Revelation Biosciences Annual Report 2022

Form 10-K (NASDAQ:REVB)

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

FORM 10-K

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the year ended December 31, 2021

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number 001-39603

REVELATION BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**84-3898466**
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification No.)
4660 La Jolla Village Drive, Suite 100, San Diego, CA	**92122**
(Address of principal executive offices)	(zip code)

650-800-3717
(Issuer's Telephone Number, Including Area Code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Units, each consisting of one share of common stock and one-half of one redeemable warrant	REVBU	The Nasdaq Stock Market LLC
Common stock, par value $0.001 per share	REVB	The Nasdaq Stock Market LLC
Redeemable warrants, each exercisable for a share of common stock at an exercise price of $11.50 per share	REVBW	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

As of June 30, 2021, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock outstanding, other than shares held by persons who may be deemed affiliates of the registrant, computed by reference to the closing sales price for common stock on June 30, 2021, as reported on The Nasdaq Stock Market LLC, was approximately $73,173,036.

As of April 13, 2022, 15,082,771 shares of common stock, par value $0.001 per share, were issued and outstanding.

EXPLANATORY NOTE

On January 10, 2022 (the "Closing Date"), Petra Acquisition, Inc., a Delaware corporation and our predecessor company ("Petra"), consummated the business combination (the "Business Combination"), pursuant to the terms of the agreement and plan of merger, dated as of August 29, 2021 (the "Business Combination Agreement"), by and among Petra, Petra Acquisition Merger, Inc., a Delaware corporation and wholly-owned subsidiary of Petra ("Merger Sub"), and Revelation Biosciences, Inc. ("Old Revelation"). Pursuant to the Business Combination Agreement, on the Closing Date, (i) Merger Sub merged with and into Old Revelation (the "Merger"), with Old Revelation as the surviving company in the Merger, and, after giving effect to such Merger, Old Revelation was renamed Revelation Biosciences Sub, Inc. and became a wholly-owned subsidiary of Petra and (ii) Petra changed its name to "Revelation Biosciences, Inc." ("Revelation" or the "Company" f/k/a Petra Acquisition, Inc.).

Because the Business Combination occurred after the end of our most-recently completed fiscal year 2021, the financial information in this Annual Report reflects the operations of Petra. The financial information for Old Revelation is presented in an Amendment to the Current Report of the Company reporting the Business Combination which was filed with the Securities and Exchange Commission (the "SEC") on April 15, 2022, which is incorporated herein by reference.

FREQUENTLY USED TERMS

Unless otherwise stated or unless the context otherwise requires, the terms " **we**," "**us**," "**our**," and "**Revelation**" refer to Revelation Biosciences, Inc., and its subsidiaries.

In this document:

"**BLA**" refers to the Biologics License Application.

"**BPCIA**" means the Biologics Price Competition and Innovation Act of 2009.

"**Business Combination**" means the business combination pursuant to the Business Combination Agreement.

"**Business Combination Agreement**" means the Agreement and Plan of Merger, dated as of August 29, 2021, by and among Petra, Merger Sub and Old Revelation.

"**Charter**" means Revelation's current third amended and restated certificate of incorporation as filed with the Secretary of State of the State of Delaware on January 10, 2022.

"**Common Stock**" means common stock of Revelation, $0.001 par value.

"Common Warrants" means the common stock purchase warrants issued to the Selling Stockholder with an exercise price of $3.29 per share.

"**cGCP**" or "**GCP**" means the current Good Clinical Practices.

"**cGMP**" means the current Good Manufacturing Practices.

"**CMO**" means contract manufacturing organization.

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**CRO**" means contract research organization.

"**DGCL**" means the Delaware General Corporation Law.

"**EMA**" means the European Medicines Agency.

"**EU**" means the European Union.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**FCA**" means the False Claims Act.

"**FDA**" means the U.S. Food and Drug Administration.

"**GAAP**" refers to the generally accepted accounting principles.

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996.

"**IFN**" means interferon.

"**IM**" means intramuscular.

"**IND**" means Investigational New Drug Application.

"**IRB**" means institutional review board.

"**JOBS Act**" means the Jumpstart Our Business Startup Act of 2012, as amended.

"**LPS**" means a major component of gram-negative bacterial cell membrane, lipopolysaccharide.

"**Nasdaq**" means The Nasdaq Stock Market, LLC.

"**Nasdaq Capital Market**" means The Nasdaq Stock Market, LLC's Nasdaq Capital Market listing tier.

"**NDA**" means New Drug Application.

"**Petra**" means Petra Acquisition, Inc., our predecessor, prior to the Business Combination.

"**Petra IPO**" means Petra's initial public offering, which was consummated on October 13, 2020.

"Pre-Funded Warrants" means the common stock purchase warrants issued to the Selling Stockholder with an exercise price of $0.00001 per share.

"**PCR**" means polymerase chain reaction.

"**PHAD®**" means phosphorylated hexaacyl disaccharide.

"**Private Warrants**" means the warrants sold by Petra in its IPO.

"**Program Products**" refers to Revelation's product candidates (REVTx-99 and REVTx-200) and Revelation's diagnostic device program (REVDx-501).

"**Public Warrants**" means the warrants underlying the Units sold in the Petra IPO.

"**QSR**" means Quality System Regulation.

"**REVDx-501**" means Revelation's lead diagnostic device program.

"**REVTx-99a**" means Revelation's therapeutic product candidate being developed as a broad anti-viral nasal drop solution for the potential prevention or potential treatment of respiratory viral infections.

"**REVTx-99b**" means Revelation's therapeutic product candidate being developed as a prevention or treatment for chronic nasal congestion and allergic rhinitis.

"**REVTx-200**" means Revelation's intranasal adjunct vaccine product candidate.

"**RSU**" means restricted stock unit.

"**Sunshine Act**" means the Physician Payment Sunshine Act.

"**TLR**" means Toll-like receptors.

"**TLR-4**" means Toll-like receptor 4.

"**Units**" means units of Petra issued in Petra's IPO consisting of one share of Common Stock and one Public Warrant.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS SUMMARY

This Annual Report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These forward-looking statements are generally identified by the words "anticipate", "believe", "expect", "estimate", "plan", "outlook", and "project" and other similar expressions. We caution investors that forward-looking statements are based on management's expectations and are only predictions or statements of current expectations and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those anticipated by the forward-looking statements. Revelation cautions readers not to place undue reliance on any such forward looking statements, which speak only as of the date they were made. The following factors, among others, could cause actual results to differ materially from those described in these forward-looking statements: the ability of Revelation to meet its financial and strategic goals, due to, among other things, competition; the ability of Revelation to grow and manage growth profitability and retain its key employees; the possibility that the Revelation may be adversely affected by other economic, business, and/or competitive factors; risks relating to the successful development of Revelation's product candidates; the clinical utility of an increase in intranasal cytokine levels as a biomarker of viral infections; the ability to successfully complete planned clinical studies of REVTx-99a and REVTx-99b; risks relating to the successful completion of RVL-CLR01 and RVL-VRL01 clinical studies; the risk that we may not fully enroll our clinical studies or enrollment will take longer than expected; risks relating to the occurrence of adverse safety events and/or unexpected concerns that may arise from data or analysis from our clinical studies; changes in applicable laws or regulations; expected initiation of the clinical studies, the timing of clinical data; the outcome of the clinical data, including whether the results of such study is positive or whether it can be replicated; the outcome of data collected, including whether the results of such data and/or correlation can be replicated; the timing, costs, conduct and outcome of our other clinical studies; the anticipated treatment of future clinical data by the FDA, the EMA or other regulatory authorities, including whether such data will be sufficient for approval; the success of future development activities for REVTx-99a, REVTx-99b, REVTx-200, REVDx-501, or any other product candidates; potential indications for which product candidates may be developed; the potential impact that COVID-19 may have on Revelation's suppliers, vendors, regulatory agencies, employees and the global economy as a whole; the ability of Revelation to maintain the listing of its securities on The Nasdaq Stock Market LLC (Nasdaq); investor sentiment relating to SPAC related going public transactions; the expected duration over which Revelation's balances will fund its operations; and other risks and uncertainties described in Item 1A. "Risk Factors" of this report and those described below.

Risks Related to Our Business

- We have a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we anticipate that we will continue to incur significant losses for the foreseeable future, and even if we were to generate revenue, we may never achieve or maintain profitability.

Risks Related to the Product Development, Regulatory Approval, Manufacturing and Commercialization of Our Program Products and Product Candidates

- If preclinical studies or clinical studies for our Program Products are unsuccessful or delayed, we will be unable to meet our future development goals.
- The results of prior preclinical or clinical studies are not necessarily predictive of our future results.
- The Clinical Studies of our Program Products' have been and are planned to be conducted outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such studies.

- Our Program Products and the administration of our Program Products may cause 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 marketing approval, if any.

- Our business depends on the success of our Program Products, including obtaining regulatory approval to market our product candidates in the United States and/or other major foreign markets such as the European Union.

- Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.

- Legislative or regulatory healthcare reforms in the United States or other countries may make it more difficult and costly for us to obtain regulatory clearance or approval of our Program Products and to produce, market and distribute our Program Products after clearance or approval is obtained.

- We face intense competition in an environment of rapid technological change and the possibility that our competitors may develop products and drug delivery systems that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our Program Products.

Risks Related to COVID-19

- There is a significant uncertainty around the effects of COVID-19 on development of our Program Products.

Risks Related to our Reliance on Third Parties

- We rely on third parties to conduct certain elements of our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our Program Products.

- We rely on third parties to manufacture the raw materials, including the active pharmaceutical ingredients that we use to create our therapeutic product candidate, and to manufacture the diagnostic devices, including the antibodies used for testing.

Risks Related to Our Intellectual Property

- If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

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

- We may not have sufficient patent lifespan to effectively protect our products and business.

- If we are unable to maintain effective proprietary rights for our Program Products or any future product candidates, we may not be able to compete effectively in our markets.

Risks Related to Our Business Operations

- Our future success depends in part on our ability to retain our senior management team, directors and other key employees and to attract, retain and motivate other qualified personnel.

Risks Related to Commercialization of Our Program Products and Product Candidates

- As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.

- We may seek to establish commercial collaborations for our Program Products and future product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development plans.

- We currently have no Program Products approved for marketing. We do not have a marketing and sales organization. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our Program Products, we may be unable to generate any product revenue.

- It may be difficult for us to profitably sell our Program Products, if and when approved, if coverage and reimbursement for these Program Products are limited by government authorities and/or third-party payor policies.

- We face the risk of product liability claims and may not be able to obtain insurance.

- Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

General Risk Factors

We are subject to several other risks of which other public companies are subject, including without limitation, the volatility of our Common Stock price; our ability to comply with corporate governance laws and financial reporting standards; and our ability to maintain an effective system of internal controls.

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PART I

References in this Annual Report on Form 10-K, unless otherwise noted, "we," "us," "our," "Revelation" and the "Company" refer to Revelation Biosciences, Inc. and its subsidiary.

ITEM 1. BUSINESS

Overview

Revelation is a clinical-stage biopharmaceutical company founded in May 2020. We are focused on the development or commercialization of innate immune system therapeutics and diagnostics.

During the year ended December 31, 2021 and prior to the Business Combination, Petra was a blank check company incorporated under the laws of Delaware for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or similar business combination with one or more businesses.

Recent Developments

On January 10, 2022, we consummated the previously announced Business Combination.

Immediately after giving effect to the Business Combination, there were 12,944,213 shares of our Common Stock outstanding, 628,573 shares of our Common Stock reserved for issuance upon vesting of Rollover RSUs and Rollover Warrants and 10,511,597 warrants outstanding.

In connection with the consummation of the Business Combination, Petra changed its name to Revelation Biosciences, Inc. Our Common Stock is listed on Nasdaq under the ticker symbol "REVB" and warrants to purchase the Common Stock at an exercise price of $11.50 per share are listed on Nasdaq under the ticker symbol "REVBW."

Business Strategy after the Business Combination

Our current product candidates were developed by Revelation to potentially prevent, treat and detect viral infections or allergies. Our therapeutic product candidates consist of, REVTx-99a, which is being developed for the prevention or treatment of a wide array of viral infections, including SARS-CoV-2, variants of SARS-CoV-2, Influenza A, Influenza B, parainfluenza, respiratory syncytial virus, rhinosinusitis, and others, REVTx-99b, which is being developed for the prevention or treatment of nasal congestion due to allergies or chronic rhinosinusitis and REVTx-200 our nonclinical stage product being developed as a potential intranasal therapy that will be administered concurrently with a commercially available intramuscular ("IM") vaccine. Our lead diagnostic, REVDx-501 (REVID^{TM} Rapid Test Kit), is being developed as a rapid point of care diagnostic product that can potentially be used to detect various respiratory viral infections. The diagnostic is similar to a home pregnancy test with a simple to read visual readout in less than 15 minutes without the need for specialized instrumentation or complicated sample collection.

Our Pipeline

Revelation is leveraging the human body's innate immune system response to develop therapeutics and diagnostics to prevent, treat and detect respiratory viral infections. Revelation's pipeline is summarized in the table below:

The Therapeutic Platform

Our therapeutic platform is based on the active ingredient PHAD®, a synthetic version of monophosphoryl lipid A or MPLA. Currently, as part of the platform we have focused on the development of REVTx-99a REVTx-99b and REVTx-200. The current differences between REVTx-99a, REVTx-99b and REVTx-200 (and as development progresses may) include indications, dosage, timing of dosing, formulations and delivery methods of the drug product.

- REVTx-99a is being developed as a broad anti-viral nasal drop solution for the potential prevention or potential treatment of respiratory viral infections, including SARS-CoV-2 including variants, Influenza A, Influenza B, parainfluenza, rhinovirus, respiratory syncytial virus, rhinovirus and others.
- REVTx-99b is being developed as a prevention or treatment for chronic nasal congestion and allergic rhinitis.
- REVTx-200 is our nonclinical stage product being developed as a potential intranasal therapy that will be administered concurrently with a commercially available IM vaccine.

The therapeutic platform focuses on the activation of protein receptors on the surface of cells exposed to the outside environment designed to recognize pathogen molecules. These cell surface receptors are called pathogen pattern receptors, a subset of which are the Toll-like receptors ("TLR"). One such TLR is TLR4 which is most well-known for recognition of lipopolysaccharide ("LPS"). The active ingredient PHAD®, mimics LPS to potentially activate TLR4, without the adverse symptoms and toxicity related to LPS.

REVTX-99a

REVTx-99a is being developed as a broad anti-viral nasal drop solution for the potential prevention or potential treatment of respiratory viral infections, including SARS-CoV-2 including variants, Influenza A, Influenza B, parainfluenza, rhinovirus, respiratory syncytial virus, rhinovirus and others. The active ingredient in REVTx-99a may stimulate the innate immune system via interaction with TLR4. The innate immune response which is a general first line of defense against viral infections and is non-specific to the type of pathogen. The active ingredient in REVTx-99a, PHAD®, is thought to interact with TLR4 to stimulate the TRIF pathway leading to the production of protective cytokines including interferons. The production of protective cytokines is thought to help reduce viral load in respiratory viral infections.

We initiated a Phase 1 study in Australia in September 2020 and released top-line data in May 2021. The top-line data suggests REVTx-99a is well tolerated and does elicit a response of protective cytokines in the nasal mucosa. Based on the data from the Phase 1 study, Revelation received approval from the Federal Agency for Medicines and Health Products and the local Committee of Medical Ethics in Belgium to conduct our Phase 2b viral challenge clinical study for the prevention of influenza infection in September of 2021.

The Phase 2b study began enrollment in December 2021, dosing commenced in January 2022, in March of 2022 we announced that enrollment had completed and on March 30, 2022 we announced that the primary endpoint of the Phase 2b study, area under the curve of viral load measured by RT-PCR from nasopharyngeal swabs, did not meet statistical significance. We are waiting for the full data package which is expected by the end of the second quarter of 2022 to help determine the future clinical development plan.

If we decide to pursue development of REVTx-99a for the treatment of influenza infection, a separate Phase 2 study will be required. Separate Phase 3 studies will be required for evaluating REVTx-99a as a prevention of respiratory viral infection and as a treatment of early respiratory viral infection. In addition, each Phase 3 study will need to demonstrate activity for each individual virus (e.g., Influenza A, Influenza B, parainfluenza, RSV, SARS-CoV-2) that will be claimed in the indication for use. To accomplish this, the Phase 3 studies may need to be global and designed to enroll at times of the year and locations with a known, predominant viral pathogen such as influenza, SARS-CoV-2, RSV, etc. to obtain data to support approval for multiple virus types.

REVTx-99b

REVTx-99b is being developed as a prevention or treatment for chronic nasal congestion and allergic rhinitis. During the development of REVTx-99a we found that there may be benefit for people that suffer from chronic nasal congestion and allergic rhinitis which lead to the early development of REVTx-99b.

There are three possible mechanisms of action via the TLR4 pathway for REVTx-99b. They are (i) by the possible induction of a physical barrier to allergens, (ii) by the possible reduction of IgE secretion as a result of IFN upregulation and (iii) possible because IP-10 competes for the native eotaxin receptor.

We were granted ethics committee approval from Bellberry Limited Human Research Ethics Committee in Australia to conduct our Phase 1b

allergen challenge study in October of 2021. The study began enrollment in December 2021 and dosing commenced in January 2022. Top-line data is expected in the second half of 2022.

REVTx-200

REVTx-200 is our nonclinical stage product being developed as a potential intranasal therapy that will be administered concurrently with a commercially available intramuscular ("IM") vaccine. We believe concurrent stimulation of the nasal mucosa with REVTx-200 upon IM vaccination may provide a more complete immunization. REVTx-200 utilizes the same active ingredient (PHAD®) used in REVTx-99a/b. However, based on feedback from the FDA, we believe REVTx-200 will be regulated as a biologic, and not as a therapeutic, since it is concurrently administered with another vaccine. As such we believe the approval process will require its own unique development pathway to be approved for this use.

We hypothesize that optimal protection from a vaccine requires both a systemic immune response elicited by the IM vaccine injection and a mucosal immune response elicited by the intranasal administration of REVTx-200 developed by recruiting immune cells into the mucosal immune system. We believe that intranasal administration of REVTx-200 will result in improved recruitment of vaccine-specific activated adaptive immune cells (e.g. T cells and B cells) into the nasal mucosa. Biomarker data from our Phase 1 therapeutic clinical study (RVL-NHV01) supports this hypothesis. In particular, we were able to see increases in local (intranasal) IL-7 and MCP-1. IL-7 is a cytokine that induces the differentiation of hematopoietic stem cells into T cells, B cells and NK cells. MCP-1 is a chemokine that attracts B cells and T cells to a particular site. This data suggest, intranasal REVTx-200 will traffic antigen activated B cells and T cells to the mucosal space. While this data is supportive of the theory, additional formulation development and preclinical testing will be necessary for the development of REVTx-200.

We plan to establish relationships with vaccine development companies with the intention of working with one or more of these companies to develop REVTx-200 during 2022. Initial development will include studying REVTx-200 using commercially available IM vaccines in nonclinical models unique to each potential partnering company during 2022.

REVDx-501

Our lead diagnostic, REVDx-501 (REVID ™ Rapid Test Kit) is being developed as a rapid point of care in vitro diagnostic test (or diagnostic device) that has the potential to detect respiratory viral infections including SARS-CoV-2, Influenza A, Influenza B, parainfluenza, or respiratory syncytial virus. REVDx-501 is intended to be a user-friendly home test kit with a simple to read visual readout that provides a result in less than 15 minutes without the need for specialized instrumentation. Preliminary evaluation of clinical samples demonstrated good correlation between REVID and PCR for SARS-CoV-2 (100% positive agreement for replicating SARS-COV-2 virus, 86% negative agreement for no replicating SARS-COV-2 virus). We plan to continue additional development during 2022 and once development is complete submit for regulatory clearance to the FDA.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on the development of immune system therapeutics and diagnostics. The key components of our strategy are to:

- **Advance the development of our product candidate, REVTx-99a, as a broad nasal drop solution for the prevention and/or treatment of respiratory viral infections.**
- **Pursue the development of REVTx-99b for the treatment of chronic nasal congestion due to allergies.**
- **Develop REVDx-501 for the detection of respiratory viral infections.**
- **Establish a commercial infrastructure or commercial partner for REVDx-501.**
- **Scale-up and optimize the manufacturing of REVDx-501.**

Our Corporate History and Team

Revelation Biosciences, Inc. was formed on May 4, 2020 as a Delaware limited liability company named Revelation Therapeutics, LLC, and underwent a statutory conversion to a Delaware corporation and changed our name to Revelation Biosciences, Inc. on August 27, 2020. We have assembled a management team of biopharmaceutical experts with extensive experience in drug development, manufacturing and commercialization of pharmaceutical products along with broad experience in building companies from inception, including La Jolla Pharmaceutical Company, Pluromed, Inc., and Horizon Pharma, Inc. We are also supported by a group of directors and leading investors whose collective experience will assist us in realizing our corporate strategy.

BACKGROUND

Influenza Disease Overview

Influenza, or the flu, is caused by the influenza virus. There are four strains of influenza virus: influenza A (Alphainfluenzavirus), B (Betainfluenzavirus), C (Gammainfluenzavirus), and D (Deltainfluenzavirus). The influenza virus is a negative-sense, segmented, single-stranded RNA virus. Through the hemagglutinin on the surface exterior, the influenza virus binds to sialic acid molecules attached to many proteins on the cell surface. Sialic acid is expressed ubiquitously on cell surface receptors throughout the body, which allows the virus to infect many different cell types.

Influenza spreads through proximal transfer of respiratory droplets via coughing, sneezing, breathing, singing, or talking. These droplets can be inhaled or land on the mouth, nose, or eyes of a nearby person. In some cases, influenza viral particles can remain suspended in airborne droplets or aerosols for several minutes or hours, leading to airborne transmission.

Typically, influenza infects 5-15% of the global population each year. The majority of influenza infections are mild to moderate. The symptoms associated with influenza infection include runny nose, cough, headache, muscle aches, fever, and chills. However, approximately 5% of all severe pneumonia cases in hospitals are due to influenza, which is also the most common cause of acute respiratory distress syndrome ("ARDS") in adults. In those suffering from seasonal influenza, caused by H1N1 and H3N2, mortality is concentrated in the very young and the elderly, whereas during flu pandemics, young adults are often affected at a high rate.

There are a number of comorbidities associated with increased severity of influenza. The most significant comorbidity for influenza prognosis is age. Those older than 65 and those two years and younger are at greatest risk for severe influenza infection. Additional comorbidities include coronary artery disease or cardiomyopathy, heart failure, diabetes, asthma, chronic obstructive pulmonary disease ("COPD"), cystic or pulmonary fibrosis, obesity, smoking, chronic kidney disease, liver disease, sickle cell disease, and pregnancy. The primary cause of death due to influenza infection is due to inflammation as part of the immune response (such as seen in macrophage activation syndrome, or cytokine storm), which can lead to pneumonia or sepsis.

The current prevalence of influenza worldwide was at 3 to 5 million cases per year, with 290,000 to 650,000 reported deaths (WHO, 2021). According to the CDC, the burden of influenza disease in the United States can vary widely and is determined by a number of factors including the characteristics of circulating viruses, the timing of the season, how well the vaccine is working to protect against illness, and how many people got vaccinated. While the impact of flu varies, it places a substantial burden on the health of people in the United States each year. CDC estimates that influenza has resulted in between 9 million–45 million illnesses, between 140,000 – 810,000 hospitalizations and between 12,000 – 61,000 deaths annually since 2010.

COVID-19 Disease Overview

COVID-19 is caused by the severe respiratory syndrome coronavirus 2 ("SARS-CoV-2") virus. The SARS-CoV-2 virus is a positive sense, single stranded RNA virus. Through the spike protein subunit on the surface exterior, the SARS-CoV-2 virus binds to the Angiotensin Converting Enzyme II receptor, or ACEII. Although the ACEII receptor is expressed on a wide range of tissues throughout the body, it appears the majority of the transmission of SARS-CoV-2 occurs in the nose, through the ciliated nasal goblet cells, and the nasal epithelial cells, where expression levels of ACEII are most prevalent (Sungnak).

SARS-CoV-2 spreads through proximal transfer of respiratory droplets via coughing, sneezing, breathing, singing, or talking. These droplets can be inhaled or land on the mouth, nose, or eyes of a nearby person. In some cases, SARS-CoV-2 viral particles can remain suspended in airborne droplets or aerosols for several minutes or hours, leading to airborne transmission.

SARS-CoV-2 produces proteins that have a negative effect on the body's natural interferon ("IFN") response. These viral associated proteins block a key enzyme in the STING pathway (stimulator of interferon genes) that results in a lack of IFN production. This disruption in the IFN production have been shown to lead to more severe SARS-CoV-2 infection including the need for hospitalization and mechanical ventilation.

The majority of infections with SARS-CoV-2 are mild to moderate, and in some cases are completely asymptomatic. The symptoms associated with SARS-CoV-2 infection include shortness of breath or difficulty breathing, runny nose, dry cough, headache, diarrhea, muscle aches, fever, chills, and loss of smell and/or taste.

In a small percentage (0.5-2%) of cases, serious illness occurs, leading to major complications including pneumonia and or trouble breathing, organ failure in several organs, heart problems, acute respiratory distress syndrome, blood clots, acute kidney injury, and potential further viral and bacterial infection.

There are a number of comorbidities associated with increased severity of COVID-19. The most significant comorbidity for COVID-19 prognosis is age. The greater in age, the more at risk a person is for severe SARS-CoV-2 infection. Additional comorbidities include coronary artery disease or cardiomyopathy, heart failure, diabetes, asthma, COPD, cystic or pulmonary fibrosis, obesity, smoking, chronic kidney disease, liver disease, sickle cell disease, and pregnancy.

As of April 13, 2022 there have been over 79 million confirmed cases of COVID-19 and over 960,000 deaths in the United States according to the CDC and there have been over 450 million confirmed cases of COVID-19 and over 6 million deaths worldwide according to the WHO.

Allergic Rhinitis and Chronic Nasal Congestion Overview

Allergic reactions are caused by the body's overreaction to normally well-tolerated proteins called allergens. Allergy symptoms include nasal congestion, sneezing, itchy watery eyes, and rash, each of which may be caused by pollen, grass, weeds, animal dander, or molds. These symptoms are primarily caused by the release of histamine.

According to the CDC, allergies are currently ranked as the 6 th leading chronic disease according to the Asthma and Allergy Foundation of America. Allergic rhinitis or "hay fever" is the most common allergy diagnosis and is a common cause of nasal congestion. 19.2 million adults were diagnosed with allergic rhinitis (7.7% of the general population) in the last 12 months (CDC). In the same time frame, 7.1 million children have been diagnosed with respiratory allergies, and of those, 5.2 million children (7.2% of the population of children age 18 or less) were diagnosed with allergic rhinitis (CDC). Over the past 20 to 30 years, allergic rhinitis has increased worldwide. Over 400 million people suffer from allergic rhinitis around the world, and "direct medical costs in the US increased from $6.1 billion in 2000 to $11.2 billion in 2005, with an estimated productivity decrease of $600 per employee yearly; this cost is greater than diabetes, coronary heart disease and asthma" combined (World Allergy Organization Review of Rhinitis). Nasal congestion is typically due to swelling in the lining of the nose from inflamed blood vessels. Nasal congestion can cause interference with hearing and speech, and more severe congestion may impact sleep and cause snoring.

In a United States survey conducted in 61,655 adults, 14% had been diagnosed with nasal allergies and nasal congestion was the most frequently reported symptom with 60% reporting a "stuffed-up nose" either every day (40%) or on most days (20%) during the month when symptoms were most prevalent (Allergies in America).

Europeans suffering from allergic rhinitis report nasal congestion as a problematic symptom. In a European survey, 59% report nasal congestion with their allergic rhinitis and out of 562 people in Belgium suffering from allergic rhinitis, 53% reported nasal congestion (Bauchau)(Bachert).

The apparent increase in the frequency of allergic rhinitis worldwide emphasizes the need for more treatment options including the problematic symptoms of this disease, such as congestion, sneezing, itchy watery eyes, and rash (Stewart).

In addition to allergic rhinitis, nasal congestion is a troublesome symptom of rhinosinusitis, which is inflammation of the paranasal sinuses and adjacent nasal mucosa (Ferrand) (Pessey). Rhinosinusitis can be acute, with symptoms lasting less than a month, or chronic with symptoms lasting 12 weeks or longer (Stewart). In clinical practice, rhinosinusitis is one of the most common diagnosis affecting 1 in 6 adults in the Unites States (Hickner). Internationally, several surveys have been conducted and the incidence of nasal congestion is common (Leggett).

Nasal congestion is caused by an array of environmental and medical conditions. Although not widely studied, the economic burden of nasal congestion incurs costs from the diseases associated with congestion and are known to be substantial. Nasal congestion is reported as the most prevalent and bothersome symptom of these diseases and more treatments are essential to the improving quality of life (Stewart).

Current Prevention, Treatment and Detection Options

Prevention of Respiratory Viral Infection

Current therapies for preventing respiratory viral infections are limited. The main prophylaxis for preventing respiratory viral infections are vaccines. Each year, vaccines are developed and administered to prevent influenza. The effectiveness of these vaccines can be quite variable due to the ability of the influenza virus to mutate. According to the CDC, in some years, the influenza vaccine has been as low as 19% effective (*https://www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm*). Several vaccines have been developed and approved for emergency use for the prevention of SARS-CoV-2. The main drawback to vaccines is their inability to offer broad protection against multiple or emerging virus types.

Treatment of Respiratory Viral Infection

Current treatments for respiratory viral infections include rest, hydration, and treating fever and/or muscle soreness with over-the-counter analgesics. For influenza, a few antiviral therapies exist. The most recognized is the antiviral Oseltamivir (Tamiflu), which works by preventing replicated virus from exiting an infected cell. For COVID-19 the available options for treatment are limited. The current treatments available include Dexamethasone, Remdesivir, and low dose heparin, to prevent the blood clots and microcoagulations that have been commonly observed in COVID-19 patients. Currently, there are monoclonal antibody treatments available for treatment of SARS-CoV-2 infection, although these treatments have demonstrated improvement in symptoms associated with SARS-CoV-2 infection, none of these treatments alone provides a significantly improved prognosis for patients with severe illness. In addition, the effectiveness of these treatments, in particular the antibody treatments, may be diminished with the introduction of new SARS-CoV-2 variants.

Treatment of Allergic Rhinitis and Chronic Nasal Congestion

There are a number of medications currently available for allergies, including antihistamines, decongestants, and steroidal sprays. Over the counter oral antihistamines include Benadryl (diphenhydramine), Claritin (loratadine), Allegra (fexofenadine), and Zyrtec (cetirizine), and nasal sprays such as Nasahist B (brompheniramine). Prescription oral antihistamines include Clarinex (desloratadine), and nasal sprays such as Astelin (azelastine nasal). Some of the decongestants available for treatment include Sudafed (pseudophedrine), Neo-Synephrine (phenylephrine) and Afrin (oxymetazoline). Many decongestants are recommended to be taken with antihistamines for optimal relief of allergy symptoms. Fluticasone is a steroidal spray also recommended to be taken in conjunction with decongestants. Many of these treatments have well known side effects, including drowsiness (“medicine-head”) or increased blood pressure, and these side effects can be more pronounced when treatments are combined.

Detection Methods

While multiple test methods exist for the detection of respiratory viral infections, they have many limitations. These limitations include their inability to detect multiple virus types, turn-around time, sample collection and cost. The current gold-standard is the polymerase chain reaction (“PCR”) test. PCR test can detect the genetic material of a specific organism, such as a virus, thus identifying the specific virus types. However, PCR tests are expensive, time-consuming and can only detect virus types based on a “primer sequence” used when running the test. Because the PCR test requires this primer sequence, its utility in detecting viral mutations may be limited. These limitations make the PCR test non-ideal for at-home testing or as a screening tool for respiratory viral infections.

Other methods for detecting viral infection include the so-called antibody and antigen tests. While these methods can be made relatively inexpensively and in an at-home test format, they also suffer from the same limitation as PCR tests in that they are specific for the detection of a single virus type.

This limitation is illustrated in the following example: if you test a person infected with influenza using a SARS-CoV-2 test kit or a PCR test, the result would be limited to solely showing the individual is not infected with SARS-CoV-2, even though they actually are infected with a respiratory viral infection and should seek medical attention and/or self-quarantine.

REVELATION’S PROGRAMS

REVTx-99a

Overview

REVTx-99a is a clinical stage candidate being developed as a broad anti-viral nasal drop solution that may have the potential to be used to prevent and/or treat respiratory viral infections, including SARS-CoV-2 including variants, Influenza A, Influenza B, parainfluenza, rhinovirus and respiratory syncytial virus. REVTx-99a may work by boosting the body’s innate immune system, potentially preventing the user from becoming infected or to combat early infections. If developed and approved as a prevention for respiratory viral infection, REVTx-99a would be taken prophylactically (before

exposure to a potential virus). If developed and approved as a treatment for respiratory viral infection, REVTx-99a would be taken upon exposure to, or at the onset of symptoms.

The active ingredient in REVTx-99a is Phosphorylated hexaacyl disaccharide PHAD ® which is also known generically as glucopyranosyl lipid A ("GLA"). REVTx-99a is formulated as a liquid for intranasal administration as drops.

We are currently developing REVTx-99a as a broad anti-viral nasal drop for the potential prevention and/or treatment of respiratory viral infections. We anticipate REVTx-99a will be regulated by FDA as a new chemical entity and will require filing of an NDA for approval. We have successfully completed our Phase 1 clinical study in Australia. Top-line data showed REVTx-99a to be well tolerated and to have stimulated the production of intranasal cytokines. We received approval from the Federal Agency for Medicines and Health Products and the local Committee of Medical Ethics in Belgium to conduct our Phase 2b viral challenge study in Belgium for the prevention of influenza in September of 2021. We began enrollment for the Phase 2b study in the December 2021, dosing commenced in January 2022 and in March of 2022 we announced that enrollment had completed. On March 30, 2022 we announced that the primary endpoint of the Phase 2b study, area under the curve of viral load measured by RT-PCR from nasopharyngeal swabs, did not meet statistical significance.

We are waiting for the full data package which is expected by the end of the second quarter of 2022 to help determine the future clinical development plan.

For FDA approval, it will be necessary to show activity in preventing infection with each individual virus and therefore, any registration study will be designed to focus on times of the year and locations with a known, predominant viral pathogen such as Influenza or SARS-CoV-2.

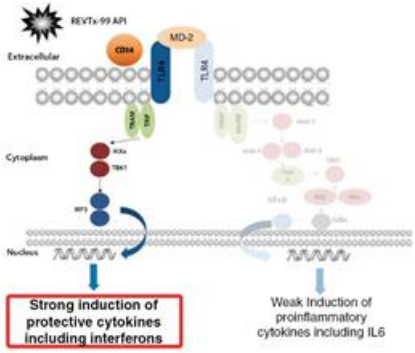
The regulatory approval pathway would differ for a prophylactic treatment vs a therapeutic treatment, and as such if we decide to develop REVTx-99a as a prevention as well as a treatment, we will need to initiate a separate Phase 3 study.

Scientific Rationale/Mechanism of Action

The innate immune system is our first line of defense against invading pathogens such as bacteria and viruses. The innate immune system is the more primitive part of the human immune system and defends against infection by producing and releasing various types of cytokines. Cytokines are proteins that direct different activities in cells to combat the invading pathogen, as well as stimulating recruitment of the so called adaptive immune system which ultimately leads to the production of antibodies. TLRs serve a vital role in starting up the innate immune system response by recognizing different molecular patterns associated with pathogens such as bacteria and viruses. For example, TLRs are associated with cells (e.g., macrophage, dendritic) found in the nasal mucosal tissue and when a respiratory pathogen, such as a virus, invades a person through the nose, TLRs recognize them as foreign and activate the innate immune response producing cytokines.

The active ingredient in REVTx-99a may stimulate the innate immune system via interaction with TLR4.

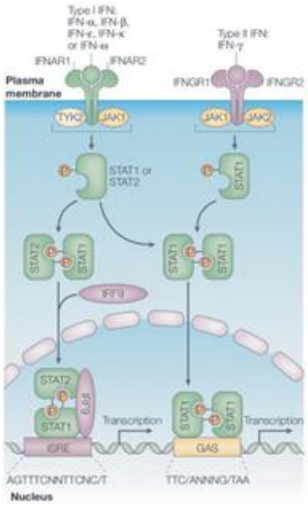
Figure 1. Interaction of REVTx-99a with TLR4



The active ingredient in REVTx-99a, PHAD®, may interact with TLR4 to stimulate the TRIF pathway leading to the production of protective cytokines including interferons. Source: Revelation Biosciences

Stimulation of TLR4 by an invading pathogen stimulates the production of numerous protective cytokines including interferons (e.g., IFN-α, IFN-β, IFN-γ). Interferons are known to respond to early phases of viral infection and interfere with viral replication by binding to cell surface receptors to activate the transcription of hundreds of anti-viral genes, as well as recruit adaptive immune cells to generate the pathogen-specific, long-lived response (Figure 2). Interferons have well known anti-viral activity (Acosta).

Figure 2. Interferon Antiviral Mechanism of Action

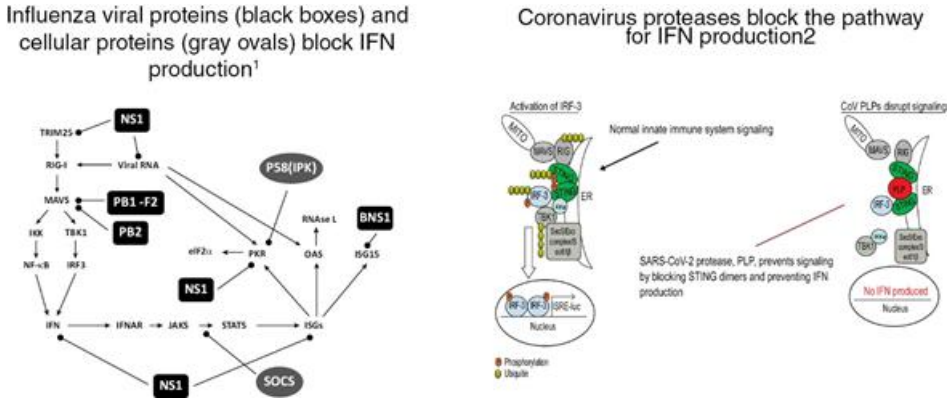


- Interferons (IFNs) have potent antiviral effects and are the first line of defense against viral infections (influenza A and B, parainfluenza, SARS-CoV-2, etc.)
- IFNs bind to cell surface receptors and activate the transcription of hundreds of genes
- IFN-induced gene expression protects cells from viral invasion
- REVTx-99 works by stimulating the endogenous production of Interferons (IFNs) and other protective cytokines via agonism of TLR-4 and preferential activation of the TRIF pathway

*Biological activity of interferons. Interferons activate the expression of hundreds of genes by interacting with multiple cell surface receptors. The expression of these genes "tie-up" your cells genetic machinery which prevents a virus from using it to multiply. S*ource: Nature Reviews Immunology, Volume 5, May 2005, pp. 375-386 doi:10.1038/nri1604

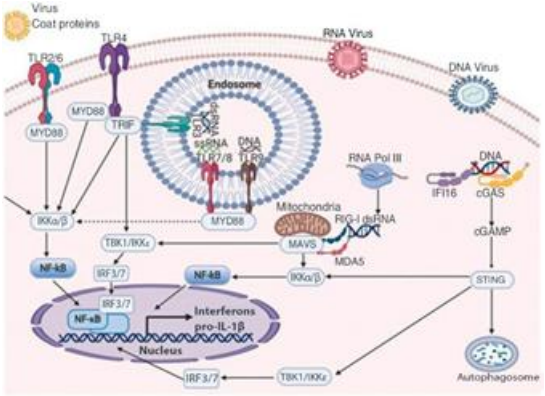
Both influenza viruses and corona viruses produce proteins that have a negative effect on the body's natural IFN response (Figure 3). Disruption IFN production can lead to more severe disease (Cell Host & Microbe *19*, 181 – 193, February 10, 2016). Stimulation of TLR4 is an alternative pathway to produce interferons (Figure 4).

Figure 3. Influenza and Corona viruses inactivate the IFN response



Influenza and corona viral associated proteins in activate the IFN response. Source:[1]Garcia-Sastre A. Induction and evasion of type I interferon responses by influenza viruses. Virus Research. 2011;162(0):12-18. doi:10.1016/j.virusres.2011.10.017, 2PLoS ONE Volume 7, Number 2, February 1, 2012, doi.org/10.1371/journal.pone.0030802

Figure 4. TLR4 is an alternative pathway for generating interferons

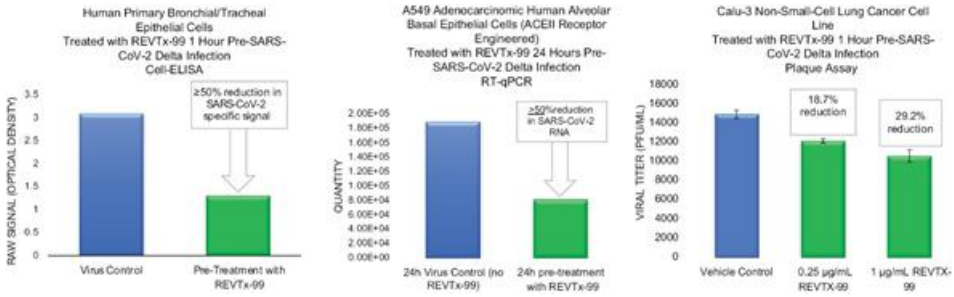


IFN production also takes place independently through the canonical TLR pathway. Each of these pathways have a direct role in the stimulation of interferon regulatory factor 3 or 7 (IRF3/7), which translocate to the nucleus to induce transcription of interferons and induce the generation of interferon stimulating genes. Source: Carty, et. al. Bio. Pharmacology Vol. 183, Jan. 2021, 114316 doi.org/10.1016/j.bcp.2020.114316

Pre-Clinical Data

Revelation recently completed preliminary analysis of anti-viral activity in three separate SARS-CoV-2 Delta variant in vitro single-cell assay models. Each cell line expressed sufficient ACEII and TLR4 to demonstrate infectivity and activity of REVTx-99a, respectively. Significant decrease in viral load was observed in all three assay systems, in comparison to the respective assay viral control (Figure 5).

Figure 5. Summary of preliminary assessment of REVTx-99a anti-viral activity against SARS-CoV-2 Delta



The anti-viral activity observed is likely due in part to interferon-stimulating genes, which are effectively establishing an anti-viral state, and reducing overall viral load. Source: Revelation Biosciences.

Clinical Development

Phase 1 Clinical Study

The Company completed a Phase 1 study, (RVL-NHV01) in Australia for REVTx-99a during 2020 and received data from the study in 2021.

The Phase 1 study enrolled 48 subjects in a total of 6 cohorts. Each cohort comprised two placebos and six treated subjects. Treated subjects in cohorts 1-5 received single doses of either 5, 15, 30, 50 or 100 µg delivered as nasal drops. Treated subjects in cohort 6 received 100 µg daily for 5 days. Placebo subjects received a solution as drops comprised the same components as REVTx-99a except for the active ingredient PHAD®.

The primary study endpoint comprised safety and tolerability of REVTx-99a and pharmacodynamic effect of REVTx-99a as measured by intranasal cytokine stimulation. Secondary and exploratory endpoints comprised change in serum cytokine levels, treatment emergent adverse events ("TEAEs") and plasma PK levels.

The primary endpoint for safety was met and all doses of REVTx-99a were well tolerated. There were no clinically significant laboratory, vital sign, ECG, or physical examination findings. Overall, 38 adverse events were reported (20 related, 18 not related), All adverse events were mild in nature (mild AEs being categorized as easily tolerated and does not interfere with normal daily activities) and did not require any medical intervention. Additionally, the primary endpoint for pharmacodynamic effect was met, REVTx-99a stimulated significant production of IP-10 in a dose-dependent fashion.

Phase 2b Clinical Study

Revelation received approval from the Federal Agency for Medicines and Health Products and the local Committee of Medical Ethics in Belgium to initiate our Phase 2b viral challenge study in Europe for the prevention of influenza in September 2021. Enrollment began in December 2021, dosing commenced in January 2022 using the following draft study design and in March of 2022 we announced that enrollment had completed.

The study enrolled 30 healthy individuals 18 to 55 years of age who were quarantined for 14 days while participating in the study. Key secondary endpoints include AUC of total symptom score, duration of symptoms, peak symptom score, peak viral load, duration of influenza virus presence, incidence of mild to moderate influenza disease (MMID), and incidence of seroconversion.

On March 30, 2022 an independent, unblinded subject matter expert panel reviewed the interim results. Based on analysis of the 30 patients through day 11 (day of discharge from the clinical unit), there were no serious adverse events reported or discontinuations due to study drug, and all subjects completed the treatment period per protocol. Efficacy data demonstrated that REVTx-99a did not meet its primary endpoint, area under the curve (AUC) of viral load by quantitative RT-PCR from nasopharyngeal swabs, and the preliminary results suggest the difference between REVTx-99a and placebo was not statistically significant.

REVTx-99b

Overview

REVTx-99b is a clinical stage candidate being developed a prevention or treatment for chronic nasal congestion and allergic rhinitis. During the development of REVTx-99a we found that there may be benefit for people that suffer from chronic nasal congestion and allergic rhinitis which lead to the early development of REVTx-99b.

The active ingredient in REVTx-99b is Phosphorylated hexaacyl disaccharide PHAD ® which is also known generically as glucopyranosyl lipid A ("GLA"). REVTx-99b is formulated as a liquid for intranasal administration as drops.

Revelation was granted ethics committee approval from Bellberry Limited Human Research Ethics Committee in Australia to conduct our Phase 1b allergen challenge study in October of 2021. The study began enrollment in December 2021 and dosing commenced in January 2022 and topline data is expected in the second half of 2022.

Scientific Rationale/Mechanism of Action

Mechanisms of Allergic Response

Upon first exposure to allergen, an allergic response is not engaged. Re-exposure to the same allergen in allergic individuals triggers degranulation of mast cells and basophils as a result of allergen-specific IgE cross-linking. Degranulated mast cells and basophils release inflammatory mediators (e.g., histamine, leukotrienes, tryptase) that elicit symptoms of allergic rhinitis (sneezing, rhinorrhea, nasal congestion, watery eyes, etc.). These mediators upregulate molecules that mobilize basophils, eosinophils, and T lymphocytes to the sites of insult, thereby compounding symptomology (Alvaro-Lozano 2020). Further, this process instigates the adaptive immune response, or the immune memory phenomenon, which is formed in part by Th2 and B cells that remember the antigen upon re-exposure and can subsequently respond quickly (Bousquet 2020). Once chronic Th2 bias has been induced, exposure to allergen results in T cell activation, enhancing local inflammation. Systemic responses, e.g., anaphylaxis, may also occur and reactions can be elicited within minutes (early phase) or hours (late phase).

It is important to mention non-IgE-mediated mechanisms that can activate mast cells and basophils (also known as immune effector cells). IgG antibody can activate the allergic cascade by binding to its respective receptor on mast cells, and to complement receptors on mast cells and basophils. In addition, PAMP signaling through toll-like receptors (TLRs; a type of PRR) on mast cells and basophils can activate allergic pathways as well.

TLR signaling establishes three potential pharmacologic mechanisms of action for REVTx-99b

TLR4 is a known PRR of the innate immune system that initiates the signaling pathways to modulate expression of proinflammatory cytokines. TLR4 is expressed on professional immune cells, such as those of myeloid lineage (Bellanti 2012), and on some nonhematopoietic cells such as nasal epithelial cells (McClure 2014). LPS is a known ligand and PAMP to TLR4 and the concerted mechanism is well-described.

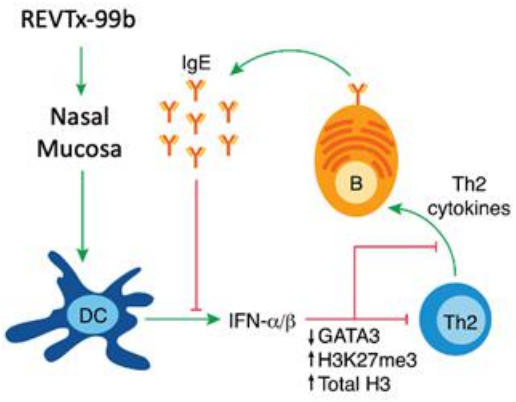
1. *REVTx-99b may induce a physical barrier to allergens*

LPS has been shown to elicit immune responses at the site of infection (e.g., nasal mucosa) that mount initial defenses that directly target the foreign pathogen/antigen. It has been shown that LPS induction of epithelial TLR4 mobilizes exosomes from stimulated epithelia. In the anterior portion of the nose, these exosomes release antimicrobial peptides and nitric oxide into nasal mucus that can destroy foreign invaders. As these products are swept to the posterior region of the nose by mucociliary action, the exosomes may also transfer their protective factors to naïve epithelia that may still be vulnerable to pathogens (Nocera 2018). In the absence of endotoxin (LPS), it is postulated that a similar TLR4 ligand (such as REVTx-99b) can mount these same initial defenses to mediate factors that promote immune tolerance. Beyond the initial barrier defenses from the immune system (e.g., nasal mucosa), LPS activity mediates intracellular and intercellular cascades that influence downstream immune responses expected to upregulate anti-infection/antiantigen factors. It is proposed these activities triggered by LPS can also be trigger by MPLA-compounds.

2. *REVTx-99b may reduce IgE secretion as a result of IFN upregulation*

The stimulation of TLR4 in response to REVTx-99b leads to generation of Type I interferons preferentially through the TRIF pathway (Figure 6). A negative reciprocal feedback loop has been observed to exist between Type I interferon activity and Th2-biased cellular activity (Gonzalez-van Horn 2015). This relationship is illustrated in Figure 6, which details Type I interferon production blocking activation of Th2 cellular activity at the molecular level (suppression of GATA3 expression, preventing access to transcription mediated expression for H3K27me3 and Total H3), which prevents generation of Th2 cytokines (IL-4, IL-5, and IL-13), reducing or eliminating secretion of IgE, therefore reducing or preventing allergic symptoms. It has been demonstrated that Type I interferons reduce or prevent Th2-biased cellular activity, which facilitates the allergic response. destabilizing establishment of Th2-biased cellular activity.

Figure 6. Upregulation of interferons via REVTx-99b may block the activation of mast cells, preventing the secretion of IgE.



Adapted from Gonzales-van Horn, S.R. and Farrar, J.D. (2015), Interferon at the crossroads of allergy and viral infections. Journal of Leukocyte Biology, 98: 185-194. https://doi.org/10.1189/jlb.3RU0315-099R

3. *IP-10 competes for the native eotaxin receptor*

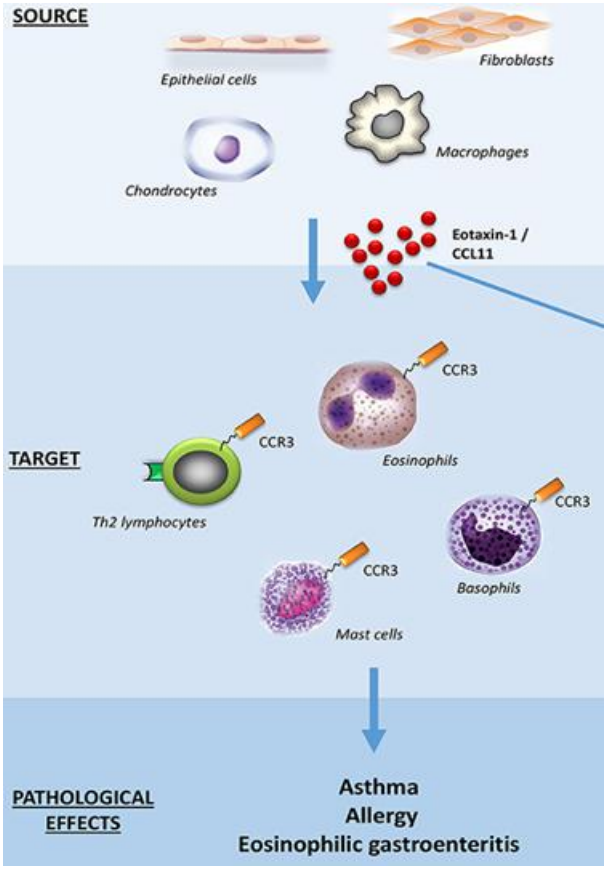
The ability of IP-10 to recruit Th1 cells has been well documented (Sauty; Quian,; Zhigang). The ability of REVTx-99b to reduce allergic responses may be evident in the cytokine and chemokine profile induced through treatment in RVL-NHV01. The interleukins classically associated with allergies are IL-4, IL-5, IL-9, IL-10 and IL-13. Although IL-4 and IL-13 were not measured in this study, the absence of an increase in IL-5, IL-9, and IL-10 indicate that REVTx-99b is likely signaling through Th1 cellular activity (Th1 bias), potentially preventing the allergic inflammation associated with an allergic response.

The receptor for IP-10, CXCR3, is present on activated Type I Helper T cells (Loetscher). These researchers found that agonists for CXCR3, such as IP-10, acted as antagonists of CCR3, the native receptor for eotaxin. This is evidence that IP-10 can directly compete with eotaxin for binding to its native receptor, preventing eotaxin from recruiting eosinophils, reducing recruitment of Th2 cells, and attenuating the allergic response.

A highly robust IP-10 local response was observed in RVL-NHV01. It is likely this local IP-10 response will effectively compete with eotaxin for the binding of CCR3, preventing the recruitment of eosinophils and basophils. The presence of IP-10, in conjunction with the observed bias toward Th1 cell signaling (a bias away from the allergic Type 2 helper cell population), indicates a possible anti-allergic role for REVTx-99b.

Additional investigation into the mechanism of action for REVTx-99b on allergies is warranted, however, the preliminary data point to a potential therapeutic role in allergies and allergic rhinitis.

Figure 7. CCR3, the native receptor of Eotaxin-1, mediates asthmatic and allergic responses via a number of different effector cells.



Teixiera, A. 2018 doi.org/10.3389/fpsyt.2018.00241

Clinical Development

Phase 1b Clinical Study

Revelation was granted ethics committee approval from Bellberry Limited Human Research Ethics Committee in Australia to conduct our Phase 1b allergen challenge study in October of 2021. The study began enrollment in December 2021 and dosing commenced in January 2022 and topline data is expected in the second half of 2022.

The Phase 1b clinical study is a randomized, double-blind, placebo-controlled, crossover design study and will enroll up to 28 participants. The primary endpoint is to evaluate the effects of REVTx-99b versus placebo on safety and tolerability. Key secondary endpoints include allergy symptoms and peak nasal inspiratory flow elicited by nasal allergen challenge. The study will have two cohorts: one cohort will receive study drug before the nasal allergen challenge (the prophylactic cohort) and the second cohort will receive study drug after the nasal allergen challenge (the treatment cohort).

REVTx-200

Overview

REVTx-200 is being developed as a potential intranasal therapy that will be administered concurrently with a commercially available intramuscular (“IM”) vaccine. We believe concurrent stimulation of the nasal mucosa with REVTx-200 upon IM vaccination will provide a more complete

immunization. REVTx-200 utilizes the same active ingredient (PHAD®) used in REVTx-99a/b. However, based on feedback from the FDA, we believe REVTx-200 will be regulated as a biologic, and not as a therapeutic, since it is concurrently administered with another vaccine. As such we believe the approval process will require its own unique development pathway to be approved for this use.

Most vaccinations for respiratory viruses (influenza, SARS-CoV-2) are being developed or have been developed for IM administration. It has been shown that IM vaccination results in a strong systemic immune response, but a weak mucosal immune response. Contrary to this, intranasal vaccination (e.g., FluMist®) has been shown to elicit a strong mucosal response and a moderate systemic response. We hypothesize that optimal protection from a vaccine requires both a systemic immune response elicited by the IM injection and a mucosal immune response developed by recruiting immune cells into the mucosal immune system. We believe that intranasal administration of REVTx-200 will result in improved recruitment of vaccine-specific activated adaptive immune cells (e.g. T and B cells) into the nasal mucosa.

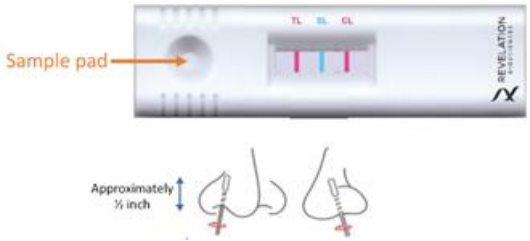
Biomarker data from our Phase 1 clinical study (RVL-NHV01) supports this hypothesis. In particular, there were increases in local (intranasal) IL-7 and MCP-1. IL-7 is a cytokine that induces the differentiation of hematopoietic stem cells into T cells, B cells and NK cells. MCP-1 is a chemokine that attracts B cells and T cells to a particular site. This data suggest, intranasal REVTx-200 will traffic antigen activated B cells and T cells to the mucosal space. While this data is supportive of the theory, additional formulation development and preclinical testing will be necessary for the development of REVTx-200.

The Company will continue to meet with vaccine development companies with the intention of working with one or more of these companies to develop REVTx-200. Revelation plans to initiate internal initial development which will include studying REVTx-200 using established vaccine and nonclinical models unique to each potential partnering company during 2022.

REVDx-501 (Diagnostic) Overview

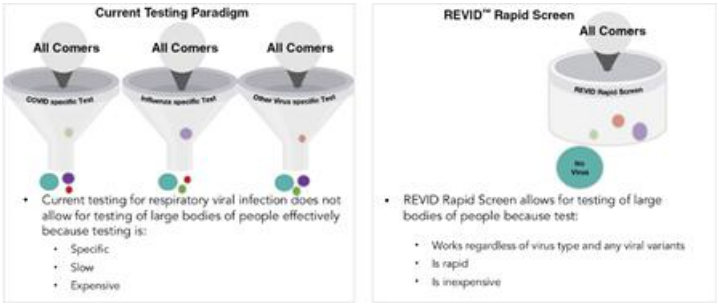
REVDx-501 (REVID™ Rapid Test Kit), a rapid point of care diagnostic product that is being developed to be potentially used to detect various respiratory viral infection including SARS-CoV-2, Influenza A, Influenza B, parainfluenza, and respiratory syncytial virus. The diagnostic is similar to a home pregnancy test with a simple to read visual readout that provides a result in less than 15 minutes without the need for specialized instrumentation (Figure 8). Sample collection is simply a swab of the anterior nares (nostrils) making sample collection easy. If approval is obtained, we anticipate the commercial version of the kit to be a self-contained, portable kit that can be shipped anywhere. The instructions will direct users with a positive result to seek confirmatory testing and/or medical treatment.

Figure 8. REVID™ Rapid Test Kit Example of Positive (Infected) Readout



While the kit could potentially be used universally at home as a self-screening method to quarantine, one potential early use for the ongoing COVID-19 pandemic would be to use the diagnostic as a screening tool for entry into at-risk facilities (e.g., hospitals and nursing homes). In addition, the diagnostic can be used to increase the efficiency of PCR testing by eliminating wasted testing on subjects who are not infected with a viral infection. Figure 9 below explains the concept of increasing the efficiency of PCR testing. The left panel shows the current state of PCR testing with most patients (>80%) being PCR negative for infection. The right panel shows the effect of the addition of the REVDx-501 screening test to rule out virus negative patients resulting in better utilization of the PCR test.

Figure 9. REVDx-501 May Increase the Efficiency of COVID-19 PCR Testing



Scientific Rationale

The innate immune system is our first line of defense against invading pathogens such as bacteria and viruses. When a respiratory pathogen, such as a virus, invades a person through the nose, the innate immune system responds by producing and releasing various types of cytokines. Cytokines are proteins that direct different activities in cells to combat the invading pathogen.

The diagnostic is based on the knowledge that respiratory viral infection results in elevated nasal mucosal secretions containing viral specific cytokines (e.g., IP-10, IFN), which can be detected rapidly after exposure. One or more of these cytokines can be detected using a lateral flow assay format (e.g., home pregnancy kit) from a mucosal sample collected from the anterior nares.

Device Testing and Data supporting the potential utility of REVDx-501

The Company has successfully translated the ELISA (enzyme-linked immunosorbent assay) format to a simple and inexpensive lateral flow assay format assay without the need of a special instrumentation. Initial assay development focused on the measurement of two cytokines (IFN-α and IL-6). Revelation has been able to achieve high sensitivity and good correlation for both IL-6 and IFN-α between the LFA assay format and the gold standard ELISA. Numerous additional cytokines were also examined and IP-10 was chosen as the key cytokine for development of the REVDx-501 product.

Clinical samples were collected under protocol and with consent from volunteers presenting at a COVID-19 testing center. Participants included those presenting with symptoms including fever, cough, loss of taste or loss of smell as well as asymptomatic (no symptoms) subjects. For each subject, a sample was collected using the nasopharyngeal method and tested by PCR for COVID-19 and a second sample of the lower nose was collected using the REVDx-501 swab and tested using the REVDx-501 test method. The results from this testing showed REVDx-501 to have excellent correlation with PCR (Table 1) for replicating SARS-CoV-2 virus (100% positive agreement for replicating SARS-CoV-2 virus, 86% negative agreement for no replicating SARS-CoV-2 virus).

Table 1. Correlation between REVDx-501 and PCR for replicating SARS-CoV-2

PCR vs. REVDx-501 Test Kit	**PCR POSITIVE**	**PCR NEGATIVE**
Test Kit POSITIVE	37	21
Test Kit NEGATIVE	0	132
TOTAL SAMPLES	37	153

Patients who reported symptoms of fever, cough, loss of taste or loss of smell were tested by REVDx-501 and PCR. REVDx-501 had a 0% false negative rate for replicating SARS-CoV-2. These results include patients who reported onset of symptoms within 24 hours of the test, which may make the diagnostic an earlier detection method than even PCR. In addition, the positive REVDx-501 results that were PCR negative for COVID-19 were likely caused by other viral infections. Source: Revelation Biosciences.

In addition to the clinical evaluation described above, the Food and Drug Administration (FDA) recommends a series of validation studies for in vitro diagnostic (IVD) devices prior to submission for approval. These studies are planned and ongoing and include limit of detection (LOD), inclusivity, cross-reactivity, flex, usability, and clinical evaluation studies.

The LOD, inclusivity, cross-reactivity, and flex test studies are generally analytical laboratory-based (“bench”) studies to test how well the diagnostic device can detect the chemical or pathogen the device is intended to measure, as well as under different conditions. For example, cross-reactivity studies test how well the device works in the presence of other chemicals and/or pathogens; flex test studies consider variables such as temperature, stability, physical abuse, etc. These studies are completed early in device development under standard quality guidelines to ensure the device is designed properly for human use.

Usability (human factors) studies are investigations that enable a device design team to improve the usability of their device to meet acceptable standards of risk — it informs the team if the device kit and instructions for use are appropriate for typical users. Initially, a small formative study of about 10 people, who match some of the demographic characteristics of the intended end users, are recruited to use a prototype of the device. These users are observed by a study team as they use the product. After the users complete the testing tasks, they provide feedback on their experience. The findings of this formative study inform the next usability study, which is called a summative study and includes 30 to 100 users. The summative study protocol is similar to that of the formative study but may include improvements or modifications to the device and/or instructions based on findings from the formative study. The goal of the summative study is to provide confirmation to the device design team the product is developed effectively and safely for clinical testing.

Generally, the final study is the clinical evaluation study, which is the largest study (at least 100 users). This study is considered the “real-world” testing of the product. For home-use tests, users are recruited by clinical sites or other appropriate methods to test the product in people who have the target condition, as well as a group of controls without the target condition. For example, a study for an at-home test that is intended to detect the presence of an upper respiratory tract infection would recruit people suspected of having an upper respiratory tract infection and a group of users who do not have an upper respiratory tract infection. These study participants will use the test kit at home or a simulated home environment. The device test kit results are compared to a reference standard test that is regularly used to diagnose the target condition (in this example, it would be a viral or bacterial test regularly used at a qualified laboratory). Overall, in order to be considered for marketing approval by FDA, users should have minimal issues using the test and the device test results should align very closely with the laboratory test.

Development of REVDx-501 will continue during 2022 and once development is completed we plan to submit for regulatory clearance to the FDA a de no clearance submission.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of REVTx-99a, REVTx-99b, REVTx-200 and any future Program Product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. We believe the key competitive factors that will affect the development and commercial success of REVDx-501 and any future product candidates are reliability, convenience, and price. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. A number of device companies are pursuing the development or marketing of devices in the same or similar space. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of respiratory viral infections, it is likely that the number of

companies seeking to develop products and therapies for the prevention or treatment of viral infection, will increase.

If REVTx-99a is approved for the prevention and/or early treatment of SARS-CoV-2, we would face competition from currently approved and marketed products as well as products currently approved under the Emergency Use Authorization, including: REGN-CoV2 from Regeneron Pharmaceuticals, Inc.; Bamlanivimab from Eli Lily and Company; Remdesivir from Gilead Sciences, Inc.; and dexamethasone. We would also have future competition that could arise from products currently in development, including: various induction of interferons therapy from Altimmune, Inc.; innate immune system activation from Pulmotect, Inc.; induction of interferons from PrEP Biopharm and Janssen Pharmaceuticals, Inc.; anti-inflammatory from Merck KGaA and Enzychem Lifesciences, Corp; protease inhibitor from Janssen Pharmaceuticals, Inc; inhibition of viral replication from BioCryst Pharmaceuticals, Inc.; blocking of viral entry from Wellona Pharma Private Limited; inhibition of viral replication from Abbvie, Inc. and Russian Academy of Science.

If REVTx-99b is approved for prevention or treatment for chronic nasal congestion and allergic rhinitis, we would face competition from currently approved and marketed products, including: Benadryl (diphenhydramine), Claritin (loratadine), Allegra (fexofenadine), Zyrtec (cetirizine), Nasahist B (brompheniramine, Clarinex (desloratadine), Astelin (azelastine nasal), Sudafed (pseudophedrine), Neo-Synephrine (phenylephrine) and Afrin (oxymetazoline) along with generics where available and others. We would also have future competition that could arise from products currently in development.

If REVDx-501 is approved, competition would arise from various companies and partnerships currently engaged in clinical studies with competing device concepts including: Quest Diagnostics, Inc., Laboratory Corporation of America Holdings, and Eurofins Advantar Laboratories. As well as from currently approved COVID-19 home test from Ellume Limited, Abbot Laboratories, and Lucira Health.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical studies of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our Program Products or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical study sites and enrolling patients for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of our Program Products or any other product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our Program Products or any other product candidates for preclinical and clinical testing, as well as for commercial manufacturing if REVTx-99a/b or any future product candidate receives marketing approval. Also, we currently rely and continue to rely on third parties for the manufacturing and development of our diagnostic devices for clinical testing, as well as for commercial manufacturing if REVDx-501 gets marketing approval. Also, there is only one supplier for PHAD®, Avanti Polar Lipids, Inc., with whom we do not have a long-term supply agreement. Currently we have purchased enough material for our planned clinical studies through purchase orders.

License

We do not currently rely on any third-party license for our therapeutic candidates and diagnostic devices.

Global Health

We entered into a Global Health Agreement (“GHA”) with AXA IM Prime Impact Fund on December 31, 2020. As part of the GHA for six years from December 31, 2020 (the “Term”) we will (i) provide REVTx-99a/b, REVTx-200 and REVDx-501 (the “GHA Program Products”), if approved by the FDA and/or the EMA, to non-profit organizations and public-sector purchasers (“Global Health Purchasers”) in certain low and middle income countries (as defined by the World Bank) (“Target Countries”), to be determined by the Global Access Committee (the “GAC”), at a price of no more than 30% above the cost of goods sold, (ii) make available up to 20% of the annual unit sales volume, (iii) allocate $50,000 per year to the GAC to work on training programs, and (iv) work with global health authorities to have the products added to protocols and treatment guidelines.

In the event that the GHA Program Products are acquired directly or through an acquisition of the Company by a third party the GHA shall continue to survive for the Term and shall be assumed by the acquirer. In the event that the Company (i) fails to use commercially reasonable efforts to obtain regulatory approvals as agreed by the GAC, (ii) fails to cure a non-compliance within the GHA, (iii) if we transfer the intellectual property and the successor fails to assume the GHA, or (iv) if the Company institutes any bankruptcy, reorganization, dissolution, liquidation, or similar proceeding, the Company will grant a nonexclusive, perpetual, irrevocable, non-terminable, fully paid up, royalty free license in the Target Countries for Global Health Purchasers.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we expect that the geographic market for a product, we develop on our own is limited or that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

We plan to seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and components thereof, their methods of use and processes for their manufacture, our kit design, our proprietary reagents and assays and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates.

As of April 13, 2022, we have six U.S. provisional patent applications filed: one for REVDx-501, two for REVTx-200, and two for REVTx-99a and one for REVTx-99b, five of the six provisional patent applications will be converted to utility patent applications during 2022. We have two international (Patent Cooperation Treaty, or PCT) patent applications, one for REVTx-200 and one for REVDx-501. In regard to our REVDx-501 program, the provisional patent application has claims directed to the rapid detection kit and methods for diagnosing early viral infections of the respiratory tract. In regard to our REVTx-99a program, the provisional patent applications have claims covering the use of REVTx-99a for the treatment and prevention of respiratory viruses, formulations of REVTx-99a/b and the use of REVTx-99b for the treatment of allergic rhinitis and chronic nasal congestion. In regard to our REVTx-200 program, the international patent application has claims directed to methods of use as an adjunct to IM vaccination when REVTx-200 is contemporaneously administered in the nasal cavity and the provisional patent has claims directed to methods of adjuvant to allergy immunotherapy. We expect to file a non-provisional patent application prior to the twelve-month convention date for each provisional patent application. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, or which effectively prevent others from commercializing competitive technologies and product candidates. Additionally, any U.S. provisional patent application that we file is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not file a non-provisional patent application in a timely manner, we may lose our priority date with respect to the provisional patent application, and may lose the ability to obtain any associated patent protection on the inventions disclosed in the provisional patent application.

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the U.S. Patent and Trademark Office (“USPTO”) in examining the patent application (patent term adjustment, or PTA) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension, or PTE), or both. In addition, we cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our products or product candidates.

We believe that we have certain know-how and trade secrets relating to our technology and product candidates. We rely on trade secrets to protect certain aspects of our technology related to our current and future product candidates. However, trade secrets can be difficult to protect. We seek to protect our trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, service providers, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Employees

As of April 13, 2022, we had 14 full-time employees, 8 of whom are engaged in research and development activities or operations and 6 of whom are engaged in general and administrative activities or operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Government Regulation

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

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, its implementing regulations, and other federal, state and local statutes and regulations. Drugs 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 United States. For drug product candidates regulated under the FD&C Act, FDA must approve a New Drug Application, or NDA. The process 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 investigational new drug application, or 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;

- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;

- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA;

- payment of user fees for FDA review of the NDA; and

- FDA review and approval of the NDA, 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 the IND process — Therapeutics

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed protocol for clinical studies, among other things, to the FDA as part of an IND. An IND is an exemption from the Federal Food, Drug, and Cosmetic Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical study and is a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved application. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical studies and places the study on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. As a result, submission of an IND may not necessarily result in the FDA allowing clinical studies to commence.

Clinical studies — Therapeutics

Clinical studies involve the administration of the investigational new drug to human subjects — healthy volunteers or patients — under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical study. Clinical studies are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical study must review and approve the plan for any clinical study before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB may also require the clinical study at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. For clinical studies involving an IND, an IRB must operate in compliance with FDA regulations. Additionally, some studies are overseen by an independent group of qualified experts organized by the study sponsor, known as a data safety monitoring board ("DSMB"). This group provides authorization as to whether or not a study may move forward at designated check points based on access that only the DSMB maintains to available data from the study.

Human clinical studies are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The investigational drug or biological product is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, side effects associated with increasing doses, pharmacological action, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The investigational drug or biological product is administered to a limited patient population to identify common adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. This phase may include administration of the investigational drug to patients with concomitant disease conditions.

- Phase 3: The investigational drug or biological product is administered to an expanded patient population in adequate and well-controlled clinical studies, typically at geographically dispersed clinical study sites, to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to permit the FDA to evaluate the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product. More than one adequate and well-controlled Phase 3 clinical study may be required by the FDA for approval of an NDA.

Progress reports detailing the results of clinical studies involving an IND must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug or biologic product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, the company usually complete additional animal studies, develop additional information about 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 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.

In some cases, the FDA may approve an application for a product candidate but require the sponsor to conduct additional clinical studies to further assess the product candidate's safety and effectiveness after approval. Such post-approval studies are typically referred to as Phase 4 clinical studies. These studies are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further document a clinical benefit in the case of drugs approved under accelerated approval regulations.

Clinical studies — Device

Clinical studies are almost always required to support pre-market approval and are sometimes required for 510(k) clearance or de novo clearance. In the United States, for significant risk devices, these studies require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, study monitoring, reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical studies for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards ("IRBs") at the clinical study sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of human research subjects. A nonsignificant risk device does not require FDA approval of an IDE; however, the clinical study must still be conducted in compliance with various requirements of FDA's IDE regulations and be approved by an IRB at the clinical study sites. The FDA or the IRB at each site at which a clinical study is being performed may withdraw approval of a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a study is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Sponsors of clinical studies of devices are required to register with clinicaltrials.gov, a public database of clinical study information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical study is made public as part of the registration.

U.S. Marketing approval — Therapeutics

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's pharmacology 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. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. Under federal law, the submission of most NDAs and BLAs is subject to a substantial application user fee, and the sponsor of an approved NDA or BLA is also subject to annual product or program fees. These fees may be increased or decreased annually.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after receipt before accepting them for filing based on the agency's threshold determination that they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information, which would also be subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs and BLAs. Most such applications for non-priority products are reviewed within ten to twelve months after filing, and most applications for priority review products, that is, drugs and biologics that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months after filing. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or biological products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. 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 adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory

approval. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA or BLA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, the agency may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions through a Risk Evaluation and Mitigation Strategy or other risk management mechanisms, 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-market studies or surveillance programs. After approval, some types of changes to the approved product, such as changes in indications, manufacturing changes and labeling, are subject to further testing requirements and FDA review and approval.

FDA's Pre-market Clearance and Approval Requirements — Device

In vitro diagnostic tests such as our REVDx-501 diagnostic program is regulated as medical devices. Each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance, de novo classification or PMA, unless it is exempt, or a pre-market approval from the FDA. In the United States, the FD&C Act, and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, 510(k), or de novo classification, and approval of a premarket approval application, or PMA.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device and assesses whether the subject device is comparable to the predicate device with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

The de novo classification process, provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. A de novo classification is a risk-based classification process through which devices are classified into class I or class II. Devices classified in response to a de novo classification request may be marketed and used as predicates for future premarket notification 510(k) submissions.

A PMA must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the quality system regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

We expect that REVDx-501 will be subject to review as a de novo clearance. A de novo clearance pathway may be a lengthier and a more rigorous process than the 510(k) clearance pathway, which may delay or terminate this program down the road, which could adversely affect our ability to grow our business.

Ongoing Regulation by the FDA — Device

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

- corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may present a risk to health; and

- post market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance or de novo classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or possibly a pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMAs.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, the California Department of Health Services ("CDHS"), requires us to register as a medical device manufacturer within the state. Because of this, the FDA and the CDHS inspect us on a routine basis for compliance with the QSR. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. We have undergone and expect to continue to undergo regular QSR inspections in connection with the manufacture of our products at our facilities. Further, the FDA requires us to comply with various FDA regulations regarding labeling. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;

- customer notifications, voluntary or mandatory recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- delay in processing submissions or applications for new products or modifications to existing products

- withdrawing approvals that have already been granted; and

- criminal prosecution.

The Medical Device Reporting laws and regulations require us to provide information to the FDA when we receive or otherwise become aware of information that reasonably suggests our device may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

We are also subject to other federal, state and local laws and regulations relating to safe working conditions, laboratory and manufacturing practices.

European Union

We anticipate that our products will be regulated in the European Union as medical devices per the European Union Directive (93/42/EEC), also known as the Medical Device Directive. An authorized third party, Notified Body, must approve products for CE marking. The CE Mark is contingent upon continued compliance to the applicable regulations and the quality system requirements of the ISO 13485 standard.

Other Regions

Most major markets have different levels of regulatory requirements for medical devices. Modifications to the cleared or approved products may require a new regulatory submission in all major markets. The regulatory requirements, and the review time, vary significantly from country to country. Products can also be marketed in other countries that have minimal requirements for medical devices.

Other U.S. 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, the CMS, other divisions of the U.S. Department of Health and Human Services ("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, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. The statutory exceptions and regulatory safe harbors are also subject to change.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act also codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy, data security and data breach notification laws, regulations, standards, and codes of conduct by both the U.S. federal government and the states. These laws, regulations, standards, and codes of conduct may govern the collection, use, disclosure and protection of health-related and other personal information. HIPAA, as amended by the HITECH, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. The federal government may impose civil, criminal, and administrative fines and penalties and/or additional reporting or oversight obligations for a violation of HIPAA's requirements. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.

HITECH also created four 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 HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition to HIPAA and HITECH, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by federal law, and may have a more prohibitive effect than federal law, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is the part of Medicare that covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Additionally, the Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. This information is made publicly available on a CMS website, and failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several state and local laws have been enacted requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical studies and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. In addition, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, private health insurers and other organizations.

Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic 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.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies, and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an

appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act and its implementing regulations, among other things, revised the methodology for calculating rebates for covered outpatient drugs and certain biologics owed by manufacturers to the state and federal government under the Medicaid Drug Rebate Program, 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, and expanded programs designed to test innovative payment models, service delivery models, or value-based arrangements, and fund comparative effectiveness research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In addition, further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 federal 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, after some pharmacy benefit managers and insurers adopted policies stating that the amount of a copay coupon would not be applied to the enrollee's deductible or out-of-pocket maximum (referred to as "accumulator adjustment programs"), some states passed legislation banning these policies. Based on a rule that will take effect in the 2020 plan year, CMS will allow accumulator adjustment programs only when used for a branded drug that has a generic equivalent. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

Future legislation or regulation

Other legislative changes have been adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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Additional Regulation

In addition to the foregoing, local, state and federal laws, including such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including, in the United States, the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, biological products and medical devices, such as those we are developing.

Disclosure of clinical study information

Sponsors of applicable clinical studies of FDA regulated products, including drugs, are required to register and disclose certain clinical study information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical study is then made public on the ClinicalTrials.gov website as part of the registration. Sponsors are also obligated to disclose the results of their clinical studies after completion. Disclosure of the results of these studies can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Expedited Programs for Serious Conditions

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval. These programs can significantly reduce the time it takes for the FDA to review a BLA or NDA, but they do not guarantee that a product will receive FDA approval. Even if a product qualifies initially, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review will not be shortened. In May 2018, the Right to Try Act also established a program to increase access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical study.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug or biologic may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A

product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, FDA will review an application in six months compared to ten months for a standard review. Products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatment. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication be submitted to FDA for review before the initial dissemination or publication.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation is taken into consideration but generally does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity in that it is shown to be safer, more effective or makes a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Pediatric information and exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA, BLA or supplement to an NDA or BLA must contain data from pediatric studies that are adequate to assess the safety and effectiveness of the drug or biological product 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, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

Pediatric exclusivity is a type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or patent protection, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an application sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical study is deemed to fairly respond to the FDA's request, the additional protection is granted.

The Hatch-Waxman Act

Abbreviated new drug applications

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent that claims to cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the ANDA applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of a 30-month period, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that the patent involved is deemed invalid or not infringed.

The ANDA also will not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be received by the FDA, except that the application may be submitted in four years if it contains a Paragraph IV certification. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and thus, no ANDA may be filed before the expiration of the exclusivity period. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical studies conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The FDA must also expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Patent term extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent term extension. The allowable patent term extension is calculated as half of the drug's testing phase, based on the time between IND application and submission of the NDA, and all of the review phase, based on the time between the NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent term extension. An interim patent term extension increases the patent term by one year and may be renewed up to four times. For each interim patent term extension granted, the post-approval patent term extension is reduced by one year. The director of the U.S. Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent term extension is being sought is likely.

Interim patent term extensions are not available for a drug for which an NDA has not been submitted.

Section 505(b)(2) new drug applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of a 30-month period, settlement of the lawsuit or a decision in the infringement case that the patent involved is deemed invalid or not infringed.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA or NDA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. 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.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;

- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologic regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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

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

Item 1A. Risk Factors

The following risk factors are not exhaustive and investors are encouraged to perform their own investigation with respect to the business, prospects, financial condition and operating results of Revelation and our business, prospects, financial condition and operating results. You should carefully consider the following risk factors in addition to the other information included in this proxy statement/prospectus, including matters addressed in the section titled "Cautionary Note Regarding Forward-Looking Statements." We may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial, which may also impair our business, prospects, financial condition or operating results. The following discussion should be read in conjunction with our financial statements and notes to the financial statements included herein.

Unless the context otherwise requires, references herein to "Program Products" refers to Revelation's REVTx-99a, REVTx-99b, REVTx-200 and REVDx-501 programs.

Risks Related to Our Business

We have a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we anticipate that we will continue to incur significant losses for the foreseeable future, and even if we were to generate revenue, we may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced our operations in May 2020, and, to date, our operations have been limited to organizing and staffing our Company, business planning, raising capital, conducting research and development activities, including early clinical study, and providing general and administrative support for these operations. Investment in biopharmaceutical product development and diagnostic device is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate and/or diagnostic device will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval or become commercially viable. We currently have no

products approved for commercial sale, we have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We have limited experience as a Company conducting clinical studies and no experience as a Company commercializing any products.

We are not profitable and have incurred net losses since our inception. As of December 31, 2021, we had an accumulated deficit of $14.5 million. Consequently, predictions about our future success or viability may not be as accurate as they would be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We have spent, and expect to continue to spend, significant resources to fund research and development of, conduct clinical studies, and seek regulatory approvals for, our Program Products, and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing and clinical study activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have, had and will continue to have a material adverse effect on our stockholders' equity and working capital.

The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance

We have no products approved for marketing in any jurisdiction, our Program Products are in early stages of development. We have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of and obtain the regulatory and marketing approvals necessary to commercialize one or more of our Program Products. We do not anticipate generating revenue from product sales in the next couple of years. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis

We may not be able to raise additional funding on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. Raising additional funding may cause dilution to our stockholders.

Developing our Program Products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our Program Products through clinical studies, manufacturing and regulatory approval. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. We do not have any committed external source of funds. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, and the terms of any financing may adversely affect the interests or rights of our stockholders. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may affect the value of your investment.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt.

If we do not raise additional capital, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted, and we may need to:

- significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of our Product Programs and future program candidates or cease operations altogether;
- seek strategic alliances for research and development programs when we otherwise would not, or at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any product candidates that we otherwise would seek to develop or commercialize ourselves.

Risks Related to the Product Development, Regulatory Approval, Manufacturing and Commercialization of Our Program Products and Product Candidates

If preclinical studies or clinical studies for our Program Products are unsuccessful or delayed, we will be unable to meet our future development goals.

Conducting clinical studies for any product candidates for approval in the United States requires filing an IND and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the institutional review board ("IRB") at each such site, manufacturing clinical quantities of product candidates and supplying drug product or devices to clinical sites. Currently, we do not have an active IND with the FDA in the United States for our Program Products. If our IND is not approved by the FDA, our clinical development timeline may be negatively impacted, and any future clinical programs may be delayed or terminated.

Even if the clinical studies are approved by FDA or other regulatory agencies, clinical study is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical studies can occur at any time during the clinical study process. We do not know whether future clinical studies, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical studies can be delayed, suspended or terminated for a variety of reasons, including failure to (i) generate sufficient positive preclinical and clinical data; (ii) recruit contract research organizations ("CRO"), clinical investigators and patients in a timely manner; (iii) manufacture sufficient quantities at the required quality of Program Products for use in clinical studies; (iv) raise sufficient capital to fund a study; (v) comply with all applicable regulatory requirements, whether in the United States or elsewhere, and (vi) obtain successful regulatory approval from regulatory authorities like the FDA.

If we experience delays in completing any clinical study of our Program Products or successfully obtaining regulatory approval, the commercial prospects of our Program Products may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical studies will increase our costs, slow down the development and approval process of our Program Products, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical studies are not necessarily predictive of our future results. Our clinical studies may fail to adequately demonstrate the safety and efficacy of our Program Products or any future product candidates.

To date, the primary focus of our product development has been on the development of REVTx-99a/b, our therapeutic products and REVDx-501, our diagnostic device. Currently, REVTx-99a/b are our only product candidates under clinical development. We have completed a Phase 1 clinical study in Australia and collected data to support continued development. We received approval from the Heads of Medicines Agency and the Federal Agency for Medicines and Health Product to conduct our Phase 2b viral challenge clinical study for the prevention of influenza infection in September of 2021. Enrollment and dosing has begun in our Phase 2b viral challenge study. On March 30, 2022 we were told from an independent data analysis group that the primary endpoint of the Phase 2b study did not meet statistical significance. We were granted ethics committee approval from Bellberry Limited for a Phase 1b allergen challenge study in October of 2021 to support the treatment of chronic nasal congestion program. Enrollment and dosing has begun in our Phase 1b allergen challenge study.

Even though our Phase 1 clinical study results are positive, our Phase 1 clinical study involved a small patient population of healthy volunteers, and because of the small sample size in such study, the results of this clinical study may be subject to substantial variability and may not be indicative of either future interim results or final results in patients for our indication. Results from preclinical studies or early-stage clinical studies are not necessarily predictive of future clinical study results, and interim results of a clinical study are not necessarily indicative of final results. As well, later stage clinical studies may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical and early clinical studies. This failure would cause us to abandon further development of our most advanced product candidate.

There is a high failure rate for product candidates proceeding through clinical studies. Failure can occur at any time during the clinical study process. Many companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical studies even after achieving promising results in preclinical testing and earlier-stage clinical studies. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the development period of our Program Products. Success in preclinical testing and early clinical studies does not ensure that later clinical studies will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical studies have subsequently suffered significant setbacks in later clinical studies. If we are unable to successfully demonstrate the safety and efficacy of our Program Products or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

The Clinical Studies of our Program Products' have been and are planned to be conducted outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such studies.

We currently have not conducted any clinical studies in the United States to date. We have conducted and we plan to conduct additional clinical studies outside the United States, including Europe, Australia, or other foreign jurisdictions. The acceptance of clinical study data by the FDA from clinical studies conducted outside the United States may be subject to certain conditions. In cases where data from clinical studies conducted outside the United States are intended to serve as the sole bases for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practices, (ii) the studies were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical study requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from studies conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional studies, which would be costly and time-consuming and delay aspects of our business plan, and may result in our Program Products' not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction.

As an organization, we have never conducted pivotal clinical studies, and we may be unable to do so for any Program Products we may develop.

We will need to successfully complete pivotal clinical studies in order to obtain the approval of the FDA, the European Medicines Agency ("EMA") or other regulatory agencies to market any of our Program Products. Carrying out later-stage clinical studies and the submission to the FDA of a successful NDA, Biologics License Application ("BLA"), 510(k) Clearance, De Novo Clearance or Premarket Approval Application ("PMA") is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical studies and have limited experience in preparing, submitting and prosecuting regulatory filings. We may be unable to conduct clinical studies at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical studies in a timely fashion, if at all. In addition, the design of a clinical study can determine whether its results will support approval of a product, and flaws in the design of a clinical study may not become apparent until the clinical study is well advanced. Because we have limited experience as a company designing clinical studies, we may be unable to successfully and efficiently execute and complete necessary clinical studies in a way that leads to successful regulatory submission and approval. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical studies, could prevent us from or delay us in commercializing our Program Products. We rely on third parties to conduct certain elements of our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our Program Products.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent us from proceeding with clinical studies.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our Program Products, and we may experience delays in our clinical studies if we encounter difficulties in enrollment. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, number and location of the clinical sites, significant adverse events or other side effects observed, if any, the nature of the study protocol, our ability to recruit clinical study investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical studies of competing drugs for the same indication, the proximity of patients to clinical sites, clinicians' and patients' perceptions as to the potential advantages of the Program Products being studied in relation to other available therapies, including any drugs that may be approved for the indications we are investigating, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical studies will drop out of the studies before completion.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical studies for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or studies, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical studies at the same clinical study sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical studies in these sites.

Our inability to enroll sufficient number of patients for our clinical studies would result in significant delays or may require us to abandon one or more clinical studies altogether. If we are unable to enroll sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for our Program Products and any future product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or studies, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical studies, which could prevent completion of these studies and adversely affect our ability to advance the development of our Program Products and any future product candidates.

Our Program Products and the administration of our Program Products may cause 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 marketing approval, if any.

The severity and frequency of undesirable side effects caused by our Program Products, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label, delay or denial of regulatory approval by the FDA or other regulatory agencies. Results of our studies could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical studies could be suspended or terminated, and the FDA or other regulatory agencies could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. Moreover, during the conduct of clinical studies, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions.

Drug-related, drug product-related, formulation-related and administration-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical study or result in potential product liability claims, which could exceed the insurance coverage. Additionally, if one or more of our Program Products receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result.

If we or others identify undesirable or unacceptable side effects caused by our Program Products or any future product candidates or products:

- we may be required to modify, suspend or terminate our clinical studies;
- we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies;
- we may be required to conduct costly additional clinical studies;

- we may be subject to limitations on how we may promote our approved products;
- sales of our approved products may decrease significantly;
- regulatory authorities may require us to take our approved products off the market;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive, or our reputation may suffer.

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

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or studies. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

In addition, adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors in the future could also result in volatility in the price of our Common Stock after this offering. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise, appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our Program Products or any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval to commercialize any of our Program Products, and the approval may be for a more narrow indication than we seek or be subject to other limitations or restrictions that limit its commercial profile.

Our Program Products have not received regulatory approval. We do not expect our Program Products or any future product candidate to be commercially available for years, if at all. Our Program Products are, and any future product candidate will be subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot commercialize a product candidate or diagnostic device until the appropriate regulatory authorities have reviewed and approved such product candidate or diagnostic device. Even if our current or future Program Products meet safety and efficacy endpoints in pivotal clinical studies, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. This may include approval of a product candidate for more limited indications than requested or they may impose significant limitations in the form of warnings. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical studies and the review process.

Our business depends on the success of our Program Products, including obtaining regulatory approval to market our product candidates in the United States and/or other major foreign markets such as the European Union ("EU").

We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of REVTx-99a, REVTx-99b, REVTx-200 and REVDx-501. If we cannot successfully develop, obtain regulatory approval for, and commercialize our Program Products, we may not be able to continue our operations. The future regulatory approval and commercial success of our Program Products are subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical studies for our Program Products, including, but not limited to, the clinical studies needed to obtain regulatory approval for commercialization;
- we may not be able to obtain regulatory authorization to proceed with various clinical studies in the United States, and even if we are able to proceed with clinical studies, the regulatory authorities may limit, delay, or put our clinical studies on hold;
- we may not be able to obtain adequate evidence from our clinical studies for our Program Products;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- we cannot be certain of the number of types of clinical studies and non-clinical studies that the regulatory agencies will require in order to approve our Program Products;
- the data from clinical studies conducted outside of the United States may not be accepted by the FDA or other regulatory authorities;
- patients in our clinical studies may suffer serious adverse events for reasons that may or may not be related to REVTx-99a/b, which could delay or prevent further clinical development;
- the regulatory agencies may find deficiencies without manufacturing processes or facilities;
- the CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the regulatory agencies may not approve the formulation, labeling or specifications of REVTx-99a/b or REVDx-501 or other future product candidates, including REVTx-200;
- the regulatory agencies may change their approval policies or adopt new regulations;
- if approved, our Program Products will likely compete with products that may reach approval for the same indication or use prior to our Program Products, products that are currently approved and the products that are currently marketed products; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs and devices in development in the pharmaceutical industry, only a small percentage results in the submission of a

marketing authorization to the FDA or comparable foreign regulatory authorities and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market our Program Products, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize our Program Products. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our Program Products, we may not be able to generate sufficient revenue to continue our business.

Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.

Even if our Program Products are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, distribution, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, quality of product or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring recall or withdrawal of the product from the market.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices ("cGMP"), regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

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

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

If one or more of our Program Products is approved for marketing in the United States or other countries, we may be subject, directly or indirectly, to United States or other countries equivalent federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Even if we obtain FDA or other comparable regulatory agencies approval for any of our Program Products and begin commercializing those products in the United States or other countries, our operations may be directly or indirectly through our relationships with physicians, patients, third-party payors and customers, subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships through which we research, market, sell and distribute our Program Products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the United States Anti-Kickback Statute, the False Claims Act, the United States Health Insurance Portability and Accountability Act of 1996, and the Physician Payments Sunshine Act ("Sunshine Act") and analogous state laws. Ensuring that our internal operations and business arrangements with third parties comply with all applicable healthcare laws and regulations will likely be costly.

Legislative or regulatory healthcare reforms in the United States or other countries may make it more difficult and costly for us to obtain regulatory clearance or approval of our Program Products and to produce, market and distribute our Program Products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA or other comparable regulatory agencies regulations and guidance are often revised or reinterpreted by the FDA or other comparable regulatory agencies in ways that may

significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our Program Products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future.

We face intense competition in an environment of rapid technological change and the possibility that our competitors may develop products and drug delivery systems that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our Program Products.

The pharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies in the market and in development that may in the future compete with our Program Products.

Even if approved, we will compete with currently approved therapies and therapies further along in development. Our competitors both in the United States and abroad include large, well-established pharmaceutical and generic companies with significantly greater name recognition. Our competitors may be able to charge lower prices than we can, which may adversely affect our market acceptance. Many of these competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources.

If our competitors market products that are more effective, safer or cheaper than our products or that reach the market sooner than our products, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in other technologies. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical studies of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical study sites and enrolling patients for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Our inability to compete effectively in any of these aspects of our business could harm our business, financial condition, results of operations and prospects.

Risks Related to COVID-19

There is a significant uncertainty around the effects of COVID-19 on development of our Program Products.

As a result of the COVID-19 pandemic, we continue to experience additional disruptions that could severely impact our clinical studies for all our Program Products, including:

- delays or difficulties in enrolling patients in a clinical study, including rapidly evolving treatment paradigms, and patients that may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, and clinical site staff, due to competition with other pharmaceutical companies starting their clinical studies that have been delayed or paused due to the COVID-19 pandemic for limited resources such as clinical sites, site investigators, clinical site staff, as well as various other resources would or the overwork of existing investigators and staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical studies and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical study sites and hospital staff supporting the conduct of our clinical studies;
- interruptions or delay in obtaining supplies for clinical studies as well as clinical drug manufacturing due to supply chain disruption caused by COVID-19;
- interruptions or delays in preclinical studies and clinical study drug manufacturing due to restricted or limited operations at research and development laboratory facilities or clinical manufacturing organizations;
- interruption of key clinical study activities, such as clinical study site monitoring, due to limitation of available personnel as well as limitations on travel imposed or recommended by federal, state or provincial governments, employers and others;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical studies, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical studies;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical studies;

- interruption in global shipping that may affect the transport of clinical study materials, such as investigational drug product;
- changes in local regulations as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical studies are conducted, which may result in unexpected costs, or to discontinue the clinical studies altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA to accept data from clinical studies in these affected geographies.

The delays to the clinical study would result in a delay in the expected timeline for data readouts and thus the timeline of regulatory filings will be negatively impacted, which would adversely affect and delay our ability to obtain regulatory approvals for our product candidates, increase our operating expenses, and have a material adverse effect on our financial condition.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct certain elements of our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our Program Products.

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical studies and certain aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it will delay our product development activities and such alternative arrangements may not be available on terms acceptable to us.

Our reliance on these 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 studies are conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA and other regulatory agencies requires us to comply with standards, commonly referred to as current Good Clinical Practices or equivalent, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected. We also are required to register ongoing clinical studies and post the results of completed clinical.

We rely on third parties to manufacture the raw materials, including the active pharmaceutical ingredients that we use to create our therapeutic product candidate, and to manufacture the diagnostic devices, including the antibodies used for testing. Our business could be harmed if existing and prospective third parties fail to provide us with sufficient quantities of these materials and products or fail to do so at acceptable quality levels or prices.

We rely on third party suppliers for certain raw materials necessary to manufacture our product candidates for our preclinical studies and clinical studies and to manufacture our diagnostic tests for our clinical studies. Some of these raw materials and test components are difficult to source. Because there are a limited number of suppliers for these raw materials and components, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our Program Products for our clinical studies, and if approved, ultimately for commercial sale. In particular, there is only one supplier for PHAD®, Avanti Polar Lipids, Inc. Although we have secured enough material through a purchase order for our planned clinical trials, we do not have a long-term supply agreement with Avanti Polar Lipids, Inc. We do not have any control over the availability of raw materials and components. If we or our manufacturers are unable to purchase these raw materials or components on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our Program Products or generate revenues from the sale of any approved products.

Until such time, if ever, as we establish a manufacturing facility that has been properly validated to comply with FDA or other comparable regulatory agencies cGMP requirements, we will not be able to independently manufacture Program Products for our planned preclinical and clinical programs. We currently rely on a third-party manufacturer for the production of our clinical study materials. And to date, REVTx-99a/b and REVTx-200 have been manufactured by a single third-party manufacturer. This manufacturer may not be able to scale production to the larger quantities required for large clinical studies and to commercialize REVTx-99a/b and REVTx-200, if approved. REVDx-501 has also been manufactured and developed by a single third-party manufacturer. This manufacturer may not be able to scale production to the larger quantities required for a clinical study and to commercialize, if approved. Also, the third-party manufacturers may not be able to produce Program Products that meet the quality requirements. In the event that this third-party manufacturer does not successfully carry out its contractual duties, meet expected deadlines or manufacture our products in accordance with regulatory requirements or if there are disagreements between us and this third-party manufacturer, we will not be able to complete, or may be delayed in completing, the clinical studies required. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

We do not have a long-term supply agreement with any third-party manufacturer. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufacture product candidates or products ourselves. For example, if we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities in a timely manner or at all, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable foreign regulatory authorities. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the possible breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture product candidates in accordance with our product specifications);

- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical study interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;

- the possible misappropriation of our proprietary information, including our trade secrets and know-how;

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and

- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Certain raw materials necessary for the manufacture of REVTx-99a/b and REVTx-200 under our current manufacturing process, such as our Active Pharmaceutical Ingredient ("API"), are available only from a single supplier. Any significant delay in the acquisition or decrease in the availability of these raw materials from our supplier could considerably delay the manufacture of REVTx-99a/b and REVTx-200, which could adversely impact the timing of any planned studies or the regulatory approvals of REVTx-99a/b and REVTx-200. The FDA and other comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable foreign regulatory authorities also inspect these facilities to confirm compliance with cGMP.

Contract manufacturers may face manufacturing or quality control problems causing drug substance, drug product, diagnostic test kit production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure to comply with cGMP requirements or other FDA or comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our Program Products or any future product candidates and market our Program Products following approval.

If our Program Products or any future product candidates are approved by the FDA or other comparable foreign regulatory authorities for commercial sale, we may need to manufacture such product candidate in larger quantities. We intend to use third-party manufacturers for commercial quantities of our Program Products to the extent we advance this product candidate and other product candidates. Our manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate.

In addition, the operations of our third-party manufacturers may be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical studies for some or all of our Program Products, to manufacture clinical and commercial scale quantities of our drug substance, drug product, diagnostic test and to market, sell and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our Program Products and any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot

control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of, and any outsourcing used by such third parties. We rely on third parties' knowledge regarding specific local laws and regulatory requirements in foreign jurisdictions, where applicable.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical study data from completed, ongoing or planned clinical studies for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

Our success will depend in significant part on our and our future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our owned and licensed intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. Our Program Products have been developed in-house and are not subject to any third-party license. In addition to taking other steps to protect our intellectual property, we file patent applications to protect inventions we have developed, seeking to protect compositions, methods of use, manufacturing methods, and other aspects of our technology. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, that the claims of these patents will exclude others from making, using or selling our product candidates or products that compete with or are similar to our product candidates.

With respect to patent rights, we cannot be certain whether any of the technology described in our patent applications for any of our product candidates will remain relevant to our future commercial products, whether any of our patent applications will issue as patents, whether any patents that may be issued to us will effectively protect our commercial processes and product candidates, or whether any patents that may be issued to us will effectively prevent others from competing with our products.

In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so.

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 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or future licensors, licensees or collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or future licensors, licensees or collaborators were the first to file for patent protection of such inventions.

Any changes we make to our Program Products or any future product candidates to cause them to have what we view as more advantageous properties may fall outside the coverage of our existing patent applications, and we may need to file new patent applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover such altered Program Products or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents may not be enforced or maintained, in a manner consistent with the best interests of our business. If our future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Similar to the patent rights of other biotechnology companies, the scope, validity and enforceability of our owned and licensed patent rights generally are highly uncertain and involve complex legal and factual questions. 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. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our future licensors', licensees' or collaborators' future patent applications may not result in patents being issued that protect our technology or product candidates, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our future licensors, licensees or collaborators to narrow the scope of the claims of our patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by those third parties.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and we may not protect our intellectual property in some countries outside the United States to the same extent as in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States.

Consequently, we 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 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 do not have patent protection, or where we do have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our Program Products or any future product candidates and our patents or other intellectual property rights may not effectively prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being revoked, invalidated or interpreted narrowly, and could provoke third parties to assert claims against us or our collaborator. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not adequately compensate us for the harm to our business.

Different countries impose different requirements for patentability and certain countries have heightened requirements for patentability, requiring more disclosure in the patent application or disfavoring the issuance of broad claims. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In such countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may not have sufficient patent lifespan to effectively protect our products and business.

All of our patents are in early stages. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its priority date. 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 the resulting products are commercialized. As a result, our owned and future in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent

terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise have expected, and our competitors may obtain approval of and launch products earlier than might otherwise have been the case.

If we are unable to maintain effective proprietary rights for our Program Products or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by any patents that may be granted, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data, trade secrets and intellectual property by maintaining the physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors.

Additionally, our reliance on third parties, including CROs and outside consultants, requires us to share our trade secrets and intellectual property, which increases the possibility that a competitor will discover them or that our trade secrets and intellectual property will be misappropriated or publicly disclosed. The steps that we have already taken to protect our intellectual property may not be sufficient or effective, and our confidentiality, non-disclosure, or invention assignment agreements with employees, consultants, partners, or other parties may be breached and may otherwise not be effective in establishing our rights in intellectual property and in controlling access to our proprietary information. Even if we do detect violations, we may need to engage in litigation to enforce our rights, and such litigation, even if successful, may not restore our proprietary rights or adequately compensate us for the damage to our rights or our business.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or license. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or license, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could assert that such patent is invalid or unenforceable, or does not cover their product candidate. 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 U.S. Patent and Trademark Office ("USPTO"), or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the subject matter alleged to be infringing on the grounds that our patents do not cover that subject matter. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would allow third parties to enter the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, inter parties review, post-grant review or interference proceedings, or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, could allow third parties to commercialize our technology or product candidates and compete directly with us, or without payment to us. 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 we successfully defend such litigation or proceeding, we may incur substantial costs and our defense may distract our management and other employees.

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

We may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development efforts.

Our commercial success depends upon our ability to develop, manufacture, market and sell our Program Products and any future product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, inter parties review, post-grant review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

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

We may not be aware of all third-party intellectual property rights potentially relating to our Program Products or any future product candidates. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of any claims that may issue. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patents were successfully asserted against us or our commercialization partners and we were unable to successfully challenge the scope, validity or enforceability of any such asserted patents, then we and our commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties' access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

Changes in United States and international patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on IP, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, which may diminish our ability to obtain and enforce patents for our inventions. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, 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. Furthermore, depending on the Supreme Court's review of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act"), or legislation to repeal or amend the Affordable Care Act, the twelve years of regulatory exclusivity currently provided to certain biologic products in the United States may be reduced or eliminated. Any such reduction or elimination could impair the length of exclusivity against similar products.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our Program Products and any future product candidates we may develop but that are not covered by the claims of the patents that we may own or license in the future;

- we, or our future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we may own or license in the future;

- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future will not result in issued patents;
- patents that we may own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the resulting information to develop competitive products for sale in major commercial markets in which we do not have sufficient patent rights to stop such sales;
- we may not develop additional proprietary technologies that are patentable;
- third-party patents may be asserted against our product candidates and technologies in a manner that threatens or harms our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

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

If our trademarks and trade names are not maintained and adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to obtain trademark registrations in the future could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we intend to operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce any future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be time-consuming and expensive and may strain the financial resources of a company of our size, and we may not ultimately be successful in enforcing our trademark rights. In addition, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Future trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Risks Related to Our Business Operations

Our future success depends in part on our ability to retain our senior management team, directors and other key employees and to attract, retain and motivate other qualified personnel.

We may not be able to attract or retain qualified directors, personnel and consultants due to the intense competition for such individuals among in the biotechnology and pharmaceutical industries. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment or consultancy arrangements with us at any time and replacing such individuals may be difficult and time-consuming because of the limited number of individuals in our industry with the necessary breadth of skills and experience. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We are in the early stages of building the full management team and employee base that we anticipate we will need to complete the development of our Program Products and other future product candidates. As of April 13, 2022, we had 14 employees.

As we advance our preclinical and clinical development programs for our product candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. We will also need to establish commercial capabilities in order to commercialize any product candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources. Our management, personnel and

systems may experience difficulty in adjusting to our growth and strategic focus.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

In addition, in order to continue to meet our obligations as a public company and to support our anticipated long-term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected.

We may not be successful in our efforts to identify, discover or license additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our lead Program Products, the success of our business also depends upon our ability to identify, discover or license additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including (i) lack of financial or personnel resources to acquire or discover additional product candidates; (ii) product candidates may not succeed in preclinical or clinical testing; (iii) product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; (iv) competitors may develop alternatives that render our product candidates obsolete or less attractive; (v) the market for a product candidate may change during our development program so that such product may become unprofitable to continue to develop; (vi) product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and (vii) product candidates may not be accepted as safe and effective by patients, the medical community, or third-party payors.

We may be forced to abandon our development efforts for a program or programs that are unsuccessful, or we may not be able to identify, license, or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Further, research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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.

Our research, development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages, such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Healthcare reform in the United States may negatively impact our ability to profitably sell our product candidates, if approved, and to recoup the upfront investment needed to obtain regulatory approval of our product candidates.

Third-party payors, whether domestic or foreign, or governmental or commercial, are continually developing and advancing new methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

Affordable Care Act for example, contains provisions that have significantly changed the way health care is financed by both governmental and private insurers. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any strategic collaborators, may receive for any approved products.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. By way of example, on January 28, 2021, President Biden issued the "Executive Order on Strengthening Medicaid and the Affordable Care Act," which, among other things revoked certain executive orders of the previous administration that had eliminated cost sharing subsidies and various other provisions of the Affordable Care Act, stating that it is the current administration's policy "to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American," and directing heads of relevant executive departments and agencies immediately to review agency actions to determine whether any such actions are inconsistent with this policy. And, on June 24, 2021, the U.S. Supreme Court dismissed a challenge to the Affordable Care Act in a decision that leaves the law intact. We cannot predict what effect further changes to the Affordable Care Act would have on our business.

It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to

encourage importation from other countries and bulk purchasing.

At the same time, 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 bills 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate product revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition, including our ability to recoup the upfront investment needed to obtain regulatory approval for our product candidates.

Risks Related to Commercialization of Our Program Products and Product Candidates

As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.

As we advance our Program Products through clinical studies, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities, such as collaborators, distributors, marketers and additional suppliers. We currently have no experience as a Company in or infrastructure for sales, marketing and distribution, and our operations are currently limited to clinical development activities and as our operations expand, we likely will need to manage additional relationships with such third parties.

If our Program Products or any future product candidate is approved, we intend either to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize our Program Products or any future product candidate or to outsource such functions to one or more third parties. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of our Program Products or any future product candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our Program Products and other future product candidates.

Maintaining third-party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical studies in which our product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

We may seek to establish commercial collaborations for our Program Products and future product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development plans.

Our drug development programs, and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our 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 studies, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

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

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay 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 currently have no Program Products approved for marketing. We do not have a marketing and sales organization. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our Program Products, we may be unable to generate any product revenue.

We have no experience selling and marketing our Program Products, and we currently have no marketing or sales organization. To successfully commercialize any product candidates that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization independently or by utilizing experienced third parties with technical expertise and supporting distribution capabilities to commercialize our Program Products in major markets, all of which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our ability to commercialize our Program Products.

Our efforts to educate the medical community, including physicians, hospital pharmacists and third-party payors on the benefits of our Program Products may require significant resources and may never be successful. If any of our Program Products are approved but fail to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

It may be difficult for us to profitably sell our Program Products, if and when approved, if coverage and reimbursement for these Program Products are limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of our Program Products, if approved, will depend on, in part, the extent to which the procedures utilizing our Program Products, performed by health care providers, will be covered by third party payors, such as government health care programs, commercial insurance and managed care organizations. In the event health care providers and patients accept our Program Products as medically useful, cost effective and safe, there is uncertainty regarding whether our Program Products will be directly reimbursed, reimbursed through a bundled payment or if the product candidates will be included in another type of value-based reimbursement program. Third party payors determine the extent to which new products will be covered as a benefit under their plans and the level of reimbursement for any covered product or procedure which may utilize a covered product. It is difficult to predict at this time what third party payors will decide with respect to the coverage and reimbursement for our Program Products.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Additionally, we may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved.

Our business entails a significant risk of clinical study and/or product liability and our ability to obtain sufficient insurance coverage could have a material effect on our business, financial condition, results of operations or prospects.

Our business exposes us to significant clinical study and/or product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Clinical study liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to study participants or patients and a decline in our Company valuation. We currently carry insurance coverage to the limit required by clinical sites for our clinical study. We do not anticipate carrying product liability insurance until such time we have a commercially available product. Our current insurance coverage or any other insurance coverage that we may obtain in the future may not provide sufficient coverage against potential liabilities. Furthermore, clinical study and product liability insurance are becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by clinical study and product liability claims that could have a material adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

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

- decreased demand for any product candidates or products that we may develop;
- product recalls or a change in the indications for which products may be used;
- termination of clinical study sites or entire study programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and

- the inability to commercialize any products that we may develop.

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

Our employees, contractors, vendors, principal investigators, consultants and future partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors, principal investigators, consultants or future partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. 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. Third-party misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a Code of Business Conduct and Ethics, it is not always possible to identify and deter 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we or our future partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our future partners violate government price reporting laws, we or our future partners may be subject to administrative civil and/or criminal penalties, among other sanctions.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to broadly applicable healthcare regulatory laws, which could expose us to penalties.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain regulatory approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws pertaining to fraud and abuse are and will be applicable to our business. Such laws include, but are not limited to, the following:

- Federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act (“FCA”), which can be enforced through civil whistleblower or qui tam actions, prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, 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 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.

- Patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose specified requirements on "covered entities," including 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.

- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.

- Analogous state, local or foreign laws, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. Several foreign jurisdictions, including the EU, its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and/or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We are currently conducting a Phase 2b clinical study in Europe and we will collect, process, use or transfer personal information from individuals located in the European Economic Area (the "EEA") in connection with our business, including in connection with conducting clinical studies in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the EEA may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised. 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.

In addition, in 2018 California enacted the California Consumer Privacy Act ("CCPA"), which created new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, the California Privacy Rights Act, or CPRA, which was passed in November 2020 and will go into effect on January 1, 2023, with a "look-back" period to January 1, 2022. The CPRA significantly modified the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CCPA and the CPRA, may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical study subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical studies, 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.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in the United States. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other stock-based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre-tax earnings in different jurisdictions, the outcome of audits or other examinations by the U.S. Internal Revenue Service and tax regulators in other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets and changes to our ownership or capital structure. The impact of the above-mentioned factors and others on our effective income tax rate may be significant and could adversely affect our results of operations.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical studies and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. We may not obtain foreign regulatory approvals on a timely basis, if at all. If we obtain

approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties; the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- our ability to supply our product candidates on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our product candidates;
- language barriers for technical training and the need for language translations;
- reduced protection of patent and other intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If any of our product candidates is approved for commercialization, we may selectively partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including requirements specific to biologics or cell therapy products;
- reduced protection for patent and other intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products in Europe to be very challenging.

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

In some countries, particularly in Europe, 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 drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical studies that compare the cost-effectiveness of our product candidates 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, possibly materially.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs and diagnostic devices. We may be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. While we currently carry clinical study insurance and product liability insurance, the amount of insurance coverage we hold now may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to

significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our Program Products, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could cause our stock price to fall.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We carry insurance for most categories of risk that our business may encounter; however, we may not have adequate levels of coverage. We currently maintain general liability, property, workers' compensation, clinical study, products liability and directors' and officers' insurance, along with an umbrella policy. We may not be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We have no current plans to pay dividends on our Shares of Common Stock.

We do not anticipate paying any cash dividends in the foreseeable future. If we incur indebtedness in the future to fund our future growth, our ability to pay dividends may be further restricted by the terms of such indebtedness.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Common Stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the Annual Report for our fiscal year ending December 31, 2022. When and if we are a "large accelerated filer" or an "accelerated filer" and are no longer an "emerging growth company" or "smaller reporting company," each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company or smaller reporting company, we intend to take advantage of an exemption available to emerging growth companies and smaller reporting companies from these auditor attestation requirements. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting, and the trading price of our Common Stock may decline.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an emerging growth company and are eligible to 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, only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure, 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 this Prospectus and our periodic reports and proxy statements, exemptions from the requirements of holding non-binding advisory votes on executive compensation and seeking stockholder approval of any golden parachute payments not previously approved and not being required to adopt certain accounting standards until those standards would otherwise apply to private companies. We could be an emerging growth company until the last day of the fiscal year following the fifth anniversary of the Petra Initial Public Offering ("IPO"), although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer (in which case we will cease to be an emerging company as of the date we become a large accelerated filer, which, generally, would occur if, at the end of a fiscal year, among other things, the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter), if we have total annual gross revenue of $1.07 billion or more during any fiscal year (in which cases we would no longer be an emerging growth company as of March 31 of such fiscal year), or if we issue more than $1.0 billion in non-convertible debt during any three year period before that time (in which case we would cease to be an emerging growth company immediately). Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

Our Common Stock price may be volatile and as a result you could lose all or part of your investment.

In addition to volatility associated with equity securities in general, the value of your investment could decline due to the impact of any of the following factors upon the market price of our shares of Common Stock:

- disappointing results from our development efforts;
- decline in demand for our shares of Common Stock;
- downward revisions in securities analysts' estimates or changes in general market conditions;
- technological innovations by competitors or in competing products;
- investor perception of our industry or our prospects; and

- general economic trends.

Stock markets in general have experienced extreme price and volume fluctuations, and the market prices of securities have been highly volatile. These fluctuations are often unrelated to operating performance and may adversely affect the market price of our shares of Common Stock.

Potential future sales pursuant to registration rights granted by the Company and under Rule 144 may depress the market price for our shares of Common Stock.

The Company has granted a number of its stockholders' registration rights with respect to their shares of Common Stock. Such future sales of our shares of Common Stock by our existing stockholders, pursuant to and in accordance with the provisions of any registration statement, may have a depressive effect on the market price of our shares of Common Stock. Further, in general, under Rule 144 under the Securities Act, a person who has satisfied a minimum holding period of between six months and one-year and any other applicable requirements of Rule 144, may thereafter sell such shares publicly. A significant number of our currently issued and outstanding shares of Common Stock held by existing stockholders, including officers and directors and other principal stockholders are currently eligible for resale pursuant to and in accordance with the provisions of Rule 144. The possible future sale of our shares by our existing stockholders, pursuant to and in accordance with the provisions of Rule 144, may have a depressive effect on the price of our Shares of Common Stock in the applicable trading marketplace.

Financial Industry Regulatory Authority ("FINRA") has adopted sales practice requirements, which may also limit a stockholder's ability to buy and sell our Common Stock.

FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our shares of Common Stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares of Common Stock.

We face risks related to compliance with corporate governance laws and financial reporting standards.

The Sarbanes-Oxley Act, as well as related new rules and regulations implemented by the SEC and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act relating to internal control over financial reporting, referred to as Section 404, materially increased our legal and financial compliance costs and made some activities more time-consuming and more burdensome,

Anti-takeover provisions contained in our Charter and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our Charter contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board;
- the right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our Board; and
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders.

Our Charter provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Charter provides that, subject to limited exceptions, any (i) derivative action or proceeding brought on our behalf of under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of Revelation to its stockholders, (iii) any action asserting a claim against Revelation or any of its directors, officers or other employees arising pursuant to any provision of the DGCL, the Charter or the Bylaws of Revelation (in each case, as may be amended from time to time), (iv) any action asserting a claim against Revelation or any of its directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware or (v) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, in all cases subject to the court's having personal jurisdiction over all indispensable parties named as defendants shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, another state or federal court located within the State of Delaware. The Charter also provides that unless a majority of the Board of Revelation, acting on behalf of Revelation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the federal district courts of the United States of America, to the fullest extent permitted by law, will be the sole and exclusive forum for the resolution of any action asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of Revelation's capital stock shall be deemed to have notice of and to have consented to the provisions of Revelation's certificate of incorporation described above. 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. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a stockholders ability to bring a claim in a judicial forum that it finds favorable for disputes with

Revelation or its directors, officers, or other employees, which, along with potential increased costs of litigating the courts provided by the choice of forum provision, may discourage such lawsuits against Revelation and its directors, officers, and employees. Alternatively, if a court were to find these provisions of Revelation's Charter inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, Revelation may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect Revelation's business and financial condition.

If Revelation is not able to comply with the applicable continued listing requirements or standards of Nasdaq, Nasdaq could delist our Common Stock.

Revelation's Common Stock, Public Warrants and Units are listed on the Nasdaq under the symbols "REVB," "REVBW" and "REVBU," respectively. If Nasdaq delists the Revelation Common Stock from trading on its exchange for failure to meet the listing standards such as the minimum public stockholders requirement or for failure to hold an annual stockholders meeting, we and our stockholders could face significant material adverse consequences including:

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

Revelation will incur significant increased expenses and administrative burdens as a public company, which could negatively impact its business, financial condition and results of operations.

As a public company, we are subject to the reporting requirements of the Exchange Act, the listing standards of the Nasdaq, and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting, and financial compliance costs, make some activities more difficult, time-consuming and costly, and place significant strain on our personnel, systems, and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, results of operations, and financial condition. Additionally, as a public company subject to additional rules and regulations and oversight, we may not have the same flexibility we had as a private company.

We may not be able to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act applicable us.

We are required to provide management's attestation on internal controls. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us 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 that are applicable to the Company. If the Company is 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, which may subject it to financial reporting misstatements and adverse regulatory consequences and could harm investor confidence and the market price of its securities.

Revelation's business and operations could be negatively affected if it becomes subject to any securities litigation or shareholder activism, which could cause Revelation to incur significant expense, hinder execution of business and growth strategy and impact its stock price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Shareholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of Revelation Common Stock or other reasons may in the future cause it to become the target of securities litigation or shareholder activism. Securities litigation and shareholder activism, including potential proxy contests, could result in substantial costs and divert management's and board of directors' attention and resources from the Revelation's business. Additionally, such securities litigation and shareholder activism could give rise to perceived uncertainties as to the Combined Entity's future, adversely affect its relationships with service providers and make it more difficult to attract and retain qualified personnel. Also, Revelation may be required to incur significant legal fees and other expenses related to any securities litigation and activist shareholder matters. Further, its stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and shareholder activism.

Our Private Warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results.

On April 12, 2021, the Acting Director of the Division of Corporation Finance and Acting Chief Accountant of the SEC together issued a statement regarding the accounting and reporting considerations for certain warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "SEC Statement"). Specifically, the SEC Statement focused on certain settlement terms and provisions related to certain tender offers following a business combination, which terms are similar to those contained in the warrant agreement governing our warrants. As a result of the SEC Statement, we reevaluated the accounting treatment of our public and private warrants, and determined to classify the private warrants as derivative liabilities measured

at fair value, with changes in fair value each period reported in earnings.

As a result, included on our balance sheet as of December 31, 2020 and 2021 contained elsewhere in this Annual Report are derivative liabilities related to embedded features contained within our Private Warrants. Accounting Standards Codification ("ASC") 815, Derivatives and Hedging ("ASC 815"), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly, based on factors which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on our Private Warrants each reporting period and that the amount of such gains or losses could be material.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTY

We lease laboratory space located at 11011 Torreyana Rd., Suite 102, San Diego, California, which consists of approximately 2,140 square feet. The lease expires on December 31, 2022. Our corporate headquarters is located at 4660 La Jolla Village Dr., Suite 100, San Diego, CA 92122, where we currently have access to office space on an as-needed basis. We believe that our current space is adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On February 18, 2022, LifeSci Capital LLC filed an action against the Company in the U.S. District Court for the Southern District of New York seeking damages in the amount of approximately $2.7 million in cash and $2.6 million in equity for unpaid banking and advisory fees. These fees arise under contracts which were entered into prior to the merger between Petra Acquisition, Inc. and Old Revelation and the Company is disputing the amount owed under those contracts. The Company's response to the suit is due May 1, 2022.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Petra's Common Stock, Public Warrants and Units were historically listed on Nasdaq under the symbols "PAIC," "PAICW" and "PAICU," respectively. On January 10, 2022, our units, common stock and warrants were listed on Nasdaq under the symbols "REVBU", "REVB" and "REVBW", respectively.

Holders

As of April 13, 2022, there were approximately 54 stockholders of record of our common stock, one holder of record of our units and two holders of record of our warrants. Because many of our securities are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have not paid any cash dividends on our shares of common stock to date and do not intend to pay cash dividends, reinvesting earnings, if any, in our clinical trial program and research and development. Further, if we incur any indebtedness in connection with our initial business combination, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

ITEM 6. [RESERVED]

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

References to the "Company," "we," "us," "our," or "Revelation" refer to Revelation Biosciences, Inc. (f/k/a Petra Acquisition, Inc.). The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with our audited financial statements and the notes related thereto which are included in "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K. Certain information contained in the discussion and analysis set forth below includes forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Special Note Regarding Forward-Looking Statements," "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Special Note Regarding Forward-Looking Statements

All statements other than statements of historical fact included in this Form 10-K including, without limitation, statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" regarding the Company's financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. When used in this Form 10-K, words such as "anticipate," "believe," "estimate," "expect," "intend" and similar expressions, as they relate to us or the Company's management, identify forward-looking statements. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, the Company's management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors detailed in our filings with the SEC.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and the notes thereto contained elsewhere in this Annual Report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties.

Overview

We are a former blank check company formed under the laws of the State of Delaware on November 20, 2019 for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or other similar business combination with one or more businesses. We completed our IPO on October 13, 2020 and our Business Combination on January 10, 2022.

All activity through December 31, 2021 relates to our formation, IPO, and search for a prospective initial business combination target.

Recent Developments

On the Closing Date, Petra consummated the previously announced Business Combination, pursuant to the terms of the Business Combination Agreement, by and among Petra, Merger Sub, and Old Revelation. Pursuant to the Business Combination Agreement, on the Closing Date, (i) Merger Sub merged with and into Old Revelation, with Old Revelation as the surviving company in the Merger, and, after giving effect to such Merger, Old Revelation was renamed Revelation Biosciences Sub, Inc. and became a wholly-owned subsidiary of Petra and (ii) Petra changed its name to Revelation Biosciences, Inc.

Results of Operations

We have neither engaged in any operations nor generated any revenues to date. Our only activities for the period from November 20, 2019 (inception) through December 31, 2021 were organizational activities, those necessary to consummate the IPO, described below, searching for a target company for a business combination, and the proposed acquisition of Old Revelation. At the consummation of the IPO, cash amounting to $10.10 per share issued in the IPO was deposited into a trust account for the shares of common stock subject to redemption (the “Trust Account”). We generate non-operating income from interest earned on cash held in the Trust Account, interest earned on cash and cash equivalents held in our operating account and gains or losses from marketable securities held in our operating account. We incur expenses as a result of being a public company (for legal, financial reporting, accounting and auditing compliance), as well as for due diligence expenses.

For the year ended December 31, 2021, we had a net loss of $2,130,625 which consisted of interest income of $222, interest expense of $41,750, realized loss on marketable securities of $17,356, as well as interest income from cash held in the Trust Account of $6,896, a change in the fair value of the warrant liability of $1,009,620, and operating costs of $3,088,248, which were primarily professional fees and insurance expense.

For the year ended December 31, 2020, we had a net loss of $1,630,500 which consisted of interest income of $9,325 and unrealized loss on marketable securities of $1,831, as well as interest income from cash held in the Trust Account of $1,590, a change in fair value of warrant liability of $1,494,092, and operating costs of $145,492 which were primarily professional fees and insurance expense.

We classify the Private Warrants issued in our private placement in connection with the IPO as liabilities at their fair value and adjust the warrant instruments to fair value at each reporting period. These liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our statements of operations.

Liquidity and Capital Resources

For the year ended December 31, 2020, cash used in operating activities was $216,664. The net loss of $1,630,500 was affected by interest earned on cash held in the Trust Account of $1,590, an unrealized loss on marketable securities of $1,831 and a change in the fair value of the warrant liability of $1,494,092. Changes in operating assets and liabilities was $80,497 from operating activities.

For the year ended December 31, 2021, cash used in operating activities was $725,618. The net loss of $2,130,625 was affected by interest earned on cash held in the Trust Account of $6,896 and a change in the fair value of the warrant liability of $1,009,620. Changes in operating assets and liabilities was $2,421,523 from operating activities.

In October 2020, we consummated our IPO and sold a total of 7,281,151 units. Each unit consists of one share of common stock of the Company, par value $0.001 per share, and one redeemable warrant of the Company, with each warrant entitling the holder thereof to purchase one share of common stock for $11.50 per share (the “Units”). The Units were sold at a price of $10.00 per Unit, generating gross proceeds to the Company of $72,781,510. Simultaneously with the IPO, the Company consummated the sale of 3,233,446 Private Warrants at a price of $1.00 per Private Warrant, generating total proceeds of $3,233,446. Each Private Warrant entitles the holder thereof to purchase one share of common stock for $11.50 per share.

Following the IPO and sale of Private Warrants, an aggregate amount of $73,509,325 was placed in the Company’s Trust Account established in connection with the IPO. Transaction costs amounted to $4,366,890, consisting of $3,450,000 of underwriting fees and $315,846 of other offering costs.

On October 13, 2021, we entered into three promissory notes payable for a total of up to an aggregate principal amount of $750,000 with a minimum draw of $50,000 (Promissory Notes Payable) with three Lenders (the Lenders). Such Promissory Notes Payable are being made for the purpose of funding a contribution of cash for each share of common stock issued in Petra’s IPO that was not redeemed in connection with the stockholder vote to approve the extension of the deadline for us to complete an initial business combination, as contemplated in the definitive proxy statement on Scheduled 14A filed by us with the SEC on September 24, 2021. The Promissory Notes Payable will bear interest at the rate of 2% per month on the outstanding balance of the Promissory Notes Payable. The Promissory Notes Payable will be forgiven if we are unable to consummate an initial business combination except to the extent of any funds held outside of the Trust Account.

On October 27, 2021 the Company paid an aggregate of $25,698,161 in cash to various Unit holders that elected to redeem 2,544,127 shares of the common stock subject to redemption.

Between October 2021 and December 2021, three contributions in the amount of $160,957 were deposited into the Trust Account for each share of common stock issued in the Petra IPO that was not redeemed in connection with the stockholder vote at the October 2021 Special Meeting. As of December 31, 2021, a total of $482,871 has been deposited into the Trust Account.

As of December 31, 2021, we had cash equivalents held in the Trust Account of $48,302,521. Interest income on the balance in the Trust Account may be used by us to pay taxes. As of December 31, 2021, we have not withdrawn any amount of interest earned on the Trust Account to pay our taxes.

Petra Acquisition, Inc. intended to use substantially all of the funds held in the Trust Account, to acquire a target business and to pay our expenses relating thereto, including a fee payable to LifeSci Capital LLC, Ladenburg Thalmann, and Ingalls & Snyder LLC, and Northland Securities, Inc., upon consummation of our initial business combination for assisting us in connection with our initial business combination. To the extent that our capital stock is used in whole or in part as consideration to effect a business combination, the remaining funds held in the Trust Account will be used as working capital to finance the operations of the target business. Such working capital funds could be used in a variety of ways including continuing or expanding the target business' operations, for strategic acquisitions and for marketing, research and development of existing or new products. Such funds could also be used to repay any operating expenses or finders' fees which we had incurred prior to the completion of our business combination if the funds available to us outside of the Trust Account were insufficient to cover such expenses.

As of December 31, 2021, we had cash and cash equivalents of $78,532. During the year ended December 31, 2021, the Company received proceeds from the sale of marketable securities of $525,287. Historically we have and intend to use any and all funds held outside the Trust Account for identifying and evaluating prospective acquisition candidates, performing business due diligence on prospective target businesses, traveling to and from the offices, plants or similar locations of prospective target businesses, reviewing corporate documents and material agreements of prospective target businesses, selecting the target business to acquire and structuring, negotiating and consummating the business combination.

Related Party Transactions

This information appears following "Item 13. Certain Relationships and Related Person Transactions, and Director Independence" of this Annual Report and is included herein by reference.

Off-balance sheet financing arrangements

We did not have any off-balance sheet arrangements as of December 31, 2021.

Contractual obligations

We do not have any long-term debt, capital lease obligations, operating lease obligations or long-term liabilities.

We have engaged to LifeSci Capital LLC, Ladenburg Thalmann, and Ingalls & Snyder LLC, and Northland Securities, Inc. (collectively, the "Advisors") as advisors in connection with a Business Combination to assist us in holding meetings with our shareholders to discuss the potential Business Combination and the target business' attributes, introduce us to potential investors that are interested in purchasing our securities in connection with a Business Combination, assist us in obtaining shareholder approval for the Business Combination and assist us with our press releases and public filings in connection with the Business Combination. We will pay the Advisors a cash fee of $2.9 million for such services upon the consummation of a Business Combination which is equal to 4% of the gross proceeds received by the Company in the IPO ("Fee") (exclusive of any applicable finders' fees which might become payable). The Company will allocate 52.5% of the Fee to LifeSci, 10% of the Fee to Ingalls, 22.5% of the Fee to Ladenburg and 15% of the Fee to Northland.

On October 13, 2021, we entered into three promissory notes payable for a total of up to an aggregate principal amount of $750,000 with a minimum draw of $50,000 (Promissory Notes Payable) with three Lenders (the Lenders). Such Promissory Notes Payable are being made for the purpose of funding a contribution of cash for each share of common stock issued in Petra's IPO that was not redeemed in connection with the stockholder vote to approve the extension of the deadline for us to complete an initial business combination, as contemplated in the definitive proxy statement on Scheduled 14A filed by us with the SEC on September 24, 2021. The Promissory Notes Payable will bear interest at the rate of 2% per month on the outstanding balance of the Promissory Notes Payable. The Promissory Notes Payable will be forgiven if we are unable to consummate an initial business combination except to the extent of any funds held outside of the Trust Account.

Critical Accounting Policies

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and income and expenses during the periods reported. Actual results could materially differ from those estimates. We have identified the following critical accounting policies:

Common stock subject to possible redemption

We account for common stock subject to possible redemption in accordance with the guidance in Accounting Standards Codification ("ASC") Topic 480 "Distinguishing Liabilities from Equity." Common stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redeemable common stock (including common stock that feature redemption rights that is either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within our control) is classified as temporary equity. At all other times, common stock is classified as stockholders' equity. Our common stock features certain redemption rights that are considered to be outside of our control

and subject to occurrence of uncertain future events. Accordingly, common stock subject to possible redemption is presented at redemption value as temporary equity, outside of the stockholders' equity section of our balance sheet.

Net loss per common share

We apply the two-class method in calculating earnings per share. Common stock subject to possible redemption which is not currently redeemable and is not redeemable at fair value, have been excluded from the calculation of basic net loss per common share since such shares, if redeemed, only participate in their pro rata share of the Trust Account earnings. Our net income is adjusted for the portion of income that is attributable to common stock subject to possible redemption, as these shares only participate in the earnings of the Trust Account and not our income or losses.

Derivative Warrant Liabilities

The Company accounts for the Warrants in accordance with the guidance contained in ASC 815 under which the Private Warrants do not meet the criteria for equity treatment and must be recorded as derivative liabilities. Accordingly, the Company classifies the Private Warrants as liabilities at their fair value and adjusts the Private Warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the Private Warrants are exercised or expire, and any change in fair value is recognized in the Company's statement of operations. The fair value of the Private Warrants was initially and subsequently measured at the end of each reporting period, using a Monte Carlo simulation.

Recent accounting standards

Management does not believe that any other recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

This information appears following Item 15 of this Annual Report and is included herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROL AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Exchange Act, such as this Annual Report, is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our principal executive officer and principal financial and accounting officer (our "Certifying Officers"), the effectiveness of our disclosure controls and procedures as of December 31, 2021, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2021, our disclosure controls and procedures were not effective as of December 31, 2021, due solely to the material weakness in our internal control over financial reporting described below. In light of this material weakness, we performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with U.S. generally accepted accounting principles. Accordingly, management believes that the financial statements included in this Annual Report on Form 10-K present fairly in all material respects our financial position, results of operations and cash flows for the period presented.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we have detected all our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the presentation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that:

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that our degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of this Annual Report, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on such assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

This Annual Report does not include an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

During the most recently completed fiscal quarter, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors, including their ages as of April 13, 2022:

Name	Age	Position
BOARD OF DIRECTORS		
George Tidmarsh, M.D., Ph.D.	62	Chairman and Director
James Rolke	53	Director and Chief Executive Officer
Jennifer Carver, BSN, MBA	68	Director
Jess Roper	57	Director
Curt LaBelle, MD	51	Director
EXECUTIVE OFFICERS		
James Rolke	53	Director and Chief Executive Officer
Chester S. Zygmont, III	41	Chief Financial Officer

Our Director and Executive Officers

George Tidmarsh, M.D., Ph.D.—Chairman. Dr. Tidmarsh has been Chairman of the Company since its inception in May 2020. Dr. Tidmarsh received his M.D. and Ph.D. from Stanford University, where he also completed his fellowship training in Pediatric Oncology and Neonatology and is currently Adjunct Faculty of Pediatrics and Neonatology since 2018. He served as clinical faculty at Stanford for a number of years after his fellowship prior to devoting his full time to clinical research and development in order to bring new treatments through the FDA approval process. Since 2018 Dr. Tidmarsh has served as a director and chairman of audit committee of Lucile Packard Foundation for Children's Health. Since the Company's inception in 2020 he has also served as chairman at Revelation Biosciences Inc. Prior to joining Revelation, Dr. Tidmarsh was President, Chief Executive Officer, Secretary and a Director of La Jolla Pharmaceutical Company ("La Jolla") from January 2012 until November 2019. While at La Jolla, Dr. Tidmarsh helped discover the use of angiotensin II for the treatment of shock and led all aspects of development including approval by the FDA and the European Medicines Agency ("EMA") for the treatment of patients suffering from distributive shock. He also led the development of artesunate for the treatment of severe malaria, which was approved by the FDA. Dr. Tidmarsh has over 30 years of experience in biotechnology, including the successful clinical development of seven FDA-approved drugs. He previously served as the Chief Executive Officer of Horizon Pharma, Inc., a company he founded in 2005, where he continued as CEO until 2008 and Director until 2010. While at Horizon, he invented and led all aspects of development of Duexis, which was approved by the FDA for the treatment of rheumatoid arthritis. He also founded Threshold Pharmaceuticals, Inc. and held senior positions at Coulter Pharmaceutical, Inc. (acquired by GlaxoSmithKline) and SEQUUS Pharmaceuticals, Inc. (acquired by Johnson & Johnson). While at Coulter and SEQUUS, Dr. Tidmarsh led the clinical development of BEXXAR and Doxil, respectively, two FDA-approved anti-cancer agents. We believe that Dr. Tidmarsh is qualified to serve as a director based on his extensive management experience in the biotechnology industry.

James Rolke — Director and Chief Executive Officer. Mr. Rolke cofounded and has been the Chief Executive Officer and a director of Revelation since its inception in May 2020. Mr. Rolke has 29 years of experience in the biotechnology industry, spanning all areas and phases of drug development. Prior to joining the Company, beginning in 2012, Mr. Rolke was employed at La Jolla in various leadership roles overseeing Research and Development and serving as Chief Scientific Officer from 2017 to 2020. While at La Jolla, Mr. Rolke oversaw the development of multiple technologies including six INDs and two marketing approvals: Giapreza for the treatment of distributive shock (US FDA and EMEA) and artesunate for the treatment of severe malaria. Prior to La Jolla, from July 2009 to January 2012 Mr. Rolke was Chief Technology Officer at Pluromed, Inc. (acquired by Sanofi) and played a key role in the approvals of two medical devices via the 510(k) and PMA approval pathways. Prior to Pluromed, Mr. Rolke held several key positions at biotechnology companies, including Director of Operations at Prospect Therapeutics, Inc., Associate Director of Pharmaceutical Development at Mersana Therapeutics, Inc., Manager of Process Development at GlycoGenesys, Inc., Principal Scientist at Surgical Sealants, Inc., Scientist at GelTex, Inc., and Associate Scientist at Alpha-Beta Technology, Inc. Mr. Rolke received his B.S. in chemistry from Keene State College. We believe that Mr. Rolke is qualified to serve as a director based on his role as our Chief Executive Officer and his extensive management experience in the biotechnology industry.

Jennifer Carver, BSN, MBA — Director. Ms. Carver has been a director of the Company since May 2020. Ms. Carver brings over 20 years of industry experience with a focus on small biotech companies and their evolution from early development through commercialization. From 2020 to 2021, Ms. Carver has served as Chief Operating Officer at Kartos Therapeutics (Kartos). Prior to Kartos from 2014, Ms. Carver was employed at La Jolla Pharmaceutical Company in various leadership roles providing leadership through the clinical development, approval and launch of Giapreza and serving as Chief Operating Officer from 2017 to 2019. Prior to La Jolla, Ms. Carver held positions at Spectrum Pharmaceuticals and Allos Therapeutics, leading teams through the development and approval of Belionostat and Folotyn respectively. Her experience in the healthcare industry spans multiple therapeutic areas including oncology, inflammatory disease, shock, iron overload, and anti-infectives. Ms. Carver has played a critical role in negotiating key alliances, evaluation of financing opportunities, and overseeing rapid organizational growth. Ms. Carver earned her B.S.N. and M.B.A. from University of Colorado. We believe that Ms. Carver's extensive experience working in the biotechnology industry makes her well-qualified to serve as a director.

Jess Roper — Director. Mr. Roper has been a director since October 2020. Mr. Roper has considerable financial and audit experience in the sectors of medical device, life sciences, technology, manufacturing, and financial institutions. He currently serves as a Board Member and Audit Chair for Biolase, a publicly traded company that is the global leader in the manufacturing of dental laser systems. Mr. Roper previously served as Senior Vice President and Chief Financial Officer of Dexcom, retiring in 2017 following a fulfilling and rewarding career. During his 12-year tenure, Dexcom transitioned from a pre-revenue privately held medical device company to a multi-national publicly traded entity. Mr. Roper previously held financial management positions with two other publicly traded companies and one venture funded company. He has played key roles in two initial public offerings, acquisitions/divestitures, and numerous equity and debt financings. Earlier in his career, Mr. Roper was an auditor with PricewaterhouseCoopers, and a bank and information systems examiner with the Office of the Comptroller of the Currency. He earned a Master of Science in Corporate Accountancy and a Bachelor of Science in Finance. Mr. Roper is a certified public accountant in the state of California. We believe that Mr. Roper is qualified to serve as a director based on his extensive financial and audit experience.

Curt LaBelle, MD — Director. Dr. LaBelle has been a director since January 2021. Dr. LaBelle has been investing in and working with life science companies for over 20 years. Since 2015, he has been President of the Global Health Investment Fund ("GHIF"). GHIF is a pioneering impact fund with a proven record of generating attractive financial returns and tangible impact. The fund works to facilitate access to therapeutics and diagnostics among low-income populations. Dr. LaBelle also works with the AXA Prime Impact Fund and serves as a Board member for Alydia Health, Atomo Diagnostics, Atticus Medical, Eyenovia, and Z Optics. He holds MD and MBA degrees from Columbia University. Dr. LaBelle is the designee of the AXA Prime Impact Fund, the holder of the outstanding shares of our Series A Preferred Stock. We believe that Dr. LaBelle's significant experience as an investor in life science companies makes him well-qualified to serve as a director.

Chester S. Zygmont, III — Chief Financial Officer. Mr. Zygmont has been the Company's Chief Financial Officer since inception. Mr. Zygmont brings over 17 years of experience in finance to the company with a wide range of industry applications. In 2016, Mr. Zygmont Co-Founded Jivanas, a social enterprise that owns and operates a factory in Nepal, that is focused on creating jobs for people at risk for human trafficking. Jivanas has operations in Nepal, Hong Kong, and the USA. During 2013, Mr. Zygmont Co-Founded oOxesis Biotechnology, LLC, a biologics lab that worked on developing therapies for unmet needs. From June 2012 to January 2016, Mr. Zygmont was the Senior Director of Finance, at La Jolla Pharmaceutical Company. During Mr. Zygmont's tenure at La Jolla, he brought the company to its Nasdaq listing. Prior to La Jolla, Mr. Zygmont served as Managing Director at Z3 Capital, LLC from March 2009 to June 2012. Z3 Capital, LLC, a privately held investment firm, focused on investment acquisition and venture funding for multiple startup companies in real estate, medical device and biotechnology. Mr. Zygmont also served as Vice President at Symmetry Advisors, Inc. a private equity leveraged buyout firm. While at Symmetry, he managed all finance and accounting for its SPAC, was a key player on a $600 million buyout of a portfolio company, and subsequently led the restructuring of its manufacturing division. Mr. Zygmont earned his M.S. in Finance from Baruch College, Zicklin School of Business and his B.A. from Eastern University.

Number and Terms of Office of Officers and Directors

Our Board is divided into three classes, designated Class A, Class B and Class C, with only one class of directors being elected in each year and each class serving a three-year term.

Our officers are appointed by the Board and serve until such person's successor is appointed or until such person's earlier resignation, death or removal. Our Board is authorized to appoint persons to the offices set forth in our bylaws as it deems appropriate. Our bylaws provide that our officers may consist of a Chief Executive Officer, President, Secretary, Treasurer, Chief Financial Officer, Vice Presidents and such other offices as may be determined by the Board.

Family Relationships

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

Involvement in Certain Legal Proceedings

None of our directors, executive officers, promoters or control persons has been involved in any events requiring disclosure under Item 401(f) of Regulation S-K.

Board Composition

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to the directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. Our directors are divided among the three classes as follows:

- The Class A directors are Dr. LaBelle and Ms. Carver, and their terms will expire at the first annual meeting of stockholder following the Business Combination;

- The Class B directors are Messrs. Rolke and Roper, and their terms will expire at the second annual meeting of stockholder following the Business Combination; and

- The Class C director is Dr. Tidmarsh, and his term will expire at the third annual meeting of stockholder following the Business Combination.

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

Leadership Structure of the Board

Our bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chairman of the board of directors and Chief Executive Officer.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also approves or disapproves any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Attendance of Directors at Board Meetings and Annual Meeting of Stockholders

During 2021, the Board of Directors met 11 times. During 2021, the Audit Committee met one time, the Nominating and Corporate Governance Committee met one time and the Compensation Committee met one time. Each director who was on the Board during this timeframe attended at least 91% of the aggregate number of meetings held during his or her term of service. The Company has not yet held an Annual Meeting of Stockholders. The Company does not have a policy requiring its directors to attend the Annual Meeting of Stockholders.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the SEC rules and regulations and the Nasdaq Listing Rules, which are posted on our website. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website.

Audit Committee

Revelation has a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act and Nasdaq Listing Rules. In addition, the board of directors adopted a written charter for the Audit Committee. The Audit Committee's duties, will include, but are not limited to:

- appoints our independent registered public accounting firm;

- evaluates the independent registered public accounting firm's qualifications, independence, and performance;

- determines the engagement of the independent registered public accounting firm;

- reviews and approves the scope of the annual audit and pre-approves the audit and non-audit fees and services;

- reviews and approves all related party transactions on an ongoing basis;

- establishes procedures for the receipt, retention and treatment of any complaints received by us regarding accounting, internal accounting controls or auditing matters;

- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;

- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- discusses on a periodic basis, or as appropriate, with our management's policies and procedures with respect to risk assessment and risk management;
- consults with management to establish procedures and internal controls relating to cybersecurity;
- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- investigates any reports received through the ethics helpline and reports to the board of directors periodically with respect to any information received through the ethics helpline and any related investigations; and
- reviews the audit committee charter and the audit committee's performance on an annual basis.

The composition of the Audit Committee consist of Mr. Roper, Dr. Tidmarsh and Ms. Carver, with Mr. Roper as Chair. Mr. Roper qualifies as an audit committee financial expert, as defined by the SEC rules. In addition, Revelation certified to Nasdaq that the Audit Committee has, and will continue to have, at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or other comparable experience or background that results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities. It has been determined that each of each of Mr. Roper, Dr. Tidmarsh and Ms. Carver satisfy such requirements.

Nominating and Governance Committee

Revelation's Nominating and Governance Committee is comprised of Ms. Carver and Drs. Tidmarsh and LaBelle, each of whom has been determined to be independent under the Nasdaq Listing Rules. The Nominating and Governance Committee adopted a written charter.

Specific responsibilities of the Nominating and Governance Committee include:

- identifying, evaluating and selecting, or recommending that board of directors approve, nominees for election to board of directors;
- evaluating the performance of board of directors and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of corporate governance practices and reporting;
- reviewing management succession plans; and
- developing and making recommendations to board of directors regarding corporate governance guidelines and matters.

Compensation Committee

Revelation has a Compensation Committee established in accordance with the Nasdaq Listing Rules. The Compensation Committee is comprised of Drs. Tidmarsh and LaBelle and Mr. Roper, each of whom has been determined to be independent under the Nasdaq Listing Rules and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of Revelation's compensation committee is Dr. LaBelle.

The Compensation Committee oversees Revelation's policies relating to compensation and benefits of its officers and employees. The Compensation Committee reviews and approves or recommends corporate goals and objectives relevant to compensation of its executive officers (other than the Chief Executive Officer), evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The Compensation Committee also reviews and approves or makes recommendations to the board of directors regarding the issuance of stock options and other awards under Revelation's stock plans to its executive officers (other than the Chief Executive Officer). The Compensation Committee reviews the performance of the Chief Executive Officer and makes recommendations to the board of directors with respect to his compensation, and the board of directors retains the authority to make compensation decisions relative to the Chief Executive Officer. The Compensation Committee reviews and evaluates, on an annual basis, the compensation committee charter and the compensation committee's performance.

Compensation Committee Interlocks and Insider Participation

No member of the Compensation Committee has ever been an officer or employee of Revelation. None of Revelation's executive officers serve, or have served during the last fiscal year, as a member of the compensation committee or other board committee performing equivalent functions of any other entity that has one or more executive officers serving as one of Revelation's directors or on the Compensation Committee.

Code of Conduct and Ethics

The Revelation Board adopted a Code of Ethics that applies to all its employees including its principal executive and financial officers.

ITEM 11. EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Executive Compensation Overview

Each of the Company's executive officers receives a base salary to compensate them for services rendered to the Company. The base salary is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, position and responsibilities.

Effective as of July 27, 2021, the Company entered into separate Executive Employment Agreements with Messrs. Rolke and Zygmont for their service as Chief Executive Officer and Chief Financial Officer, respectively (collectively, the "Executive Employment Agreements"). The Executive Employment Agreements provide for a term of three years, unless terminated earlier in accordance with their terms.

The Executive Employment Agreements provide for an annual base salary of $400,000 for Mr. Rolke and $320,000 for Mr. Zygmont. Messrs. Rolke and Zygmont are also eligible to receive an annual performance bonus targeted at 40% for Mr. Rolke and 35% for Mr. Zygmont of their respective base salaries or as otherwise determined in the sole discretion of the board (each, an "Annual Bonus"), as well as equity incentive grants as determined by the Board in its sole discretion.

Pursuant to the Executive Employment Agreements, if his employment is terminated as a result of a "Covered Termination Event" that is not in connection with a change in control of the Company, then each of Messrs. Rolke and Zygmont will be entitled to receive a lump sum payment equal to twelve months of severance payments at his then current base salary, plus a pro-rata portion of his Annual Bonus for the fiscal year in which his termination occurs based on actual achievement of the applicable bonus objectives and/or conditions for such year, plus continuation of medical benefits. If Mr. Rolke's or Mr. Zygmont's employment is terminated as a result of a "Covered Termination Event" in connection with a change in control of the Company, then each of Messrs. Rolke and Zygmont will be entitled to receive a lump sum payment equal to one times the sum of his then current base salary, plus his target bonus in effect for the year in which his termination of employment occurs, plus a pro-rata portion of his Annual Bonus for the fiscal year in which his termination occurs based on actual achievement of the applicable bonus objectives and/or conditions for such year, continuation of medical benefits and acceleration of vesting of all outstanding and unvested equity-based awards. "Covered Termination Event" means (i) a dismissal or discharge other than for Cause and other than by reason of death or disability, or (ii) a voluntary termination for Good Reason.

Historically, our executive compensation program has reflected our growth and development-oriented corporate culture. To date, the compensation of our Chief Executive Officer and President and our other executive officers identified in the 2021 and 2020 Summary Compensation Table below, who we refer to as the named executive officers, has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of restricted common stock awards and incentive stock options. Our named executive officers who are full-time employees, like all other full-time employees, are eligible to participate in our retirement and health and welfare benefit plans. As we transition from a private company to a publicly traded company, we will evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances merit. At a minimum, we expect to review executive compensation annually with input from a compensation consultant. As part of this review process, we expect the board of directors and the compensation committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive with our peers. In connection with our executive compensation program, we will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

Summary Compensation Table

The following table shows the total compensation awarded to, earned by, or paid to during the years ended December 31, 2021 and 2020 to our executive officers who earned more than $100,000 during each of the fiscal years ended December 31, 2021 and 202 and were serving as named executive officers as of such date.

Our named executive officers for 2021 and 2020 who appear in the Summary Compensation Table are:

- James Rolke, our President and Chief Executive Officer; and
- Chester S. Zygmont, III, our Chief Financial Officer.

The following table sets forth, for the years ended December 31, 2021 and 2020, all compensation paid, distributed or earned for services, including salary and bonus amounts, rendered in all capacities by the Company's named executive officers. The information contained below represents compensation earned by the Company's officers for their work related to the Company:

						Non-equity incentive plan compensation ($)			
Name and Position	**Year**	**Salary ($)**	**Bonus ($)**	**Stock-based awards ($)[3]**	**Option-based awards ($)**	**Annual incentive plans**	**Long term incentive plans**	**All other compensation ($)**	**Total compensation ($)**
James Rolke	2021	400,000	66,630	151,813	—	—	—	—	618,443
CEO	2020	166,667(1)	—	19,996	—	—	—	—	186,663
Chester S. Zygmont, III	2021	320,000	46,641	36,379	—	—	—	—	403,020
CFO	2020	133,333(2)	—	15,995	—	—	—	—	149,328

(1) For the year ended December 31, 2020, includes $83,333.33 of deferred compensation paid in January 2021.
(2) For the year ended December 31, 2020, includes $66,666.66 of deferred compensation paid in January 2021.
(3) Amounts shown in this column represent the aggregate grant date fair value of RSU awards granted during the year. The assumptions used in calculating the fair value of the RSU awards can be found under Note 7 to the audited and unaudited Financial Statements appearing elsewhere in this Prospectus. These amounts reflect the grant date fair value for these RSU's and do not necessarily correspond to the actual value that will be realized by the named executive officers.

Outstanding Equity Awards at Fiscal Year End

The following table provides information regarding the 2020 Equity Incentive Plan awards for each named executive officer outstanding as of December 31, 2021:

		Option-based Awards			Stock-based Awards		
Name	Date of Grant	Number of securities underlying unexercised options (#)	Option exercise price ($)	Option expiration date	Value of unexercised in-the-money options at December 31, 2020 ($)	Number of shares or units of shares that have not vested (#)	Market or payout value of share awards that have not vested ($)
James Rolke	2/23/2021 (1)	—	—	—	—	65,050	151,813
CEO	10/31/2020 (2)	—	—	—	—	8,568	19,996
Chester S. Zygmont, III	2/23/2021 (1)	—	—	—	—	15,588	36,379
CFO	10/31/2020 (2)	—	—	—	—	6,853	15,995

(1) The RSU awards vest 25% on the one-year anniversary of the grant date, and thereafter quarterly over a three-year period, subject to continued service through each such vesting date.
(2) The RSU awards vest quarterly over four years, subject to continued service through each such vesting date.

Director Compensation

The general policy of the Board is that compensation for independent directors should be a fair mix between cash and equity-based compensation. Additionally, the Company reimburses directors for reasonable expenses incurred during the course of their performance. There are no long-term incentive or medical reimbursement plans. The Company does not pay directors who are part of management for Board service in addition to their regular employee compensation. The Board determines the amount of director compensation. The Board may delegate such authority to the compensation committee. The following table provides a summary of compensation paid to directors during the fiscal year ended December 31, 2021.

The following table sets forth the total cash and equity compensation paid to our non-employee directors for service on our board of directors during 2021:

Name	Fees earned or paid in cash ($)	Stock-based awards ($)(1)	Total ($)
George Tidmarsh, M.D., Ph.D.	25,000	49,996	74,996
Jennifer Carver, BSN, MBA	25,000	49,996	74,996
Jess Roper	25,000	49,996	74,996
Curt LaBelle, M.D.	25,000	49,996	74,996

(1) Each director was granted 21,422 RSU awards that RSU awards will vest quarterly over one year, subject to continued service through each such vesting date.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The following table also sets forth information known to us regarding the beneficial ownership of our Common Stock as of April 13, 2022:

- each person who is, or is expected to be, the beneficial owner of more than 5% of the outstanding shares of our Common Stock;
- each of our current officers and directors; and
- all current executive officers and directors of the Company, 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. Shares of Common Stock issuable pursuant to options or warrants are deemed to be outstanding for purposes of computing the beneficial ownership percentage of the person or group holding such options or warrants but are not deemed to be outstanding for purposes of computing the beneficial ownership percentage of any other person.

The beneficial ownership of our Common Stock is based on 15,082,771 shares of Common Stock issued and outstanding as of April 13, 2022.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of Common Stock owned by them.

	Number of Shares and Shares subject to exercisable Warrants beneficially owned prior to this Offering	
Name	Shares	%
Five Percent Holders:		
AXA IM Prime Impact Fund (1)	1,958,984	13.0%

Petra Investment Holdings, LLC [2]	1,769,538	11.7%
Armistice Capital Master Fund Ltd. [3]	1,293,541	8.6%
LifeSci Venture Partners II, LP & Affiliates [4]	1,043,749	6.9%
Monashee Solitario Fund LP [5]	915,569	6.1%
Directors and Officers of Revelation[6]:		
James Rolke[7]	706,992	4.7%
George F. Tidmarsh M..D., Ph.D [8]	2,097,880	13.9%
Jennifer Carver, BSN, MBA [9]	110,974	0.7%
Jess Roper[10]	42,844	0.3%
Curt LaBelle, M.D. [11]	21,422	0.1%
Chester S. Zygmont, III[12]	690,891	4.6%
All Directors and Officers as a Group (Six Individuals)	3,671,004	24.3%

(1) AXA IM Prime Impact Master Fund ISCA SICAV-RAIF is managed by AXA Investment Managers UK Limited located at 22 Bishopsgate, London EC2N 4BQ, United Kingdom. AXA IM PRIME IMPACT GP S.à r.l., 2-4, rue Eugène Ruppert, L-2453 Luxembourg, is the general partner of the fund. Messrs. Paul Guillaume, Mirko Dietz, Arnold Spruit are the directors of both entities and collectively make voting and investment decisions with respect to the shares owned.

(2) Represents securities held by Petra Investment Holdings, LLC, our sponsor, of which Mr. Typaldos and Mr. Fitzpatrick are each a member, with Mr. Typaldos owning 80% and Mr. Fitzpatrick owning 20%.

(3) The shares are directly held by Armistice Capital Master Fund Ltd. (the "Master Fund"), a Cayman Islands corporation, and may be deemed to be indirectly beneficially owned by Armistice Capital, LLC ("Armistice"), as the investment manager of the Master Fund. Armistice and Steven Boyd disclaim beneficial ownership of the reported securities except to the extent of their respective pecuniary interest therein. The warrants are subject to certain beneficial ownership limitations that prohibit the Master Fund from exercising any portion of them if, following the exercise, the Master Fund's ownership of our common stock would exceed the relevant ownership limitation. The address of the Master Fund is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(4) Consists of 412,722 shares held by Andrew McDonald, 256,021 shares held by Paul Yook, 214,245 shares held by LifeSci Venture Partners II, LP, 136,260 shares held by Yehuda Rice.

(5) Monashee Investment Management LLC is the investment advisor Monashee Solitario Fund LP. Jeff Muller may be deemed to have shared voting and investment power of the shares held by the Monashee Solitario Fund LP. The address for Monashee Investment Management LLC is 75 Park Plaza, 2nd Floor, Boston, MA 02116.

(6) Unless otherwise indicated, the business address of each of the individuals is c/o Revelation Biosciences, Inc., 4660 La Jolla Village Dr., Suite 100, San Diego, CA 92122.

(7) Consists of (i) 681,302 shares of Common Stock held directly by Mr. Rolke, (ii) 2,144 shares of Common Stock held by Mr. Rolke's spouse, and (iii) 23,547 shares of Common Stock from Rollover RSU's vesting and issuable within 60 days to Mr. Rolke.

(8) Consists of (i) 1,523,335 shares of Common Stock held by George Tidmarsh, Trustee George Francis Tidmarsh 2021 Irrevocable Trust, (ii) 531,701 shares of Common Stock held directly by Dr. Tidmarsh, and (iii) 42,844 shares of Common stock from Rollover RSU's vesting to Dr. Tidmarsh.

(9) Consists of (i) 68,130 shares of Common Stock held directly by Ms. Carver and (ii) 42,844 shares of Common stock from Rollover RSU's vesting to Ms. Carver.

(10) Consists of 42,844 shares of Common stock from Rollover RSU's vesting to Mr. Roper.

(11) Consists of 21,422 shares of Common stock from Rollover RSU's vesting to Dr. LaBelle.

(12) Consists of (i) 463,285 shares of Common Stock held by The Zygmont Family Trust Dated October 25, 2016, (ii) 218,017 shares of Common Stock held by Czeslaw Capital Fund, LLC, (iii) 2,144 shares held by Mr. Zygmont's spouse, and (iv) 7,445 shares of Common stock from Rollover RSU's vesting and issuable within 60 days to Mr. Zygmont.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Petra

On January 21, 2020, Petra issued an aggregate of 3,593,750 shares of its common stock (" **Founder Shares**") for an aggregate purchase price of $25,000, or approximately $0.007 per share, to Petra Investment Holdings, LLC (the "**Sponsor**"). On August 24, 2020, pursuant to an amendment to the terms of Petra's offering, the Sponsor agreed to cancel 1,437,500 Founder Shares, resulting in an aggregate amount of 2,156,250 Founder Shares outstanding.

Between May 2020 and September 2020, our sponsor agreed to transfer 10,000 Founder Shares to each of our then director nominees, Messrs. Dobkin, Hayes, Nicholson, Dennis and Angelides. Mr. William Carson subsequently replaced Mr. Angelides as a director, although Mr. Carson has not yet been transferred any Founder Shares.

Between May 2020 and September 2020, our Sponsor transferred 10,000 Founder Shares to each of our then director nominees, Messrs. Dobkin, Hayes, Nicholson, Dennis and Angelides. Mr. William Carson subsequently replaced Mr. Angelides as a director, although Mr. Carson has not yet been transferred any Founder Shares.

On October 7, 2020, the Sponsor agreed to cancel an additional 143,750 Founder Shares, resulting in an aggregate amount of 1,962,500 Founder Shares outstanding and held by the Sponsor and 50,000 shares outstanding and held by our directors and Mr. Angelides.

Simultaneously with the consummation of the IPO, Petra completed the private sale of an aggregate of 3,150,000 private warrants (the " **Private**

Warrants") to the Sponsor at a purchase price of $1.00 per Private Warrant, generating gross proceeds to Petra of $3,150,000.

At inception, our Sponsor, Petra Investment Holdings LLC, loaned us an aggregate of $140,000 on a non-interest bearing basis for payment of expenses related to the IPO pursuant to a promissory note issued to Sponsor by us, which allows us to borrow up to an aggregate principal amount of $150,000. The note was repaid on October 16, 2020, including prior advances of $10,000 converted into the note, less $25,000 applied to the purchase of Founder Shares.

On October 16, 2020, Petra consummated the sale of an additional 278,151 Units (the " **Over-Allotment Option Units**") at $10.00 per Unit, generating gross proceeds of $2,781,510. Simultaneously with the closing of the sale of additional units, Petra consummated the sale of an additional 83,446 Private Warrants at a price of $1.00 per Private Warrant, generating total proceeds of $83,446. Following the closing of the over-allotment option and sale of additional Private Warrants, an aggregate amount of $73,509,325 was placed in Petra's Trust Account established in connection with the IPO.

In addition, the Founder Shares held by the Sponsor (prior to the exercise of the over-allotment) included an aggregate of up to 262,500 Founder Shares subject to forfeiture by the Sponsor to the extent that the underwriters' over-allotment option was not exercised in full. Since the underwriters exercised the over-allotment option in part, 192,962 Founder Shares were subject to forfeiture and were cancelled by the Sponsor on December 30, 2020, resulting in 1,769,538 Founder Shares held by the Sponsor.

The Petra IPO prospectus and original charter provided that Petra initially had until October 13, 2021 to complete its initial business combination. At a special meeting of Petra's stockholders held on October 9, 2021 (the "**October 2021 Special Meeting**"), Petra's stockholders approved a proposal to amend Petra's second amended and restated certificate of incorporation, to extend the date by which Petra has to consummate a business combination from October 13, 2021 to November 13, 2021, plus an option for Petra to further extend such date to December 13, 2021 (which option was exercised), plus an option for Petra to further extend such date to January 13, 2022 (which option was exercised) (all three such extensions, the "Extensions").

Petra's stockholders elected to redeem an aggregate of 2,544,127 shares in connection with the October 2021 Special Meeting. As of October 12, 2021, following such redemptions and the deposit of the initial Contribution described below, the amount of funds remaining in the Trust Account is approximately $48 million. Accordingly, following such redemptions, Petra had 6,553,562 Shares of Common Stock issued and outstanding (1,819,538 of which are founder shares not eligible for redemption) and the pro rata portion of the funds available is approximately $10.20 per public share.

In connection with the October 2021 Special Meeting, Petra issued to Pine Valley Investments, LLC (" **Pine Valley**"), an affiliate of Petra's sponsor, that certain promissory note dated September 17, 2021 (the "**Pine Valley Note**"), pursuant to which, Pine Valley agreed to advance certain contributions of cash into the Trust Account, for each share of common stock issued in the Petra IPO that was not redeemed in connection with the stockholder vote at the October 2021 Special Meeting to approve the Extensions (the "Extension Loan"). On October 12, 2021, the first such contribution in the amount of $160,957 was deposited into the Trust Account. As of the date of this proxy statement, in connection with the Extensions, a total of $482,871 has been deposited into the Trust Account. Petra now has until January 13, 2022 to consummate a business combination.

On October 12, 2021 Petra and Pine Valley, collectively agreed that it was in the best interest of both Petra and Pine Valley to replace Pine Valley as the lender to Petra in connection with the Extension Loan. Accordingly, on October 13, 2021, Petra and Pine Valley entered into that certain note cancellation agreement, dated as of October 13, 2021 (the "**Note Cancellation Agreement**"), pursuant to which the Pine Valley Note was terminated and cancelled effective as of October 13, 2021, and, Petra issued promissory notes (the "**Replacement Notes**") to each of T3 Investments, LLC, Miro Kesic and Jared Solomon (collectively, the " **New Lenders**"), pursuant to which the New Lenders agreed to make certain advances to Petra in an aggregate amount of up to $750,000 (the "**New Loan Amounts**") for purposes of the Extension Loan. The Replacement Notes will bear interest at the rate of 2% per month on the outstanding New Loan Amounts and such amounts will be repayable by Petra to the New Lenders upon consummation of an initial business combination. Any outstanding New Loan Amounts under the Replacement Notes will be forgiven if Petra is unable to consummate an initial business combination except to the extent of any funds held outside of the Trust Account established by Petra in connection with the IPO.

The New Lenders have agreed that with respect to each Extension that is approved, they or their affiliates will contribute to the Company as a loan (each loan being referred to herein as a "**Contribution**") $0.027 for each share of common stock issued in our IPO (the "public shares") that is not redeemed in connection with the stockholder vote to approve such Extension. Accordingly, if the Company takes the additional extensions, the New Lenders would make aggregate Contributions of approximately $750,000 (assuming no public shares were redeemed). Each Contribution will be deposited in the Trust Account within two business days prior to the beginning of the additional extension period (or portion thereof), other than the first Contribution which was made on October 12, 2021. Accordingly, if the Company takes the full time through the Extended Termination Date to complete an initial business combination, the redemption price per share at the meeting for such business combination or the Company's subsequent liquidation will be approximately $10.20 per share (without taking into account any interest). The New Lenders will not make any Contribution unless the related Extension is approved and the Extension is completed. The Contribution(s) will bear interest at the rate of 2.0% per month on the outstanding loan amount and will be repayable by the Company to the New Lenders upon consummation of an initial business combination. The loans will be forgiven if the Company is unable to consummate an initial business combination except to the extent of any funds held outside of the Trust Account. The Company will have the sole discretion whether to continue extending for the additional periods until the Extended Termination Date and if the Company determines not to continue extending for the additional periods, its obligation to make additional Contributions will terminate. If this occurs, or if the Company's board of directors otherwise determines that the Company will not be able to consummate an initial business combination by the Extended Termination Date and does not wish to seek an additional extension, the Company would wind up the Company's affairs and redeem 100% of the outstanding public shares. The purpose of each Extension is to allow Petra more time to complete its proposed business combination.

David Dobkin, one of our directors, is a principal of LifeSci Capital, which (i) was one of the representatives of the underwriters in the Petra IPO, (ii) is entitled to certain fees upon the completion of the Business Combination under the terms of the BCMA, and (iii) is the exclusive financial and mergers and acquisitions advisor to Petra in the Business Combination, under the terms of the LifeSci Engagement Letter.

In addition, LifeSci Venture Partners II, LP ("LVP"), an affiliate of LifeSci Capital, together with other affiliates of LifeSci Capital, collectively own approximately 11.2% of Revelation's total outstanding shares of capital stock prior to the Business Combination, which were purchased in Revelation's Series Seed financing and Series A-1 financing. On May 11, 2020, LifeSci Venture Master SPV, LLC ("LVPLLC") purchased 500,000 shares of Revelation's Series Seed Preferred Stock (the "Series Seed Preferred Stock"), at a per share price of $1.00 per share, for an aggregate investment of $500,000, representing a $2 million pre-money valuation. On August 27, 2020, pursuant to a statutory conversion of Revelation into a Delaware corporation, all of LVPLLC's shares of Series Seed Preferred Stock were exchanged for 250,000 shares of Revelation's Class A common stock (the "Class A Common Stock"). On December 23, 2020, LVPLLC transferred all of its shares of Class A Common Stock, to affiliates of LifeSci Capital. On

December 24, 2020 (i) LVP purchased 78,616 shares of Class A Common Stock at a price of $6.36 per share, for an aggregate investment of $499,997.76, and (ii) another affiliate of LifeSci Capital purchased 31,446 shares of Class A Common Stock at a price of $6.36 per share, for an aggregate investment of $199,996.56. On December 30, 2020, pursuant to an amendment of Revelation's certificate of incorporation, all shares of Class A Common Stock, were converted on a one-for-one basis into shares of Revelation's common stock. On January 31, 2021, affiliates of LifeSci Capital purchased an aggregate of 47,170 shares of Revelation's Series A-1 preferred stock at a price of $6.36 per share, for an aggregate investment of $300,001.20. The December 2020 and January 2021 financings were done roughly contemporaneously and at a pre-money valuation of $11.6 million.

Other than the repayment of the $150,000 loan to the Sponsor, the loans evidenced by the Replacement Notes and the compensation payable to LifeSci described above, no compensation or fees of any kind, including finder's, consulting fees and other similar fees, will be paid to the Sponsor, initial stockholders, members of our management team or their respective affiliates, for services rendered prior to or in connection with the consummation of the Merger. However, such individuals will receive reimbursement for any out-of-pocket expenses incurred by them in connection with activities on our behalf, such as identifying potential target businesses, performing business due diligence on suitable target businesses and business combinations as well as traveling to and from the offices, plants or similar locations of prospective target businesses to examine their operations. There is no limit on the amount of out-of-pocket expenses reimbursable by us.

Backstop Agreements

On December 21, 2021, Petra entered into certain backstop agreements (the "Backstop Agreements") with AXA Prime Impact Master Fund ("AXA") (through a backstop agreement with Old Revelation, LifeSci Venture Partners ("LifeSci") and other Petra and Old Revelation institutional, and individual investors, including Dr. Tidmarsh, chairman of the Company (such additional institutional and individual investors, together with LifeSci and Old Revelation collectively, the "Backstop Subscribers"). Pursuant to the Backstop Agreements, the Backstop Subscribers agreed to subscribe for and purchase, in the aggregate, up to $4.5 million of shares of Petra's common stock, par value $0.001 per share (the "Petra Common Stock"), in the event that more than $31.5 million of shares of Petra Common Stock are submitted for redemption in connection with Petra's proposed business combination with Old Revelation (the "Business Combination"). On January 6, 2022, pursuant to the Backstop Agreements, the Backstop Subscribers purchased an aggregate of 432,072 shares of Petra Common Stock.

Old Revelation obtained the financing for its Backstop Agreement through a convertible note financing in an amount of up to $2.5 million from an AXA (the "Convertible Note"), the proceeds of which may be used by Old Revelation solely to purchase shares of Petra Common Stock from redeeming Petra stockholders who redeem shares of Petra Common Stock in connection with the Business Combination. On January 6, 2022, Old Revelation purchased 245,019 shares of Petra Common Stock with the proceeds from the Convertible Note. Repayment of the Convertible Note is in process in accordance with the exchange terms of the Convertible Note, by which the shares of Petra's Common Stock purchased by Old Revelation are transferred to AXA.

Forward Share Purchase Agreement

On December 21, 2021, Petra also entered into a forward share purchase agreement (the "Purchase Agreement") with Meteora Capital Partners and its affiliates (collectively, "Meteora") pursuant to which Meteora has committed, subject to certain customary closing conditions, to purchase additional shares of Petra Common Stock in open market transactions or from redeeming stockholders so that Meteora holds at least 750,000 shares of Petra common stock as of the closing of the Business Combination, and to not redeem any of such 750,000 shares of Petra Common Stock, in connection with the business combination.

The Purchase Agreement provides that Meteora may elect to sell and transfer to Petra, and that Petra will purchase from Meteora, on the one month anniversary of the closing of the Business Combination up to 750,000 shares of Petra Common Stock (the "Petra Share Repurchase") held by Meteora at the time of closing of the Business Combination (the "Meteora Shares"). The price at which Meteora has the right to sell the Meteora Shares to the Petra is $10.2031 per share. Meteora will notify the Petra in writing not less than five business days prior to the closing date of the Petra Share Repurchase (the "Closing Date"), specifying the number of Meteora Shares that Petra will be required to purchase.

Pursuant to the Purchase Agreement, Meteora is also permitted at its election to sell any or all of the Meteora Shares in the open market commencing after the closing of the Business Combination, so long as the sale price exceeds $10.2031 per share.

Pursuant to an escrow agreement dated December 21, 2021 (the "Escrow Agreement"), by and among Petra, Continental Stock Transfer and Trust Co. ("Continental") and Meteora, to secure its purchase obligation to Meteora, at the closing of the Business Combination, Petra will place into escrow with Continental an aggregate amount of $7,652,325. If and when Meteora sells the Meteora Shares to any third party, an amount equal to Petra's purchase price obligation for that portion of such Meteora Shares, which Meteora sells in the open market, will be released from escrow to Petra.

Related Party Policy

Our Code of Ethics requires us to avoid, wherever possible, all related party transactions that could result in actual or potential conflicts of interests, except under guidelines approved by the board of directors (or the audit committee). Related-party transactions are defined as transactions in which (1) the aggregate amount involved will or may be expected to exceed $120,000 in any calendar year, (2) we or any of our subsidiaries is a participant, and (3) any (a) executive officer, director or nominee for election as a director, (b) greater than 5% beneficial owner of our Shares of Common Stock, or (c) immediate family member, of the persons referred to in clauses (a) and (b), has or will have a direct or indirect material interest (other than solely as a result of being a director or a less than 10% beneficial owner of another entity). A conflict of interest situation can arise when a person takes actions or has interests that may make it difficult to perform his or her work objectively and effectively. Conflicts of interest may also arise if a person, or a member of his or her family, receives improper personal benefits as a result of his or her position.

Our audit committee, pursuant to its written charter, will be responsible for reviewing and approving related-party transactions to the extent we enter into such transactions. The audit committee will consider all relevant factors when determining whether to approve a related party transaction, including whether the related party transaction is on terms no less favorable to us than terms generally available from an unaffiliated third-party under the same or similar circumstances and the extent of the related party's interest in the transaction. No director may participate in the approval of any

transaction in which he is a related party, but that director is required to provide the audit committee with all material information concerning the transaction. We also require each of our directors and executive officers to complete a directors' and officers' questionnaire that elicits information about related party transactions.

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

To further minimize conflicts of interest, we have agreed not to consummate an initial business combination with an entity that is affiliated with any of our sponsor, officers or directors including (i) an entity that is either a portfolio company of, or has otherwise received a material financial investment from, any private equity fund or investment company (or an affiliate thereof) that is affiliated with any of the foregoing, (ii) an entity in which any of the foregoing or their affiliates are currently passive investors, (iii) an entity in which any of the foregoing or their affiliates are currently officers or directors, or (iv) an entity in which any of the foregoing or their affiliates are currently invested through an investment vehicle controlled by them, unless we have obtained an opinion from an independent investment banking firm, or another independent entity that commonly renders valuation opinions, and the approval of a majority of our disinterested independent directors that the business combination is fair to us and to our unaffiliated stockholders from a financial point of view.

Revelation

Revelation has adopted a code of ethics and it relies on its board to review related party transactions on an ongoing basis to prevent conflicts of interest. Revelation's Board reviews a transaction in light of the affiliations of the director, officer or employee and the affiliations of such person's immediate family. Transactions are presented to Revelation's Board for approval before they are entered into or, if this is not possible, for ratification after the transaction has occurred. If Revelation's Board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Revelation's Board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of Revelation.

Director Independence

Our board of directors currently consists of five members. Our board of directors has determined that all of our directors, other than Mr. Rolke, qualify as "independent" directors in accordance with the rules of the SEC and the Nasdaq, Marketplace Rules, or the Nasdaq Listing Rules, which the Company has adopted as its independence standards. Mr. Rolke is not considered independent because he is an executive officer of the Company. Under the Nasdaq Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Nasdaq Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationships exist that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's relationships as they may relate to us and our management.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following is a summary of fees paid or to be paid to dbb *mckennon* for services rendered.

Audit Fees. Audit fees consist of fees billed for professional services rendered for the audit of our year-end financial statements and services that are normally provided by dbbmckennon in connection with regulatory filings. The aggregate fees billed by dbbmckennon for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the year ended December 31, 2021 and for the period from November 20, 2019 (inception) through December 31, 2020 totaled $60,440 and $72,969, respectively. The above amounts include interim procedures and audit fees, as well as attendance at audit committee meetings.

Audit-Related Fees. Audit-related services consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our financial statements and are not reported under "Audit Fees." These services include attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards. We did not pay dbbmckennon for consultations concerning financial accounting and reporting standards for the year ended December 31, 2021 and for the period from November 20, 2019 (inception) through December 31, 2020.

Tax Fees. We did not pay dbbmckennon for tax planning and tax advice for the year ended December 31, 2021 and for the period from November 20, 2019 (inception) through December 31, 2020.

All Other Fees. We did not pay dbbmckennon for other services for the year ended December 31, 2021 and for the period from November 20, 2019 (inception) through December 31, 2020.

ITEM 15. Exhibits.

The following documents are filed as part of this Annual Report:

EXHIBIT	DESCRIPTION
2.1[(3)]	Agreement and Plan of Merger, dated as of August 29, 2021 by and among Petra Acquisition, Inc., Petra Acquisition Merger Inc., and Revelation Biosciences, Inc.
3.1[(3)]	Third Amended and Restated Certificate of Incorporation
3.2[(3)]	Second Amended and Restated Bylaws.
4.1[(3)]	Specimen Unit Certificate

4.2[3]	Specimen Common Stock Certificate
4.3[3]	Specimen Warrant Certificate
4.4[3]	Specimen Common Stock Certificate of the Combined Entity
4.5[2]	Warrant Agreement, dated October 7, 2020, between Continental Stock Transfer & Trust Company and the Company.
4.6[5]	Form of Unregistered Pre-Funded Common Stock Purchase Warrant dated January 25, 2022
4.7[5]	Form of Unregistered Common Stock Purchase Warrant dated January 25, 2022
4.8[5]	Form of Unregistered Placement Agent Warrant dated January 25, 2022
4.9*	Description of Securities
10.1[1]	Form of Letter Agreement from each of the Registrant's sponsor, initial stockholder, officers and directors.
10.2[2]	Registration Rights Agreement, dated October 7, 2020, between the Company and Investors.
10.3[2]	Subscription Agreement, dated October 7, 2020, between the Company and Petra Investment Holdings LLC
10.4[2]	Business Combination Marketing Agreement, dated October 7, 2020, by and among the Company, LifeSci Capital LLC, Ladenburg Thalmann & Co. Inc., Northland Securities, Inc., and Ingalls & Snyder LLC
10.5[2]	Escrow Agreement, dated October 7, 2020, by and among the Company, Continental Stock Transfer & Trust Company and the Company's Initial Stockholders.
10.6[1]	Promissory Note
10.7†[3]	Revelation Biosciences, Inc. 2021 Equity Incentive Plan.
10.8[3]	Global Health Agreement by and between Revelation and AXA IM Prime Impact Fund dated December 31, 2020
10.9[3]	Executive Employment Agreement between Revelation Biosciences, Inc. and James Rolke, effective July 27, 2021
10.10[3]	Executive Employment Agreement between Revelation Biosciences, Inc. and Chester Zygmont, III, effective July 27, 2021
10.11[3]	Revelation Common Stock Warrant Issued to National Securities Corporation
10.12[5]	Securities Purchase Agreement dated January 23, 2022 by and between the Company and Armistice Capital Master Fund Ltd.
10.13[5]	Registration Rights Agreement dated January 23, 2022 by and between the Company and Armistice Capital Master Fund Ltd.
14[1]	Code of Ethics
21.1[4]	List of Subsidiaries.
24.1*	Power of Attorney (contained on signature page to the Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a_14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a_14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

99.1[1]	Audit Committee Charter
99.2[1]	Compensation Committee Charter
99.3[1]	Nominating Committee Charter
101.INS*	XBRL Instance Document – the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Scema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

The annexes, schedules, and certain exhibits to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Petra hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

(1) Previously filed as an exhibit to Petra Acquisition Inc.'s Registration Statement on Form S-1, as amended (File No. 333-240175).
(2) Previously filed as an exhibit to Petra Acquisition Inc.'s Current Report on Form 8-K filed on October 13, 2020.
(3) Previously filed as an exhibit to Petra Acquisition Inc.'s Current Report on Form S-4 filed, as amended (File No. 333- 259638).
(4) Previously filed as an exhibit to Revelation Biosciences, Inc.'s Current Report on Form 8-K filed on January 14, 2022.
(5) Previously filed as an exhibit to Revelation Biosciences, Inc.'s Current Report on Form 8-K filed on January 27, 2022.
* Filed herewith.
† Indicates a management contract or compensatory plan.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Revelation Biosciences, Inc.

Date: April 15, 2022

By: */s/ James Rolke*
James Rolke
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Chester S. Zygmont, III and Joseph P. Galda, jointly and severally, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

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

Date: April 15, 2022 BY: */s/ James Rolke*
Chief Executive Officer and Director

Date: April 15, 2022 BY: */s/ George Tidmarsh*
Chairman and Director

Date: April 15, 2022 BY: */s/ Chester S. Zygmont, III.*
Chief Financial Officer
and Principal Accounting Officer

Date: April 15, 2022 BY: */s/ Jennifer Carver*
Director

Date: April 15, 2022 BY: */s/ Jess Roper*
Director

Date: April 15, 2022 BY: */s/ Curt LaBelle*
Director

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Revelation Biosciences, Inc (f/k/a Petra Acquisition, Inc.)

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Revelation Biosciences, Inc (f/k/a Petra Acquisition, Inc.) (the "Company") as of December 31, 2021 and 2020, and the related statements of operations, stockholders' deficit, and cash flows, for the years ended December 31, 2021 and 2020, 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 the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ dbb*mckennon*

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

Newport Beach, California
April 15, 2022

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)
BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,532	$ 11,734
Marketable securities	-	525,287
Prepaid expenses	4,834	114,270
Total current assets	83,366	651,291
Cash held in Trust Account	48,302,521	73,510,915
Total assets	$ 48,385,887	$ 74,162,206
LIABILITIES AND STOCKHOLDER'S DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,321,514	$ 33,772
Promissory Notes Payable and accrued interest expense	774,345	-
Warrant liability	2,390,258	3,399,878
Total current liabilities	5,486,117	3,433,650
Deferred underwriting commissions	2,911,260	2,911,260
Total liabilities	8,397,377	6,344,910
Commitments and Contingencies (Note 7)		
Common stock subject to possible redemption, 4,734,024 and 7,278,151 shares at redemption value as of December 31, 2021 and 2020, respectively	47,811,164	73,509,325
Stockholder's equity deficit:		
Preferred stock, par value $0.001, 1,000,000 shares authorized; zero shares issued and outstanding as of December 31, 2021 and 2020	-	-
Common stock, par value $0.001, 100,000,000 shares authorized; 1,819,538 shares issued and outstanding (excluding 4,734,024 and 7,278,151 shares subject to possible redemption) as of December 31, 2021 and 2020, respectively	1,820	1,820
Accumulated deficit	(7,824,474)	(5,693,849)
Total stockholder's deficit	(7,822,654)	(5,692,029)
Total liabilities and stockholder's deficit	$ 48,385,887	$ 74,162,206

The accompanying footnotes are an integral part of the financial statements.

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)
STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
Operating expenses:		
General and administrative	$ 3,088,248	$ 145,492
Loss from operations	(3,088,248)	(145,492)
Other income (expense):		
Interest income	222	9,325
Interest expense	(41,759)	-
Realized loss on marketable securities	(17,356)	-
Unrealized loss on marketable securities	-	(1,831)
Interest earned on cash held in Trust Account	6,896	1,590
Change in fair value of warrant liability	1,009,620	(1,494,092)
Other income (expense), net	957,623	(1,485,008)
Net loss	$ (2,130,625)	$ (1,630,500)
Weighted-average common shares subject to redemption outstanding, basic and diluted	6,825,087	1,568,687
Basic and diluted net income per common share subject to redemption	$ 0.00	$ 0.00
Weighted-average common shares outstanding, basic and diluted	1,819,538	2,409,951
Basic and diluted net loss per common share	$ (1.17)	$ (0.68)

The accompanying footnotes are an integral part of the financial statements.

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)
STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-in	Accumulated	Total Stockholder's
	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019	-	-	-	(3,638)	(3,638)
Sale of common stock to sponsors	3,593,750	3,594	21,406		25,000
Cancellation of founders shares	(1,774,212)	(1,774)	1,774	-	-
Excess of cash received over fair value of private warrants	-	-	1,327,660	-	1,327,660
Accretion of common stock to redemption amount	-	-	(1,350,840)	(4,059,711)	(5,410,551)
Net loss	-	-	-	(1,630,500)	(1,630,500)
Balance at December 31, 2020	1,819,538	1,820	-	(5,693,849)	(5,692,029)
Net loss	-	-	-	(2,130,625)	(2,130,625)
Balance at December 31, 2021	1,819,538	$ 1,820	$ -	$ (7,824,474)	$ (7,822,654)

The accompanying footnotes are an integral part of the financial statements.

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)
STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,130,625)	$ (1,630,500)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest earned on cash held in Trust Account	(6,896)	(1,590)
Unrealized loss on marketable securities	-	1,831
Change in fair value of warrant liability	(1,009,620)	1,494,092
Changes in operating assets and liabilities:		
Changes in prepaid expenses	109,436	(114,270)
Changes in accounts payable and accrued liabilities	2,287,742	33,773
Accrued interest expense on Promissory Notes Payable	24,345	-

Net cash used in operating activities	(725,618)	(216,664)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment of cash in Trust Account	(482,871)	(73,509,325)
Investment in marketable securities	-	(527,000)
Cash paid from Trust Account for redemption of common stock	25,698,161	-
Proceeds from sale of marketable securities	525,287	-
Net cash used in investing activities	25,740,577	(74,036,325)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from related party advances	-	150,000
Repayments of advances	-	(150,000)
Proceeds from notes payable - related party	-	140,000
Repayments of notes payable - related party	-	(125,000)
Proceeds from Promissory Notes Payable	750,000	-
Cash proceeds received for private warrants	-	3,233,446
Cash proceeds received for public offering	-	71,325,880
Cash paid from Trust Account for redemption of common stock	(25,698,161)	
Deferred offering costs	-	(309,603)
	(24,948,161)	74,264,723
NET CHANGE IN CASH	66,798	11,734
Cash - Beginning of period	11,734	-
Cash - End of period	$ 78,532	$ 11,734
SUPPLEMENTAL CASH FLOW INFORMATION:		
Non-cash investing and financing activities:		
Founders shares issued in partial relief of advances to related party	$ -	$ 25,000
Cancellation of founders' shares	$ -	$ 1,774
Deferred underwriting commissions	$ -	$ 2,911,260
Advance converted to related party note payable	$ -	$ 10,000
Private warrants recorded as liability	$ -	$ 1,905,786

The accompanying footnotes are an integral part of the financial statements.

REVELATION BIOSCIENCES, INC. (F/K/A PETRA ACQUISITION, INC.)
NOTES TO FINANCIAL STATEMENTS

NOTE 1 – NATURE OF OPERATIONS, BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES

Corporate History and Nature of Operations

Revelation Biosciences, Inc., formerly known as Petra Acquisition, Inc. (the "Company" or "Petra") was incorporated in Delaware on November 20, 2019. The Company was formed for the purpose of entering into a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities. The Company is not limited to a particular industry or sector for purposes of consummating a business combination. The Company is an early stage and emerging growth company and, as such, the Company is subject to all of the risks associated with early stage and emerging growth companies.

As of December 31, 2021, the Company had not commenced any operations. All activity for the period from November 20, 2019 (Inception) through December 31, 2021 relates to the Company's formation, IPO, and search for an acquisition target, which is described below. The Company will not generate any operating revenues until after the completion of a business combination, at the earliest. The Company generates non-operating income from interest earned on cash held in the Trust Account, interest earned on cash and cash equivalents held in the Company's operating account and gains or losses from marketable securities held in the Company's operating account. The Company has selected December 31 as its fiscal year end.

Business Combination

On January 10, 2022, Petra consummated the Business Combination, pursuant to the terms of the Business Combination Agreement, by and among Petra, Merger Sub, and Old Revelation. Pursuant to the Business Combination Agreement, on the Closing Date, (i) Merger Sub merged with and into Old Revelation, with Old Revelation as the surviving company in the Merger, and, after giving effect to such Merger, Old Revelation was renamed Revelation Biosciences Sub, Inc. and became a wholly-owned subsidiary of Petra and (ii) Petra changed its name to "Revelation Biosciences, Inc".

In accordance with the terms and subject to the conditions of the Business Combination Agreement, at the effective time of the Merger (the "Effective Time"), (i) each share of common stock and preferred stock of Old Revelation outstanding as of immediately prior to the Effective Time was exchanged for shares of common stock, par value $0.001 per share, of Revelation based on the agreed upon conversion rate of 2.725 (the "Common Stock Exchange Ratio); (ii) each Old Revelation RSU award (as defined in the Business Combination Agreement) outstanding as of immediately prior to the Effective Time was assumed by Revelation and was converted into that number of whole Revelation Rollover RSU awards (as defined in the Business Combination Agreement) based on the Common Stock Exchange Ratio; and (iii) each Old Revelation Warrant (as defined in the Business Combination Agreement) outstanding as of immediately prior to the Effective Time was assumed by Revelation and was converted into that number of whole Revelation Rollover Warrants (as defined in the Business Combination Agreement) based on the Common Stock Exchange Ratio, at an exercise price per share of common stock equal to (x) the exercise price per share of Old Revelation common stock of such Old Revelation Warrant divided by (y) the Common Stock Exchange Ratio.

At the Closing Date of the Business Combination, up to 10,500,000 shares of Common Stock were to be issued constituting the merger consideration (the "Merger Consideration"), (i) an aggregate of 9,871,343 shares of Common Stock were issued in exchange for the Old Revelation stock outstanding as of immediately prior to the Effective Time, (ii) 167,867 shares of Common Stock were reserved for issuance for Revelation Rollover

Warrants outstanding as of immediately prior to the Effective Time and (iii) 460,706 shares of Common Stock were reserved for issuance for Revelation Rollover RSU's outstanding as of immediately prior to the Effective Time.

Immediately after giving effect to the Business Combination, there were 12,944,213 shares of Common Stock outstanding, and 1,294,421 shares of Common Stock reserved for future issuance under the 2021 Equity Incentive Plan. The pre-merger stockholders of the Company retained an aggregate of 3,072,870 shares of common stock of the Company, representing 23.7% ownership of the post-Merger Company. Therefore, upon consummation of the Business Combination, there was a change in control of the Company, with the former owners of Revelation effectively acquiring control of the Company.

Additionally, in connection with the Business Combination, stockholders holding 3,480,692 shares of Petra common stock exercised their right to redeem such shares for cash at a price of approximately $10.20 per share for payments in the aggregate of approximately $ 35.5 million. On the Closing Date, pursuant to the Backstop Agreements, the Backstop Subscribers purchased an aggregate of 432,072 shares of Petra Common Stock and approximately $7.6 million was escrowed pursuant to the Forward Share Purchase Agreement entered into by and between Petra and Meteora and approximately $4.2 million was released to the Company.

The Business Combination will be accounted for as a reverse recapitalization, in accordance with U.S. GAAP. Under this method of accounting, although Petra will issue shares for outstanding equity interests of Revelation in the Business Combination, Petra will be treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination will be treated as the equivalent of Revelation issuing stock for the net assets of Petra, accompanied by a recapitalization. The net assets of Petra will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be those of Revelation.

At the Closing of the Business Combination, Petra changed its name to "Revelation Biosciences, Inc." and adopted the third amended and restated certificate of incorporation (the "Restated Charter"), which became effective upon filing with the Secretary of State of the State of Delaware on January 10, 2022.

Business Prior to the Business Combination

The registration statement for the Company's Initial Public Offering became effective on October 7, 2020. On October 13, 2020, the Company consummated the Initial Public Offering of 7,000,000 units (the "Units" and, with respect to the shares of common stock included in the Units sold, the "Public Shares") at $10.00 per Unit, generating gross proceeds of $ 70,000,000, which is described in Note 3.

Simultaneously with the closing of the Initial Public Offering, the Company consummated the sale of 3,150,000 warrants (the "Private Placement Warrants") at a price of $1.00 per Private Placement Warrant in a private placement to Petra Investment Holdings, LLC, a Delaware limited liability company (the "Sponsor"), for gross proceeds of $3,150,000. The funds for the Private Placement Warrants had been placed in our Trust Account in anticipation of the exercise prior to September 30, 2020.

Transaction costs amounted to $ 4,682,736, consisting of $ 4,366,980 of underwriting discounts ($ 2,911,260 of which payment is deferred) and $315,846 of professional fees, printing, filing, regulatory and other costs which have been charged to additional paid in capital upon completion of the Initial Public Offering.

Following the closing of the Initial Public Offering in October 2020, an amount of $ 73,509,325 from the net proceeds of the sale of the Units in the Initial Public Offering and the sale of the Private Placement Warrants was placed in the Trust Account which are to be invested in U.S. government securities, within the meaning set forth in Section 2(a)(16) of the Investment Company Act, with a maturity of 185 days or less or in any open-ended investment company that holds itself out as a money market fund selected by the Company meeting the conditions of Rule 2a-7 of the Investment Company Act of 1940, as amended (the "Investment Company Act"), as determined by the Company, until the earlier of: (i) the consummation of a Business Combination and (ii) the distribution of the funds in the Trust Account, as described below.

Basis of Presentation

The accompanying financial statements are presented in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC.

Certain amounts previously reported in the financial statements have been reclassified to conform to the current year presentation. Such reclassifications did not affect net income (loss) or stockholders' deficit.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of 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 independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, 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 Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a 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 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.

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statement and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from those estimates.

Cash and cash equivalents in the Trust Account and Operating Account

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents.

At December 31, 2021 and 2020, cash equivalents held in the Trust Account were held in money market funds. During the year ended December 31, 2021, the Company withdrew no interest income from the Trust Account to pay the Company's taxes.

Marketable Securities Held in Operating Account

At December 31, 2020, the marketable securities held in the Company's operating account were investments that substantially hold bonds and fixed income securities.

Common Stock Subject to Possible Redemption

The Company accounts for its common stock subject to possible redemption in accordance with the guidance in Accounting Standards Codification ("ASC") Topic 480 "Distinguishing Liabilities from Equity." Common stock subject to mandatory redemption is classified as a liability instrument and is measured at fair value. Conditionally redeemable common stock (including common stock that feature redemption rights that is either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) is classified as temporary equity. At all other times, common stock is classified as stockholders' equity. The Company's common stock features certain redemption rights that are considered to be outside of the Company's control and subject to occurrence of uncertain future events. Accordingly, common stock subject to possible redemption is presented at redemption value as temporary equity, outside of the stockholders' equity section of the Company's balance sheets.

Offering Costs

Offering costs consist of underwriting discounts, professional fees, printing, filing, regulatory and other costs incurred through the balance sheet date that are directly related to the Initial Public Offering. The deferred offering costs were offset against the IPO and overallotment proceeds and were reclassified to additional paid-in capital upon completion of the IPO and overallotment transaction during the year end December 31, 2020.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2021 and 2020. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception.

On March 27, 2020, the CARES Act was enacted in response to COVID-19 pandemic. Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. The CARES Act made various tax law changes including among other things (i) increasing the limitation under Section 163(j) of the Internal Revenue Code of 1986, as amended (the "IRC") for 2020 and 2021 to permit additional expensing of interest (ii) enacting a technical correction so that qualified improvement property can be immediately expensed under IRC Section 168(k), (iii) making modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2020 and 2021 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and (iv) enhancing the recoverability of alternative minimum tax credits.

Net Loss per Common Share

Net loss per share of common stock is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. The Company applies the two-class method in calculating earnings per share. Accretion associated with the redeemable shares of common stock

is excluded from earnings per share as the redemption value approximates fair value.

At December 31, 2021, the Company had outstanding warrants to purchase of up to 10,511,597 shares of common stock. The weighted-average of these shares was excluded from the calculation of diluted net loss per share of common stock since the exercise of the Warrants is contingent upon the occurrence of future events. As of December 31, 2021 and 2020, the Company did not have any dilutive securities or other contracts that could, potentially, be exercised or converted into shares of common stock and then share in the earnings of the Company. As a result, diluted net loss per share of common stock is the same as basic net loss per share of common stock for the period.

	Year Ended December 31, 2021
Common stock subject to possible redemption	
Numerator: Earnings allocable to common stock subject to possible redemption	
Interest earned on cash held in Trust Account	$ 6,896
Net income attributable	$ 6,896
Denominator: Weighted-average common stock subject to possible redemption	
Basic and diluted weighted-average shares outstanding, common stock subject to possible redemption	6,825,087
Basic and diluted net income per share, common stock subject to possible redemption	$ 0.00
Non-redeemable common stock	
Numerator: Net Loss minus Net Earnings	
Net loss	$ (2,130,625)
Less: Net income allocable to common stock subject to possible redemption	6,896
Non-redeemable Net Loss	$ (2,137,521)
Denominator: Weighted-average non-redeemable common stock	
Basic and diluted weighted-average shares outstanding, common stock	1,819,538
Basic and diluted net loss per share, common stock	$ (1.17)

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage of $250,000. As of December 31, 2021, the Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

Fair Value of Financial Instruments

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts represented in the accompanying balance sheet, primarily due to their short-term nature.

Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

NOTE 2 – MANGEMENT'S LIQUIDITY PLANS

As of December 31, 2021, the Company had approximately $ 79,000 in cash and cash equivalents in its operating bank account, and a working capital deficiency of approximately $5,403,000.

The Company's liquidity needs during the year ended December 31, 2021, had been primarily satisfied through the funds received from the Initial Public Offering (See Note 3). Over this time period, the Company used these funds for paying operational expenses, identifying and evaluating prospective initial Business Combination candidates, performing due diligence on prospective target businesses, paying for travel expenditures, selecting the target business to merge with or acquire, and structuring, negotiating and consummating the Business Combination. In addition, the Company received cash in an aggregate principal amount of $750,000 through various Promissory Notes Payable from the Lenders (See Note 5).

Based on the foregoing and the funds received from the Initial Public Offering, management believes that the Company will have sufficient working capital and borrowing capacity to meet its needs through the earlier of the consummation of a Business Combination or one year from this filing. Over this time period, the Company will be using these funds for paying operational expenses, identifying and evaluating prospective initial Business Combination candidates, performing due diligence on prospective target businesses, paying for travel expenditures, selecting the target business to merge with or acquire, and structuring, negotiating and consummating the Business Combination.

Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that the specific impact is not readily determinable as of the date of the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 3 –PUBLIC OFFERING

Pursuant to the Initial Public Offering on October 13, 2020, the Company sold 7,000,000 units at a price of $10.00 per Unit for a total of $70,000,000. Each Unit consists of one share of common stock and one warrant ("Public Warrant"). Each whole Public Warrant entitles the holder to purchase one share of common stock at a price of $11.50 per share, subject to adjustment (see Note 8).

On October 14, 2020, the underwriters exercised the over-allotment option in part, and the closing of the issuance and sale of an additional 278,151 Units occurred (the "Over-Allotment Option Units") on October 16, 2020 at $ 10.00 per Unit, generating gross proceeds of $ 2,781,510.

NOTE 4 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following amounts:

	December 31, 2021	December 31, 2020
Accounts payable	$ 784,800	$ 33,772
Accrued legal fees	1,536,714	-
Total accounts payable and accrued expenses	$ 2,321,514	$ 33,772

NOTE 5 – PROMISSORY NOTES

On October 13, 2021, the Company entered into three promissory notes payable for a total of up to an aggregate principal amount of $ 750,000 with a minimum draw of $50,000 (Promissory Notes Payable) with three Lenders (the Lenders). Such Promissory Notes Payable are being made for the purpose of funding a contribution of cash for each share of common stock issued in Petra's initial public offering (the "IPO") that was not redeemed in connection with the stockholder vote to approve the extension of the deadline for the Company to complete an initial business combination, as contemplated in the definitive proxy statement on Scheduled 14A filed by the Company with the Securities and Exchange Commission on September 24, 2021. The Promissory Notes Payable will bear interest at the rate of 2% per month on the outstanding Promissory Notes Payable and such amounts will be repayable by the Company to the Lenders upon consummation of an initial business combination. The Lenders have agreed that with respect to each Extension that is approved, they or their affiliates will contribute to the Company as a loan (each loan being referred to herein as a "Contribution") $0.027 for each share of common stock issued in the Company's IPO (the "public shares") that is not redeemed in connection with the stockholder vote to approve such Extension. Accordingly, if the Company takes the additional extensions, the Lenders would make aggregate Contributions of approximately $750,000 (assuming no public shares were redeemed). Each Contribution will be deposited in the Trust Account within two business days prior to the beginning of the additional extension period (or portion thereof), other than the first Contribution which was made on October 12, 2021. Accordingly, if the Company takes the full time through the Extended Termination Date to complete an initial business combination, the redemption price per share at the meeting for such business combination or the Company's subsequent liquidation will be approximately $10.20 per share (without taking into account any interest). The Lenders will not make any Contribution unless the related Extension is approved and the Extension is completed. The Contribution(s) will bear interest at the rate of 2.0% per month on the outstanding loan amount and will be repayable by the Company to the Lenders upon consummation of an initial business combination. The loans will be forgiven if the Company is unable to consummate an initial business combination except to the extent of any funds held outside of the Trust Account. The Company will have the sole discretion whether to continue extending for the additional periods until the Extended Termination Date and if the Company determines not to continue extending for the additional periods, the Company's obligation to make additional Contributions will terminate. If this occurs, or if the Company's board of directors otherwise determines that the Company will not be able to consummate an initial business combination by the Extended Termination Date and does not wish to seek an additional extension, the Company would wind up our affairs and redeem 100% of the outstanding public shares. The purpose of each Extension is to allow the Company more time to complete the Company's proposed business combination.

As of December 31, 2021, the aggregate principal amount of the Promissory Notes Payable was $ 750,000. The related accrued interest on the three promissory notes as of December 31, 2021 was $24,345.

NOTE 6 - RELATED PARTY TRANSACTIONS

Sponsor Shares

On January 21, 2020, the Company's sponsor, Petra Investment Holdings, LLC, (the "Sponsor") purchased 3,593,750 shares (the "Founder Shares") of the Company's common stock for an aggregate price of $25,000. The $25,000 was paid through relief of the related party note disclosed below. Of the original Founder Shares, 1,774,212 were forfeited. As of December 31, 2021, no additional Founder Shares are subject to forfeiture.

Private Warrants

Concurrent with the Initial Public Offering, our sponsor purchased 3,150,000 Private Placement Warrants at a price of $ 1.00, see Note 1. Simultaneously with the closing of the sale of the Over-Allotment Option Units, the Company consummated the sale of an additional 83,446 Private Warrants at a price of $1.00 per Private Warrant, generating total proceeds of $ 83,446.

The fair value of the Private Warrants at December 31, 2020 was a liability of $ 3,399,878. At December 31, 2021, the fair value was $ 2,390,258. For the year ended December 31, 2021, the gain on the change in fair value was $1,009,620 and is reflected in change in fair value of warrant liability on the statements of operations.

Related Party Loans

In addition, in order to finance transaction costs in connection with a Business Combination, certain of the Company's officers and directors or their affiliates may, but are not obligated to, loan the Company funds as may be required ("Working Capital Loans").

If the Company completes a Business Combination, the Company would repay the Working Capital Loans out of the proceeds of the Trust Account released to the Company. Otherwise, the Working Capital Loans would be repaid only out of funds held outside the Trust Account. In the event

that a Business Combination does not close, the Company may use a portion of proceeds held outside the Trust Account to repay the Working Capital Loans but no proceeds held in the Trust Account would be used to repay the Working Capital Loans. Except for the foregoing, the terms of such Working Capital Loans, if any, have not been determined and no written agreements exist with respect to such loans. The Working Capital Loans would either be repaid upon consummation of a Business Combination, without interest, or, at the lender's discretion, up to $1,500,000 of such Working Capital Loans may be converted into warrants of the post Business Combination entity at a price of $1.00 per warrant. There have been no Working Capital Loans to date.

Pine Valley Investments LLC

On September 17, 2021, the Company entered into a senior promissory with Pine Valley Investments LLC, a New Jersey Limited Liability Company ("Pine Valley"), an affiliate of the Company's sponsor, LifeSci Capital LLC, with a principal amount of $ 850,000. Interest was to accrue at 2% per month on all outstanding principal. The Company was able to drawdown requests on the note in amounts no less than $50,000 unless agreed upon by the parties. The outstanding principal and any accrued interest was due upon the Company's consummation of a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combinations. On October 13, 2021, the Company and Pine Valley entered into a Note Cancellation Agreement pursuant to which the Pine Valley Note was terminated and cancelled effective as of October 13, 2021.

Backstop Agreements

On December 21, 2021, Petra entered into certain backstop agreements (the "Backstop Agreements") with AXA Prime Impact Master Fund ("AXA") (through a backstop agreement with Old Revelation, LifeSci Venture Partners ("LifeSci") and other Petra and Old Revelation institutional, and individual investors, including Dr. Tidmarsh, chairman of the Company (such additional institutional and individual investors, together with LifeSci and Old Revelation collectively, the "Backstop Subscribers"). Pursuant to the Backstop Agreements, the Backstop Subscribers agreed to subscribe for and purchase, in the aggregate, up to $4.5 million of shares of Petra's common stock, par value $ 0.001 per share (the "Petra Common Stock"), in the event that more than $31.5 million of shares of Petra Common Stock are submitted for redemption in connection with Petra's proposed business combination with Old Revelation (the "Business Combination"). On January 6, 2022, pursuant to the Backstop Agreements, the Backstop Subscribers purchased an aggregate of 432,072 shares of Petra Common Stock.

Forward Share Purchase Agreement

On December 21, 2021, Petra also entered into a forward share purchase agreement (the "Purchase Agreement") with Meteora Capital Partners and its affiliates (collectively, "Meteora") pursuant to which Meteora has committed, subject to certain customary closing conditions, to purchase additional shares of Petra Common Stock in open market transactions or from redeeming stockholders so that Meteora holds at least 750,000 shares of Petra common stock as of the closing of the Business Combination, and to not redeem any of such 750,000 shares of Petra Common Stock, in connection with the business combination.

The Purchase Agreement provides that Meteora may elect to sell and transfer to Petra, and that Petra will purchase from Meteora, on the one month anniversary of the closing of the Business Combination up to 750,000 shares of Petra Common Stock (the "Petra Share Repurchase") held by Meteora at the time of closing of the Business Combination (the "Meteora Shares"). The price at which Meteora has the right to sell the Meteora Shares to the Petra is $10.2031 per share. Meteora will notify the Petra in writing not less than five business days prior to the closing date of the Petra Share Repurchase (the "Closing Date"), specifying the number of Meteora Shares that Petra will be required to purchase.

Pursuant to the Purchase Agreement, Meteora is also permitted at its election to sell any or all of the Meteora Shares in the open market commencing after the closing of the Business Combination, so long as the sale price exceeds $10.2031 per share.

Pursuant to an escrow agreement dated December 21, 2021 (the "Escrow Agreement"), by and among Petra, Continental Stock Transfer and Trust Co. ("Continental") and Meteora, to secure its purchase obligation to Meteora, at the closing of the Business Combination, Petra will place into escrow with Continental an aggregate amount of $7,652,325. If and when Meteora sells the Meteora Shares to any third party, an amount equal to Petra's purchase price obligation for that portion of such Meteora Shares, which Meteora sells in the open market, will be released from escrow to Petra.

NOTE 7 – COMMITMENTS AND CONTINGENCIES

Registration Rights

The holders of the Founder Shares, private warrants, and warrants that may be issued upon conversion of Working Capital Loans (and all underlying securities) will be entitled to registration rights pursuant to a registration rights agreement to be signed prior to or on the effective date of the Initial Public Offering. The holders of the majority of these securities are entitled to make up to two demands that the Company register such securities. The holders of the majority of the Founder Shares can elect to exercise these registration rights at any time commencing three months prior to the date on which the Founder Shares are to be released from escrow.

Underwriting Agreement

The Company granted the underwriters a 45-day option from the date of the prospectus filed on October 13, 2020 to purchase up to 1,050,000 additional units to cover over-allotments, if any, at the Initial Public Offering price less the underwriting discounts and commissions.

The underwriters are entitled to a cash underwriting discount of $ 0.20 per unit, or $ 1,400,000 in the aggregate (or $ 1,610,000 in the aggregate if the underwriters' over-allotment option is exercised in full), payable upon the closing of the Proposed Public Offering, and deferred compensation of $0.40 per unit, or $2,800,000 upon completion of a business combination or $ 3,220,000 in the aggregate if the underwriters' over-allotment option is exercised in full. As of December 31, 2021, a total of $2,911,260 has been recorded for the payment of the deferred underwriting fee.

See Note 3 for partial exercise of over-allotment subsequent to the Initial Public Offering. The remaining portion of the over-allotments units expired.

Business Combination Marketing Agreement

The Company has engaged LifeSci Capital LLC as an advisor in connection with a Business Combination to assist the Company in holding meetings with its stockholders to discuss the potential Business Combination and the target business' attributes, introduce the Company to potential

investors that are interested in purchasing the Company's securities in connection with a Business Combination, assist the Company in obtaining shareholder approval for the Business Combination and assist the Company with its press releases and public filings in connection with the Business Combination. The Company will pay LifeSci Capital LLC a cash fee for such services upon the consummation of a Business Combination in an amount equal to 4.0% of the gross proceeds of the Initial Public Offering, exclusive of any applicable finders' fees which might become payable.

Agreement and Plan of Merger

On August 29, 2021, the Company entered into an Agreement and Plan of Merger (the "Agreement") with Petra Acquisition Merger Inc., a Delaware corporation ("Merger Sub"), and Revelation Biosciences, Inc., a Delaware corporation ("Revelation"). Pursuant to the terms of the Agreement, Merger Sub shall be merged with and into Revelation becoming a wholly-owned subsidiary of the Company and the Company will change its name to Revelation Biosciences, Inc.

In accordance with the terms of the Agreement, at the Closing the Company will issue 10,500,000 shares of its common stock to Revelation as consideration for 100% of Revelation's outstanding equity interests. Immediately following the Closing, the Company will have 12,944,213 (excluding 4,734,024 shares subject to redemption) shares of common stock issued and outstanding. The pre-merger stockholders of the Company will retain an aggregate of 1,819,538 shares of common stock of the Company, representing 14% ownership of the post-Merger Company. Therefore, upon consummation of the Merger, there will be a change in control of the Company, with the former owners of Revelation effectively acquiring control of the Company. The Merger will be treated as a reverse recapitalization effected by a share exchange for financial and reporting purposes since the Company will be deemed to be a shell corporation with nominal operations and assets at the time of the Merger. Revelation will be considered the acquirer for accounting purposes, and the Company's historical financial statements before the Merger will be replaced with the historical financial statements of Revelation before the Merger in future filings.

Pursuant to the terms of the Agreement, at the Closing Date, the Company shall file a certificate of merger with the Secretary of State of the State of Delaware, executed in accordance with the relevant provisions of the DGCL (the "Certificate of Merger"). The Merger shall become effective upon the filing of the Certificate of Merger or at such later time as is agreed to by the parties and specified in the Certificate of Merger. As of December 31, 2021, the Company did not file the Certificate of Merger with the Secretary of State of the State of Delaware.

In accordance with the terms and subject to the conditions of the Business Combination Agreement, at the Effective Time, (i) each share of common stock and preferred stock of Old Revelation outstanding as of immediately prior to the Effective Time was exchanged for shares of common stock, par value $0.001 per share, of Revelation based on the agreed upon the Common Stock Exchange Ratio; (ii) each Old Revelation RSU award (as defined in the Business Combination Agreement) outstanding as of immediately prior to the Effective Time was assumed by Revelation and was converted into that number of whole Revelation Rollover RSU awards (as defined in the Business Combination Agreement) based on the Common Stock Exchange Ratio; and (iii) each Old Revelation Warrant (as defined in the Business Combination Agreement) outstanding as of immediately prior to the Effective Time was assumed by Revelation and was converted into that number of whole Revelation Rollover Warrants (as defined in the Business Combination Agreement) based on the Common Stock Exchange Ratio, at an exercise price per share of Common Stock equal to (x) the exercise price per share of Old Revelation common stock of such Old Revelation Warrant divided by (y) the Common Stock Exchange Ratio.

NOTE 8 - STOCKHOLDERS' EQUITY

Common Stock

The authorized common stock of the Company is up to 100,000,000 shares of common stock. If the Company enters into an Initial Business Combination, it may (depending on the terms of such an Initial Business Combination) be required to increase the number of shares of common stock which the Company is authorized to issue at the same time as the Company's stockholders vote on the Initial Business Combination to the extent the Company seeks stockholder approval in connection with the Initial Business Combination. Holders of the Company's common stock are entitled to one vote for each share of common stock. At December 31, 2021, there were 6,553,562 shares of common stock issued and outstanding, of which 4,734,024 shares were subject to possible redemption and are classified outside of permanent equity at the balance sheet. On October 27, 2021 the Company paid an aggregate of $25,698,161 in cash to various Unit holders to redeem 2,544,127 shares of the common stock subject to redemption.

Preferred Stock

The Company is authorized to issue 1,000,000 shares of preferred stock with such designations, voting and other rights and preferences as may be determined from time to time by the Company's board of directors. At December 31, 2021, there were no shares of preferred stock issued or outstanding.

Warrants

As of December 31, 2021 there were 7,278,151 Public Warrants and 3,233,446 Private Warrants issued and outstanding.

The Public Warrants will become exercisable on the later of (a) 30 days after the completion of a Business Combination or (b) 12 months from the closing of the Initial Public Offering. No warrants will be exercisable for cash unless the Company has an effective and current registration statement covering the shares of common stock issuable upon exercise of the warrants and a current prospectus relating to such shares of common stock. Notwithstanding the foregoing, if a registration statement covering the shares of common stock issuable upon exercise of the public warrants is not effective within a specified period following the consummation of a Business Combination, warrant holders may, until such time as there is an effective registration statement and during any period when the Company shall have failed to maintain an effective registration statement, exercise warrants on a cashless basis pursuant to the exemption provided by Section 3(a) (9) of the Securities Act, provided that such exemption is available. If that exemption, or another exemption, is not available, holders will not be able to exercise their warrants on a cashless basis. The Public Warrants will expire five years after the completion of a Business Combination or earlier upon redemption or liquidation.

Once the warrants become exercisable, the Company may redeem the Public Warrants as follows:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption;
- if, and only if, the reported last sale price of the Company's common stock equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period ending on the third business day prior to the notice of redemption to the warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying the warrants.

If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement.

The Private Warrants are identical to the Public Warrants underlying the Units being sold in the Initial Public Offering, except that the Private Warrants and the shares of common stock issuable upon the exercise of the Private Warrants will not be transferable, assignable or salable until after the completion of a Business Combination, subject to certain limited exceptions. Additionally, the Private Warrants will be exercisable for cash or on a cashless basis at the holder's option, and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Private Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

See Note 6 for Private Warrants issued for cash.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of common stock at a price below its exercise price. Additionally, in no event will the Company be required to net cash settle the warrants. If the Company is unable to complete a Business Combination within the Combination Period and the Company liquidates the funds held in the Trust Account, holders of warrants will not receive any of such funds with respect to their warrants, nor will they receive any distribution from the Company's assets held outside of the Trust Account with the respect to such warrants. Accordingly, the warrants may expire worthless.

In addition, if (x) the Company issues additional shares of common stock or equity-linked securities for capital raising purposes in connection with the closing of an initial Business Combination at an issue price or effective issue price of less than $9.50 per share of common stock (with such issue price or effective issue price to be determined in good faith by the Company's board of directors, and in the case of any such issuance to our sponsor, initial stockholders or their affiliates, without taking into account any founders' shares held by them prior to such issuance), (y) the aggregate gross proceeds from such issuances represent more than 60% of the total equity proceeds, and interest thereon, available for the funding of an initial Business Combination on the date of the consummation of an initial Business Combination (net of redemptions), and (z) the volume weighted average trading price of the common stock during the 20 trading day period starting on the trading day prior to the day on which the Company consummated an initial Business Combination (such price, the "Market Value") is below $9.50 per share, the exercise price of the warrants will be adjusted (to the nearest cent) to be equal to 115% of the greater of (i) the Market Value or (ii) the price at which the Company issues the additional shares of common stock or equity-linked securities.

NOTE 9 – FAIR VALUE MEASUREMENTS

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually.

The fair value of the Company's financial assets and liabilities reflects management's estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on our assessment of the assumptions that market participants would use in pricing the asset or liability.

The following table presents information about the Company's assets that are measured at fair value on a recurring basis at December 31, 2021 and 2020 and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	December 31, 2021	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash held in Trust Account	$ 48,302,521	$ 48,302,521	$ -	$ -
Cash held outside of Trust Account	$ 78,532	$ 78,532	$ -	$ -
Liabilities:				

Warrant Liability—Private Placement Warrants	$ 2,390,258	$ -	$ -	$ 2,390,258

Description	December 31, 2020	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash held in Trust Account	$ 73,510,915	$ 73,510,915	$ -	$ -
Marketable securities held outside of Trust Account	$ 525,287	$ 525,287	$ -	$ -
Liabilities:				
Warrant Liability—Private Placement Warrants	$ 3,399,878	$ -	$ -	$ 3,399,878

The fair value of the Private Warrants have been using a Monte Carlo simulation since the initial measurement date. For the year ended December 31, 2021, the Company recognized a gain in the statement of operations resulting from a decrease of $1,009,620 in the fair value of warrant liabilities, presented as change in fair value of derivative warrant liability. For the year ended December 31, 2020, the Company recognized a loss in the statement of operations resulting from an increase of $1,494,092 in the fair value of warrant liabilities, respectively, presented as change in fair value of derivative warrant liability.

The estimated fair value of the Private Placement Warrants prior to being separately listed and traded, is determined using Level 3 inputs. Inherent in a Monte Carlo simulation are assumptions related to expected stock-price volatility, expected life, and risk-free interest rate. The Company estimates the volatility of its common stock warrants based on implied volatility from the Company's traded warrants and from historical volatility of select peer companies' common stock that matches the expected remaining life of the Warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the Warrants. The expected life of the Warrants is assumed to be equivalent to their estimated remaining life.

The following table provides quantitative information regarding Level 3 fair value measurement inputs for the Private Warrants at December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Risk free interest rate	1.27%	0.46%
Expected term (years)	5.09	5.71
Expected volatility	10.6%	17.20%

The following table represents the changes in fair value of the Private Placement Warrants:

Fair value as of December 31, 2019	$ -
Initial measurement on October 13, 2020	1,905,786
Change in valuation inputs or other assumptions	1,494,092
Fair value as of December 31, 2020	$ 3,399,878
Change in valuation inputs or other assumptions	(1,009,620)
Fair value as of December 31, 2021	$ 2,390,258

There were no transfers in or out of Level 3 from other levels in the fair value hierarchy.

NOTE 10 – INCOME TAXES

The Company accounts for income taxes under ASC 740 - Income Taxes ("ASC 740"), which provides for an asset and liability approach of accounting for income taxes. Under this approach, deferred tax assets and liabilities are recognized based on anticipated future tax consequences, using currently enacted tax laws, attributed to temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts calculated for income tax purposes.

Significant components of the Company's deferred tax assets as of December 31, 2021 and 2020 are summarized below:

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operation loss carryforwards	$ 821,000	$ 35,000
Total deferred tax asset	821,000	35,000
Valuation allowance	(821,000)	(35,000
	$ -	$ -

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. The Company assessed the need for a valuation

allowance against its net deferred tax assets and determined a full valuation allowance is required as the Company has no history of generating taxable income. Therefore, a valuation allowance of $821,000 was recorded as of December 31, 2021. Deferred tax assets were calculated using the Company's combined effective tax rate, which it estimated to be approximately 26%. The effective rate is reduced to 0% for 2021 due to the full valuation allowance on its net deferred tax assets.

The Company's ability to utilize net operating loss carryforwards will depend on its ability to generate adequate future taxable income. Future utilization of the net operating loss carry forwards is subject to certain limitations under Section 382 of the Internal Revenue Code. As of December 31, 2021, the Company had net operating loss carryforwards available to offset future taxable income in the amounts of approximately $3,277,000. Federal net operating loss carryforwards generated do not expire whereas state carryforwards begin to expire in 2040.

The Company has evaluated its income tax positions and has determined that it does not have any uncertain tax positions. The Company will recognize interest and penalties related to any uncertain tax positions through its income tax expense.

The Company is subject to franchise tax filing requirements in the State of Delaware. The Company's tax returns in all jurisdictions remain open to examination.

NOTE 11 – SUBSEQUENT EVENTS

Business Combination

On January 10, 2022 (the "Effective Date" or "Closing Date"), the Company consummated the business combination pursuant to the terms of the Agreement. Pursuant to the terms of the Agreement, at the effective time of the Merger, (i) each share of common stock and preferred stock of Old Revelation outstanding as of immediately prior to the Effective Date will be exchanged for shares of common stock, par value $0.001 per share, of Revelation common stock based on the Common Stock Exchange Ratio; (ii) each Revelation Rollover RSU award (as defined in the Agreement) outstanding as of immediately prior to the Effective Date was assumed by Revelation and was converted into that number of whole Revelation Rollover RSU awards (as defined in the Agreement) based on the Common Stock Exchange Ratio; and (iii) each Revelation Rollover Warrant (as defined in the Agreement) outstanding as of immediately prior to the Effective Date was assumed by Revelation and was converted into that number of whole Revelation Rollover Warrants (as defined in the Agreement) based on the Common Stock Exchange Ratio, at an exercise price per share of Common Stock equal to (x) the exercise price per share of Revelation common stock of such Revelation Rollover Warrant divided by (y) the Common Stock Exchange Ratio.

At the Closing Date, up to 10,500,000 shares of Common Stock constituting the Merger Consideration, (i) an aggregate of 9,871,343 shares of Common Stock were issued in exchange for the Old Revelation stock outstanding as of immediately prior to the Effective Date, (ii) 167,867 shares of Common Stock were reserved for issuance for Revelation Rollover Warrants outstanding as of immediately prior to the Effective Date and (iii) 460,706 shares of Common Stock were reserved for issuance for Revelation Rollover RSU's outstanding as of immediately prior to the Effective Date.

Immediately after giving effect to the Business Combination, there were 12,944,213 shares of Common Stock outstanding, and 1,294,421 shares of Common Stock reserved for future issuance under the 2021 Equity Incentive Plan. The pre-merger stockholders of the Company retained an aggregate of 3,072,870 shares of common stock of the Company, representing 23.7% ownership of the post-Merger Company. Therefore, upon consummation of the Business Combination, there was a change in control of the Company, with the former owners of Revelation effectively acquiring control of the Company.

The Business Combination will be accounted for as a reverse recapitalization, in accordance with U.S. GAAP. Under this method of accounting, although Petra will issue shares for outstanding equity interests of Revelation in the Business Combination, Petra will be treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination will be treated as the equivalent of Revelation issuing stock for the net assets of Petra, accompanied by a recapitalization. The net assets of Petra will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be those of Revelation.

Additionally, in connection with the Merger, holders of 3,480,362 shares of the Company's common stock exercised their right to redeem such shares for cash at a price of approximately $10.20 per share for payments in the aggregate of approximately $35.5 million. On the Closing Date, pursuant to the Backstop Agreements, the Backstop Subscribers purchased an aggregate of 432,072 shares of Petra Common Stock and approximately $7.6 million was escrowed pursuant to the Forward Share Purchase Agreement entered into by and between the Company and Meteora and approximately $4.2 million was released to the Company.

At the Closing of the Business Combination, Petra changed its name to "Revelation Biosciences, Inc." and adopted the third amended and restated certificate of incorporation (the "Restated Charter"), which became effective upon filing with the Secretary of State of the State of Delaware on January 10, 2022.

Premium Finance Agreement

On January 10, 2022, REVB entered into a Premium Finance Agreement (the "Finance Agreement") with a lender that directly paid the Company's D&O insurance due upon closing of the business combination with Petra Acquisition, Inc in the amount of $825,000. Under the terms of the Finance Agreement, the financing accrues interest at a fixed rate of 3.75% per annum payable monthly for a total of $ 9,856.41 over the term of the Finance Agreement. Monthly payments of $74,428.49, are to be paid in nine monthly installments, which commenced on February 10, 2022 with a maturity date of October 10, 2022. Upon entering into the Premium Finance Agreement, a payment of $165,000.00 was due and paid on February 14, 2022.

PIPE Investment/Securities Purchase Agreement

On January 23, 2022, the Company entered into a Securities Purchase Agreement with an institutional investor ("Purchaser") pursuant to which Purchaser agreed to purchase, and the Company agreed to issue and sell to Purchaser in a private placement, 1,293,126 shares of common stock at a gross purchase price of $3.00 per share (the "Shares") (the "PIPE Investment"), 1,293,541 unregistered pre-funded warrants to purchase common stock (the "Pre-Funded Warrants") and 2,586,667 unregistered warrants to purchase common stock (the "Common Warrants" and together with the Pre-Funded Warrants and Placement Agent Warrants (as hereinafter defined), collectively, the "Warrants"). The closing under the Securities Purchase Agreement was consummated on January 25, 2022. The gross proceeds to the Company, before deducting placement agent fees and other offering expenses, are approximately $7.76 million.

Each Pre-Funded Warrant has been funded to the amount of $ 3.00, with $0.00001 per share of common stock payable upon exercise, is immediately exercisable, may be exercised at any time until exercised in full and is subject to customary adjustments. Each Common Warrant has an exercise price of $3.29 per share of common stock, is exercisable at any time after the sixth month anniversary of the date of issuance, will expire five and one-half years from the date of issuance and is subject to customary adjustments. The Pre-Funded Warrants may not be exercised if the aggregate number of shares of the Company's common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the Company's outstanding common stock immediately after exercise. The Common Warrants may not be exercised if the aggregate number of shares of the Company's common stock beneficially owned by the holder (together with its affiliates) would exceed 4.99% of the Company's outstanding common stock immediately after exercise. However, in each case, the holder may increase (upon 61 days' prior notice from the holder to the Company) or decrease such percentages, provided that in no event such percentage exceeds 9.99%.

The Company intends to use the net proceeds from the private placement to advance its clinical and preclinical pipeline and for general working capital purposes.

Also on January 23, 2022 and in connection with the private placement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchaser, pursuant to which the Company agreed to use its best efforts to file a registration statement on Form S-1 to register for resale the Shares and any shares of the Company's common stock issuable upon exercise of the Warrants by January 31, 2022, but in no event later than February 4, 2022.

ROTH Capital Partners, LLC (the "Placement Agent') was engaged by the Company to act as its exclusive placement agent for the private placement. The Company agreed to pay the Placement Agent a cash fee equal to 6.0% of the gross proceeds received by the Company in the private placement, totaling approximately $465,600. In addition, the Company agreed to issue to the Placement Agent warrants to purchase up to 362,134 shares of common stock (representing 7.0% of the aggregate number of shares of common stock sold in the private placement (including shares of common stock issuable upon the exercise of any of the Warrants)) (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the Common Warrants.

Using the Black-Scholes option pricing model, the Common Warrants were valued in the aggregate at $ 3.6 million and the Placement Agent Warrants were valued in the aggregate at $0.5 million. Both were included in the issuance costs of the private placement.

Common Stock Issuance

On January 31, 2022, 300,000 shares of the Company's common stock were issued as collateral to Loeb & Loeb, LLP in connection with deferral of cash payment of 50% of legal fees due upon the Closing Date of the Business Combination.

Rollover Warrant Exercise

On February 2, 2022, the Company received a notice of cash exercise for the Company's Rollover Warrants for 1,891 shares of common stock at a purchase price of $5,073.14.

Forward Purchase Agreement Exercise

On February 4, 2022, Meteora exercised the Forward Share Purchase agreement entered into by and between the Company. 750,000 shares were repurchased by the Company and approximately $7.6 million that was escrowed was returned to Meteora.

Legal Proceedings

On February 18, 2022, LifeSci Capital LLC filed an action against the Company in the U.S. District Court for the Southern District of New York seeking damages in the amount of approximately $2.7 million in cash and $2.6 million in equity for unpaid banking and advisory fees. These fees arise under contracts which were entered into prior to the merger between Petra Acquisition, Inc. and Old Revelation and the Company is disputing the amount owed under those contracts. The Company's response to the suit is due May 1, 2022.

Pre-Funded Warrants Exercise

On February 22, 2022, the Company received a notice of cash exercise for the Pre-Funded Warrants issued in connection with the PIPE Investment for 1,293,541 shares of common stock at purchase price of $ 12.94.

Stock Option Grants

On February 25, 2022, 354,452 stock options, with and exercise price of $ 1.40 per share, were granted to employees which resulted in a fair value of $0.7 million of stock-based compensation expense using the Black-Scholes option pricing model. The grants were granted from shares of the 2021 Equity Plan and vest over four years, with 25% vesting on the one-year anniversary and the remainder vesting quarterly thereafter.