951
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	(1,954,767)	—
Changes in operating assets and liabilities:		
Accounts receivable	(293,821)	109,868
Prepaid expenses and other current assets	460,895	(16,069)
Due from related parties	286	1,810
Accounts payable	1,019,751	130,063
Accrued expenses and other current liabilities	380,401	22,905
Security deposits	(11,000)	—
Deferred revenue	—	(28,949)
Net cash used in operating activities	(7,924,004)	(2,154,408)
Cash flows from investing activities:		
Purchases of property and equipment	(28,607)	(11,464)
Net cash flows used in investing activities	(28,607)	(11,464)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of offering costs	—	9,349,675
Net proceeds from Transaction and Maxim Private Placement	3,307,162	—
Repayment of insurance premium financing	(604,876)	—
Proceeds from issuance of convertible notes	—	750,000
Proceeds from common stock purchase agreement	748,888	—
Proceeds from exercise of public warrants	1,150	—
Proceeds from exercise of stock options	659,501	180,000
Net cash provided by financing activities	4,111,825	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,840,786)	8,113,803
Cash, cash equivalents and restricted cash at beginning of period	6,560,140	180,427
Cash, cash equivalents, and restricted cash at end of period	$ 2,719,354	$ 8,294,230
Supplemental information:		
Cash and cash equivalents	$ 2,669,354	8,269,230
Restricted cash	50,000	25,000
Total cash, cash equivalents, and restricted cash shown in statements of cash flows	$ 2,719,354	$ 8,294,230
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of right-of-use asset	$ 162,634	$ 404,625
Financing of insurance premiums	$ 1,516,000	$ —
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 stock issuance costs	$ 3,443,750	$ —
Issuance of Series A preferred stock to settle stock issuance costs	$ 910,000	$ —
Accretion on convertible preferred stock	$ 287,984	$ —
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 condensed consolidated financial statements.

COMERA LIFE SCIENCES HOLDINGS, INC.

NOTES TO CONDENSED 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 for as Legacy Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded.

Unless the context otherwise requires, "Comera," "Company," "we," "us," and "our" refer to Comera Life Sciences Holdings, Inc., and its subsidiaries at and after the Closing (as defined below) and give effect to the Closing. "CLS Holdings", "Legacy Comera" and "OTR" refer to Comera Life Sciences Holdings, Inc., Comera Life Sciences, Inc. and OTR Acquisition Corp., respectively, prior to the Closing.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed 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").

The condensed consolidated financial statements do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with Legacy Comera's financial statements and related notes for the years ended December 31, 2021 and 2020 included in the Current Report on Form 8-K filed with the SEC on September 6, 2022.

The financial information as of September 30, 2022 and 2021, and the three and nine months ended September 30, 2022 and 2021, is unaudited. In the opinion of management, all adjustments, consisting only of normal recurring adjustments considered necessary for the fair presentation of financial position, results of operations, and cash flows at the dates and for the periods presented, have been included. The balance sheet data as of December 31, 2021 was derived from Legacy Comera's audited financial statements. The results of the Company's operations for any interim periods are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933 (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012, (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

The Company is also a "smaller reporting company" as defined in the Securities Exchange Act of 1934 (the "Exchange Act"). The Company may continue to be a smaller reporting company even after the Company is no longer an emerging growth company. The Company may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less

than $250.0 million measured on the last business day of the Company's second fiscal quarter, or the Company's annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of the Company's second fiscal quarter.

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, entering into collaborations with partners for the Company's SQore™ platform 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 September 30, 2022, the Company has funded its operations primarily with proceeds from the issuance of equity instruments, convertible notes, and preferred stock. The Company has incurred recurring losses since its inception, including a net loss of $15.0 million for the nine months ended September 30, 2022. In addition, as of September 30, 2022, the Company had an accumulated deficit of $31.9 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 and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund its operations and capital expenditure requirements for the next twelve months from the date the condensed consolidated financial statements are issued. The Company 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 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 condensed 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.

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict.

The Company plans to continue to closely monitor the ongoing impact of the COVID-19 pandemic on the Company's employees and other business operations. In an effort to provide a safe work environment for the Company's employees, the Company has, among other things, limited employees in the Company's office and lab facilities to those where on-site presence is needed for their job activities, implemented various social

distancing measures in the Company's offices and labs and are providing personal protective equipment for the Company's employees present in the Company's office and lab facilities, as needed. The Company is continuing to monitor the impact and effects of the COVID-19 pandemic and the Company's response to it, and the Company expects to continue to take actions as may be required or recommended by government authorities or that are determined to be in the best interests of the Company's employees and other business partners in light of the pandemic.

Use of Estimates

The preparation of condensed 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 condensed 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 condensed consolidated financial statements include, but are not limited to, the valuation of the derivative warrant liabilities, Legacy Comera's common stock, and stock-based compensation. 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.

Summary of Significant Accounting Policies

The significant accounting policies of the Company are set forth in Note 2 to the consolidated financial statements included in the Current Report on Form 8-K filed with the SEC on September 6, 2022, and the accounting policies followed by the Company for interim financial reporting are consistent with the accounting policies therein and as supplemented below.

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 condensed 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 (the "Exchange Ratio") established in the Transaction.

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.

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.

Reclassification of Prior Year Presentation

Certain prior year amounts within prepaid expenses and other current assets (Note 5) have been reclassified for consistency with current period presentation. These reclassifications had no effect on the reported results of operations or financial position.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the condensed consolidated financial statements are issued to provide evidence relative to certain estimates or to identify matters that require additional disclosure. The Company evaluated all events and transactions through the date these condensed consolidated financial statements were filed with the SEC.

Recently Issued 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, 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 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 convertible preferred stock, stockholders' deficit and members' capital:

	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 Legacy 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' capital.

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, 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 September 30, 2022:

	Fair Value Measurements at September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Private Placement Warrants	$ —	$331,612	$ —	$331,612

There were no assets for which fair value was required to be disclosed as of September 30, 2022. There were no assets or liabilities for which fair value was required to be disclosed as of December 31, 2021. During the nine months ended September 30, 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:

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 1,274,263	$ —
Contract assets	—	85,018
Insurance recovery receivable	—	136,250
Other	51,490	49,380
Prepaid expenses and other current assets	$ 1,325,753	$ 270,648

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Lab equipment	$ 587,650	$ 587,650
Leasehold improvements	36,149	17,973
Computer equipment	32,178	21,747
Other equipment	9,411	9,411
	665,388	636,781
Less accumulated depreciation	(472,798)	(402,614)
Property and equipment, net	$ 192,590	$ 234,167

Depreciation expense for the nine months ended September 30, 2022 and 2021 was $70 thousand and $62 thousand, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Accrued bonus	$ 447,488	$ 349,000
Professional fees	255,822	123,756
Accrued vacation	27,851	25,945
Other	155,851	7,910
Accrued expenses and other current liabilities	$ 887,012	$ 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 September 30, 2022 was $0.9 million.

9. Legacy Comera Convertible Preferred Stock

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.

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 September 30, 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 September 30, 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	$ 4,431,838	$ 4,431,838	342,754

In May 2022, the Company issued 4,305 shares of Series A Preferred Stock. The Series A Preferred Stock was issued in connection with the Transaction and the Settlement Agreement (Note 3) in settlement of $4.3 million of 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 September 30, 2022, the holders of the Series A Preferred Stock have the following rights and preferences:

Voting Rights—

The holders of the Series A 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 Series A 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 September 30, 2022, no cash dividends have been declared or paid and the Company has $288 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 Series A 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 Series A Preferred Stock then outstanding.

The Company evaluated its preferred stock and determined that its Series A 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 Series A Preferred Stock is considered to be clearly and closely related to the preferred stock host instrument. Accordingly, the conversion feature for Series A 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 Series A 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, the preferred stock 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 $87 and $288 thousand during the three and nine months ended September 30, 2022, respectively, which is considered a deemed dividend.

11. Common Stock

As of September 30, 2022, the authorized capital stock of the Company included 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 Series A Preferred Stock set forth above.

In connection with the Settlement Agreement, the Company sold 97,561 shares of common stock to Maxim for aggregate proceeds of $1.0 million in a private placement.

Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock on an as converted to common stock basis, 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 September 30, 2022, no cash dividends have been declared or paid.

As of September 30, 2022, the Company has reserved the following shares of common stock for future issuance:

Exercise of outstanding stock options	1,982,641
Available for issuance under equity compensation plans	77,197
Exercise of outstanding common stock warrants	11,041,332
Conversion of Series A Preferred Stock	1,028,262
Reserved for issuance pursuant to the Purchase Agreement	4,283,819
Total shares of authorized common stock reserved for future issuance	18,413,251

Common Stock Purchase Agreement

On August 31, 2022, the Company entered into a purchase agreement (the "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 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 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 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 Purchase Agreement. The $650 thousand fair value of the Commitment Shares along with $376 thousand of other issuance costs related to the Purchase Agreement were recognized as a loss within other expense, net.

As of September 30, 2022, the Company had sold 420,000 shares of common stock under the Purchase Agreement at a weighted-average price of $1.78 per share, resulting in net proceeds of $0.7 million for the nine months ended September 30, 2022.

12. Stock-Based Compensation

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 September 30, 2022, there are 1,168,441 Exchanged Options outstanding 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 2,059,838. 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 September 30, 2022, there were 1,982,641 options outstanding with a weighted-average exercise price of $1.70 and 77,197 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:

	Nine Months Ended September 30, 2022
Expected option life (years)	6.1
Risk-free interest rate	3.18%
Expected volatility	62.65%
Expected dividend yield	— %

Stock Option Activity

The following table summarizes the Company's stock option activity for the nine months ended September 30, 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	814,200	3.30		
Exercised	(1,385,310)	0.59		
Cancelled or forfeited	(136,184)	0.59		
Outstanding as of September 30, 2022	1,982,641	$ 1.70	9.1	$ 1,192
Exercisable as of September 30, 2022	406,894	$ 0.59	8.8	$ 415

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 as of September 30, 2022.

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2022 and 2021 was $1.97 and $0.41, respectively.

As of September 30, 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 3.5 years.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of revenue	$ 484	$ 448	$ 1,409	$ 19,530
Research and development	2,670	2,829	7,681	410,644
General and administrative	124,536	31,011	217,895	642,436
Total stock-based compensation	$ 127,690	$ 34,288	$ 226,985	$ 1,072,610

13. Common Stock Warrants

During the nine months ended September 30, 2022, there were 100 warrants exercised. 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 September 30, 2022:

Description	Issue Date	Classification	Exercise Price	Expiration Date	Number of Shares Underlying Warrants	
					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 nine months ended September 30, 2022 and 2021, two customers accounted for 97% and 100% of revenue recognized, respectively.

As of September 30, 2022, two customers accounted for 100% of accounts receivable.

15. Income Taxes

The Company had no income tax expense due to operating losses incurred for the three and nine months ended September 30, 2022 and 2021.

Management of the Company evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. As a result, a full valuation allowance was recorded as of September 30, 2022.

The Company applies ASC 740, *Income Taxes*, for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. Unrecognized tax benefits represent tax positions for which reserves have been established. A full valuation allowance has been provided against the Company's deferred tax assets, so that the effect of the unrecognized tax benefits is to reduce the gross amount of the deferred tax asset and the corresponding valuation allowance. The Company has no material uncertain tax positions as of September 30, 2022. The Company has never been examined by the Internal Revenue Service, or any other jurisdiction, for any tax years and, as such, all years within the applicable statutes of limitations are potentially subject to audit.

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

For the three and nine months ended September 30, 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, the shares or units and net loss per share or unit, prior to the Transaction, have been retroactively adjusted to amounts reflecting the Exchange Ratio established in the Transaction.

For the three and nine months ended September 30, 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, options to purchase common stock, warrants to purchase common stock, Earn-Out Shares, 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 period end, were excluded from the computation of diluted net loss per share or unit because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2022	2021
Options to purchase common stock	1,982,641	2,674,384
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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss available to common stockholders or unit holders —basic and diluted	$ (3,163,657)	$ (913,700)	$ (15,329,488)	$ (3,427,675)
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	16,024,011	144,163	8,294,938	3,955,649
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (0.20)	$ (6.34)	$ (1.85)	$ (0.87)

17. Commitments and Contingencies

Leases

On March 8, 2018, the Company entered into a noncancelable operating lease agreement for office and laboratory space in Woburn, Massachusetts (the “Woburn Lease”). On March 10, 2021, the Company extended the Woburn Lease through June 30, 2024 with a monthly lease payment of $12 thousand. 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 September 30, 2022, are as follows:

	Operating Leases
Maturity of lease liabilities	
2022 (remaining 3 months)	$ 54,386
2023	217,545
2024	123,077
Total lease liabilities	395,008
Less imputed interest	(28,159)
Present value of operating lease liability as of September 30, 2022	$366,849
Reported as of September 30, 2022	
Lease liabilities — current	$195,253
Lease liabilities — noncurrent	171,596
	$366,849

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 September 30, 2022 is 8.0%. The weighted-average lease term as of September 30, 2022 is 1.8 years. During the nine months ended September 30, 2022 and 2021 operating cash flows used for operating leases was $142 thousand and $100 thousand, respectively. During the nine months ended September 30, 2022 and 2021, lease cost was $145 thousand and $103 thousand, respectively.

Amounts included in restricted cash as of September 30, 2022 and December 31, 2021 consist of cash held to collateralize a letter of credit issued as a security deposit in connection with the Company's lease of its corporate facility and for certain credit cards.

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 as of September 30, 2022, 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. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. In addition, the Company maintains officers and directors insurance coverage. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Through September 30, 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 nine months ended September 30, 2022 which was recorded as other expense, net in the Company's 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 nine months ended September 30, 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.

Comera Life Sciences Holdings, Inc.

7,218,726 Shares of Common Stock

P R O S P E C T U S

February 10, 2023