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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

☐ 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: 001-40793

Ocean Biomedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	87-1309280
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
55 Claverick St., Room 325 Providence, RI	02903
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (401) 444-7375

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	OCEA	The NASDAQ Stock Market LLC
Warrants, each exercisable for one share of common stock at an exercise price of $11.50	OCEAW	The NASDAQ Stock Market LLC

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant on June 30, 2023, based on the closing price of $6.01 for shares of the registrant's common stock as reported by The Nasdaq Stock Market, was approximately $1,630,831.53.

There were 34,818,628 common stock shares of the registrant outstanding on November 22, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OCEAN BIOMEDICAL, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K ("Report"), including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and are being made pursuant to the safe harbor provisions contained therein. These forward-looking statements relate to current expectations and strategies, future operations, future financial positioning, future revenue, projected costs, prospects, current plans, current objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from expectations, estimates, and projections expressed or implied by these forward-looking statements and, consequently, you should not rely on these forward-looking statements as a guarantee, an assurance, a prediction or a definitive statement of fact or probability of future events. In some cases, you can identify forward-looking statements through the use of words or phrases such as "may", "should", "could", "predict", "potential", "plan", "seeks", "believe", "will likely result", "expect", "continue", "will continue", "will", "will be", "anticipate", "seek", "estimate", "intend", "plan", "projection", "would", "outlook", and similar expressions, or the negative version of those words or phrases or other comparable words or phrases of a future or forward-looking nature, but the absence of such words does not mean that a statement is not forward-looking. These forward-looking statements are not historical facts, but instead they are predictions, projections and other statements about future events are based upon estimates and assumptions that, while considered reasonable by the registrant and its management, are inherently uncertain. These forward-looking statements are provided for illustrative purposes only and actual events and circumstances are difficult or impossible to predict and will differ from assumptions.

Forward-looking statements in this Report refer to Ocean Biomedical and include, but are not limited to, statements about:

- our future financial performance;
- estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the success, cost and timing of product development activities and clinical trials of product candidates, including the progress of, and results from, planned clinical trials;
- the success, cost and timing of completing IND-enabling studies of preclinical product candidates, and the timing of planned Investigational New Drug Application, or IND, submissions for such candidates;
- plans to initiate, recruit and enroll patients in, and conduct planned clinical trials at the projected pace;
- the intended benefits of our business model;
- our ability to acquire licenses or otherwise obtain new product candidates to add to our portfolio for clinical development;
- plans and strategy to obtain and maintain regulatory approvals of product candidates;
- plans and strategy to obtain funding for operations, including funding necessary to complete further development and, upon successful development, if approved, commercialize any product candidates;
- the potential benefit of any future orphan drug designations for product candidates;
- our ability to compete with companies currently marketing or engaged in the development of treatments for fibrosis;
- plans and strategy regarding obtaining and maintaining intellectual property protection for product candidates and the duration of such protection;

- plans and strategy regarding the manufacture of product candidates for clinical trials and for commercial use, if approved;
- plans and strategy regarding the commercialization of any products that are approved for marketing;
- the size and growth potential of the markets for product candidates, and our ability to serve those markets, either alone or in combination with others;
- expectations regarding government and third-party payor coverage and reimbursement;
- success in retaining or recruiting, or changes required in, officers, key employees or directors;
- public securities' potential liquidity and trading;
- impact from the outcome of any known and unknown litigation;
- future financial performance, including financial projections and business metrics and any underlying assumptions thereunder;
- future business or product expansion, including estimated revenues and losses, projected costs, prospects and plans;
- trends in the healthcare industry;
- ability to scale in a cost-effective manner;
- ability to obtain and maintain intellectual property protection;
- future capital requirements and sources and uses of cash; and
- impact of competition and developments and projections relating to competitors and industry.

Many factors may cause actual results to differ materially from these forward-looking statements including, but not limited to:

- the risk of changes in applicable laws or regulations;
- the risk of the need and ability to raise additional capital and the terms on which such capital is received;
- the risk of our inability to succeed in clinical development or obtain FDA approval of lead pipeline indications;
- increased regulatory costs and compliance requirements in connection with drug development;
- the risk of our potential inability to comply with FDA post-approval requirements;
- the risk of failure to comply with manufacturing regulations or unexpected increases in manufacturing costs;
- the risk of the inability of our products to achieve broad market acceptance of existing or planned products and services and achieving sufficient production volumes at acceptable quality levels and prices;
- the risk of increased competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations;
- new FDA approved drugs that compete with us in targeted indications;
- the risk of failure of third party service providers to comply with contractual duties;
- the risk of failure to comply with international, federal and state healthcare;
- the impact of COVID-19 on operations including its preclinical studies and clinical trials;
- risks related to the ongoing COVID-19 pandemic and response, including supply chain disruptions;
- the possibility that we may be adversely impacted by other economic, business, and/or competitive factors
- changes in the markets in which we compete, including with respect to our competitive landscape, technology evolution, or regulatory changes;
- the risk that we may fail to keep pace with rapid technological developments to provide new and innovative products and services or make substantial investments in unsuccessful new products and services;

- the risk that the addressable market we intend to target does not grow as expected;
- the risk of our inability to expand and diversify our manufacturing customer base;
- changes in domestic and global general economic conditions;
- the risk of loss of any key executives;
- the risk of loss of any relationships with key partners;
- the risk of loss of any relationships with key suppliers;
- the risk of our inability to protect patents and other intellectual property;
- the risk of lower than expected adoption rates;
- the risk of the inability to develop, license or acquire new therapeutics;
- the risk of the inability to initiate and increase engagement with distributors;
- the risk of fluctuations in results of our major manufacturing customers;
- the risk of our inability to execute our business plans and strategies, including growth strategies;
- the risk that we experience difficulties in managing growth and expanding operations;
- the risk that we may not be able to develop and maintain effective internal controls;
- the risk of our inability to maintain sufficient inventory and capacity to meet customer demand;
- the risk of our inability to deliver expected cost and manufacturing efficiencies;
- the risk that we will need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at all;
- the risk of product liability or regulatory lawsuits or proceedings relating to our business;
- the risk of cyber security or foreign exchange losses;
- general economic conditions and geopolitical uncertainty;
- future exchange and interest rates; and
- other risks and uncertainties, including those in the section entitled “Risk Factors” in this Report, and other documents filed or to be filed with the SEC by the Company.

The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties that are described in the section entitled “Risk Factors” in this Report, which are incorporated herein by reference, as well as other documents to be filed by us from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and while we may elect to update these forward-looking statements at some point in the future, they assume no obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. We are not giving any assurance that we will achieve our expectations. These forward-looking statements should not be relied upon as representing our assessments as of any date subsequent to the date of this Report. Accordingly, undue reliance should not be placed upon the forward-looking statements.

SUMMARY OF RISK FACTORS

You should read this summary together with the description of each risk factor contained in Item 1A of this Report, as well as other documents to be filed by us from time to time with the SEC, for a more detailed discussion of certain risks that could materially adversely affect our financial conditions and the market price of our securities. The following list describes some of our principal risk factors after the Closing of the Business Combination:

- We have incurred significant net losses since inception and we are expected to continue to incur significant net losses for the foreseeable future.
- We may not be successful in our efforts to use our differentiated business model to build a pipeline of product candidates with commercial value.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts and/or other operations.
- We are a biopharmaceutical company with a limited operating history, and many of our development programs are in early stages of development. This may make it difficult to evaluate our prospects and likelihood of success.
- Our underlying technology is unproven and may not result in marketable products.
- Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.
- Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- The market opportunities for our product candidates may be relatively small since the patients who may potentially be treated with our product candidates are those who are ineligible for or have failed prior treatments, and our estimates of the prevalence of our target patient populations may be inaccurate.
- We rely on third parties to conduct all or certain aspects of our preclinical studies and clinical trials. 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 of or commercialize any potential product candidates.
- The intellectual property that we have in-licensed has been discovered through government funded programs and thus may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.
- We have entered into and may enter into license, sublicense or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such agreements with third parties, we could lose license or sublicense rights that may be important to our future business.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

- Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.
- We may encounter difficulties in managing our growth, which could adversely affect our operations.
- If we lose key management or scientific personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.
- We identified a material weakness in the Company's internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.
- Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.
- The price of our common stock and warrants may be volatile, and you could lose all or part of your investment.
- We are "controlled company" within the meaning of Nasdaq rules and the rules of the SEC. As a result, we qualify for exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.
- Our principal stockholders and management own a significant percentage of our Common and are able to exert significant control over matters subject to stockholder approval.
- Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans, employee stock purchase plan or otherwise will dilute all other stockholders.
- We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to compliance with its public company responsibilities and corporate governance practices.
- Our management team has limited experience managing a public company.
- There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and warrants.
- We qualify as an "emerging growth company" as well as a "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

PART I

ITEM 1. BUSINESS.

Unless otherwise noted or the context otherwise requires, the disclosures in this Item 1 refer to Ocean Biomedical, Inc. and its subsidiaries following the consummation of the Business Combination and all references to "we," "us," "our," "Ocean Biomedical," or the "Company," are to Ocean Biomedical, Inc.

Introduction

We were originally incorporated in June 2021 as a Delaware corporation under the name "Aesther Healthcare Acquisition Corp." We were a special purpose acquisition company, formed for the purpose of effecting an initial business combination with one or more target companies. On September 17, 2021 (the "IPO Closing Date"), we consummated our initial public offering (the "IPO" or the "Public Offering"). On February 14, 2023 (the "Closing Date"), we consummated the previously announced Business Combination (as defined below) pursuant to that certain Agreement and Plan of Merger, dated August 31, 2022, as amended on December 5, 2022 by Amendment No. 1 (as amended, the "Business Combination Agreement"), by and among the registrant, AHAC Merger Sub, Inc., a Delaware corporation ("Merger Sub"), Aesther Healthcare Sponsor, LLC (the "Sponsor"), in its capacity as purchaser representative, Ocean Biomedical Holdings, Inc., formerly known as Ocean Biomedical, Inc., a Delaware corporation ("Legacy Ocean"), and Dr. Chirinjeev Kathuria, in his capacity as seller representative.

Pursuant to the Business Combination Agreement, on the Closing Date, Merger Sub merged with and into Legacy Ocean, with Legacy Ocean continuing as the surviving entity and a wholly-owned subsidiary of the Company. In connection with the closing of the Business Combination, we changed our name from "Aesther Healthcare Acquisition Corp." to "Ocean Biomedical, Inc."

As contemplated by the Business Combination Agreement, on the Closing Date, Merger Sub merged with and into Legacy Ocean, with Legacy Ocean continuing as the surviving entity and a wholly-owned subsidiary of the registrant (the "Merger," and, together with the other transactions and ancillary agreements contemplated by the Business Combination Agreement, the "Business Combination"). In connection with the closing of the Business Combination (the "Closing"), we changed our name from "Aesther Healthcare Acquisition Corp." to "Ocean Biomedical, Inc." and Legacy Ocean changed its name from "Ocean Biomedical, Inc." to "Ocean Biomedical Holdings, Inc."

As of the open of trading on February 15, 2023, our common stock and public warrants began trading on the Nasdaq Stock Market LLC ("Nasdaq") as "OCEA" and "OCEAW," respectively.

Substantially concurrently with the filing of our previous Annual Report on Form 10-K, we filed an Amendment No. 2 to our Current Report on Form 8-K, initially filed on February 15, 2023, which included the audited consolidated financial statements of Legacy Ocean for the year ended December 31, 2022 and related Management's Discussion and Analysis of Financial Condition and Results of Operations and unaudited proforma financial information for the Company and Legacy Ocean as of December 31, 2022 and for the year then ended. Interested parties should refer to our Current Reports on Form 8-K for more information.

As used in this Annual Report on Form 10-K, unless otherwise noted or the context otherwise requires: (i) references to the "Company," "Ocean Biomedical," "we," "us," "our" and similar terms refer to Ocean Biomedical, Inc. (f/k/a Aesther Healthcare Acquisition Corp.) and its subsidiaries; (ii) references to "Aesther" are to Aesther Healthcare Acquisition Corp. prior to the close of the Business Combination; (iii) references to "Legacy Ocean" are to Ocean Biomedical Holdings, Inc. (f/k/a Ocean Biomedical, Inc.) prior to the close of the Business Combination; and (iv) references to "Sponsor" are to Aesther Healthcare Sponsor, LLC.

Description of Business

We are a biopharmaceutical company that seeks to bridge the "bench-to-bedside" gap between medical research discoveries and patient solutions. We do this by leveraging our strong relationships with research universities and medical centers to license their inventions and technologies with the goal of developing them into products that address diseases with significant unmet medical needs. We believe that our differentiated business model positions us to capture inventions created at these institutions that might otherwise fail to be commercialized to benefit patients. Our team of accomplished scientists, business professionals and entrepreneurs brings together the interdisciplinary expertise and resources required to develop and commercialize a diverse portfolio of assets. We are organized around a licensing and subsidiary structure that we believe will enable us to create mutual value for us and potential licensing partners. We believe this structure, combined with the networks of our leadership team, allows us to opportunistically build a continuous pipeline of promising product innovations through our existing and potential future relationships with research institutions. Our goal is to optimize value creation for each of our product candidates, and we intend to continuously assess the best pathway for each as it progresses through the preclinical and clinical development process—including through internal advancement, partnerships with established companies and spin-outs or initial public offerings—in order to benefit patients through the commercialization of these products. Our current active assets are licensed directly or indirectly from Brown University and Rhode Island Hospital. Our scientific co-founders and members of our board of directors, Dr. Jack A. Elias and Dr. Jonathan Kurtis, are both affiliated with Brown University and with Rhode Island Hospital.

Our Pipeline

Our pipeline consists of preclinical programs. We anticipate moving certain preclinical product candidates in our oncology, fibrosis and/or infectious disease platforms, all licensed exclusively from Brown University and Rhode Island Hospital, into the clinic in the next 12 to 18 months.

Our programs in oncology and fibrosis are based on discoveries of disease pathways and of related drug targets emerging from pioneering work in the field of chitinase biology by our scientific co-founder and member of our board of directors, Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University.

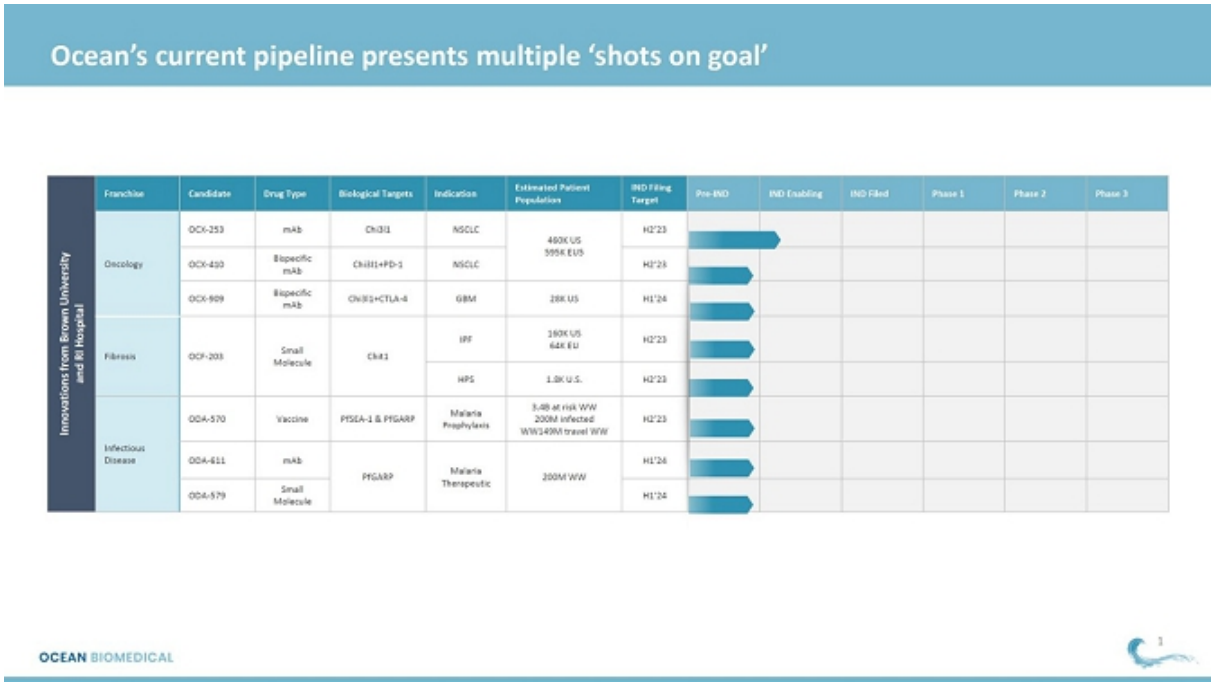
In oncology, our product candidates are based on Dr. Elias' findings that a protein called chitinase 3-like-1, or Chi3l1, is a key driver of multiple disease pathways, including those involved in primary and metastatic tumor development. In animal models of both lung cancer and glioblastoma, inhibition of Chi3l1 resulted in significant tumor reduction, and the reduction was even greater when the inhibition of Chi3l1 was combined with immune checkpoint inhibitors, which are used as immuno-therapies to stimulate the body's immune response against cancer. Neutralizing antibodies against Chi3l1 have been developed that are highly avid, specific, react with mouse, human and monkey Chi3l1 and are effectively expressed and humanized. We are developing a mono-specific antibody, or mAb, and two bi-specific monoclonal antibodies, or BsAbs, product candidates targeting Chi3l1 for the treatment of non-small cell lung cancer, or NSCLC, which affects approximately 460,000 people in the United States, and of glioblastoma multiforme, or GBM, a usually lethal form of brain cancer that affects approximately 28,000 people in the United States. The median survival for individuals diagnosed with GBM is approximately 15 months and the five year survival rate is just 8% for those aged 45-54 and 5% for those aged 55-64.

Our product candidate in fibrosis is based on a drug target investigated by Dr. Elias and closely related to the Chi3l1 oncology target described above. Dr. Elias found that an enzyme called chitinase 1, or Chit1, is a key driver of fibrosis. Fibrosis is observed in an estimated 50% of all diseases. Fibrosis in the lungs tends to be progressive and can reduce their function. In animal models of idiopathic pulmonary fibrosis, or IPF, and Hermansky-Pudlak syndrome, or HPS, inhibition of Chit1 showed statistically significant reduced levels of fibrotic markers. We are developing a small molecule product candidate targeting Chit1 for the treatment of IPF, a debilitating lung disease affecting approximately 160,000 people in the United States, and of HPS, an ultra-rare disease affecting approximately 1,800 in the United States.

In infectious diseases we are developing therapeutic and vaccine candidates against malaria, a mosquito-borne disease that kills 500,000 children under the age of five globally each year, that infects 200-300 million people annually worldwide, and for which 3.4 billion people worldwide are at risk. Our product candidates in malaria are based on the discovery by Jonathan Kurtis, M.D., Ph.D., Chair of Pathology and Laboratory Medicine and Director of the M.D./Ph.D. Program at Brown University, of two novel malaria antigens, PfSEA-1 and PfGARP (as defined below). In non-human primate models of malaria, vaccination with PfGARP resulted in an 11.5-fold reduction of parasites in blood compared to controls. In in-vitro models, our therapeutic antibody candidate against PfGARP reduced parasite count by 99% compared to controls. We have three product candidates based on these new antigens: (1) a malaria vaccine candidate against PfSEA-1 and/or against PfGARP; (2) a humanized mAb malaria product candidate against PfGARP; and (3) a small molecule malaria product candidate, also against PfGARP.

Importantly, Dr. Kurtis' antigen discoveries described above were enabled by his development of our Whole Proteome Differential Screening target discovery platform (the "WPDS" platform). We believe the WPDS platform may enable us to discover new targets for other infectious diseases in the future. The WPDS platform leverages the fact that the immune system, when exposed to an infectious disease such as malaria, will often naturally produce a wide array of antibodies to try fighting the infection. Only a small subset of these antibodies may prove effective, and the WPDS platform is designed to identify these antibodies and their corresponding antigens. We believe that such antibodies and antigens could inform the development of therapeutic and/or vaccine candidates against the particular infectious disease. Prior to in-licensing our product candidates, the preclinical developments of the oncology, fibrosis and malaria programs described above have, to date, been funded through grants to our licensors totaling $105.6 million.

The table below summarizes our product candidate pipeline, target indications, estimated addressable patient populations, and stage of development.



Our Team

Our scientific co-founders and members of our board of directors are Dr. Elias and Dr. Kurtis. Our executive chairman and co-founder is Chirinjeev Kathuria, M.D., an investor and entrepreneur who has co-founded and driven the initial public offerings, or IPOs, of companies in various industries including healthcare. Our chief executive officer, Michelle Berrey, brings a proven track record of building successful portfolios in biopharma companies and raising over $2 billion for such companies. Our team brings expertise in science, medicine, agile drug development, pharma strategy, and innovation management. Collectively, members of the team have evaluated more than 3,500 innovations; been involved in more than 80 drug discovery / development programs, 17 clinical development programs, and 8 approved drugs; have secured more than $120 million in venture capital funding; and have been involved in the launch of 8 biotech or life sciences companies and 3 IPOs. In addition, beyond our day-to-day leadership team, our scientific co-founders and members of our scientific advisory board and board of directors, Dr. Elias and Dr. Kurtis, have authored or co-authored more than 350 papers, secured more than $110 million in grant funding, and are listed as inventors in more than 50 patents.

Our Strategy and Competitive Strengths

Our goal is to facilitate the flow of academic discoveries from bench-to-bedside by efficiently carrying out the translational and clinical development required to advance them commercially. The number of potential opportunities at research universities and medical centers is large but only a small fraction of these opportunities is currently tapped by venture capitalists or pharmaceutical companies. There is a growing yet still small number of accelerator programs and incubators aiming to bridge the bench-to-bedside gap at specific institutions; however, the gap remains wide and we believe this presents an attractive opportunity for us to become an industry leader by addressing a need to accelerate the advancement of therapeutics that can address significant unmet medical needs.

The core elements that we believe differentiate our business model include:

- Harnessing inventions and technologies from research universities and medical centers. We search for opportunities wherever they can be found, and we believe "hidden gems" can be uncovered by our team. We are experienced at identifying and sourcing breakthrough discoveries at academic and research institutions, including our current partnerships with Brown University and Rhode Island Hospital. We know how to assess and test their scientific merits and commercial relevance, and we have extensive experience working with these institutions and licensing their assets. For example, our leadership team has evaluated thousands of innovations, taken multiple products through IND filings and into clinical development, and been involved in the launch of 8 biotech companies.

- Developing new drug therapies through an operationally efficient, evidence-based and milestone-driven approach. Once we select an asset for development, we pursue what we believe are appropriate development strategies that we aim to execute efficiently by leveraging contract research and contract manufacturing organizations, or CROs and CMOs, respectively, and other drug development experts and consultants. We aim to rapidly and efficiently advance our product candidates to objective critical decision points. We direct resources toward the opportunities that we believe are the most promising, and we discontinue programs that do not meet our performance thresholds. We are skilled at objectively directing internal resources, and at leveraging external resources (such as CROs and CMOs), in order to progress product candidates in accordance with well-defined criteria for advancement within a lean cost structure.

- Building a diverse portfolio of product candidates. We are evidence-based and program agnostic, meaning that our resources are driven strictly by program progress and milestone achievements. Our approach is to develop multiple diverse programs in parallel. Our success is not dependent on any one particular program, disease area or indication, which mitigates business risk, and allows us the flexibility to opportunistically develop product candidates, regardless of therapeutic area. We believe that this model ensures that we remain focused on assets with the most promise. The unifying theme in our portfolio is to address significant unmet medical needs by commercializing innovative therapeutic products, if approved.

- Providing attractive economic upside to our partners at research universities and medical centers. We have a structure wherein Ocean Biomedical houses each of its programs in a subsidiary. We believe this structure is optimal to provide attractive economic incentives to the discovering institution and its researchers. Our subsidiary structure is intended to enable us to offer equity in future programs to the licensing institution and the researchers who discover our product candidates. We believe this structure will make us a partner of choice for both institutions and researchers and aligns our interests with theirs toward the goal of maximum returns.

- Employing a multi-disciplinary approach to drug discovery and development across our programs. Our business model is based on bringing together the appropriate disciplines and expertise needed for each of our programs and leveraging learnings across programs and disease areas. Common ties between many diseases are becoming apparent and similar therapeutic strategies are increasingly being applied to different diseases. For example, our oncology and fibrosis programs are both based upon chitinase biology. Another example is the confluence of thinking about immunology and oncology therapeutic approaches which led to the advent of immune checkpoint inhibitors.

- Exploiting multiple commercialization options to maximize each program's value. Throughout the development of our product candidates, we continually assess that program's potential paths to market, and we will endeavor to maximize commercial value through various options, including internal advancement, partnerships with established companies, and spin-outs or IPOs. We believe that our structure and operational strategy enables us to assess and pursue the course that maximizes outcomes for patients and value for our shareholders.

- Leadership team comprised of academic, scientific and business innovators. We have assembled an industry-leading, multi-disciplinary team consisting of physicians, scientists and business leaders with significant experience in progressing product candidates from early-stage research through clinical trials, regulatory approval and ultimately to commercialization.

We believe our differentiated business model enables us to advance the commercialization of our products, if approved, and will allow us to replicate our licensing partnerships through aligned incentive structures with research universities and medical centers.

Feeding our Pipeline: Harnessing Innovations from Research Centers

Our innovative business model is aimed at translating biomedical inventions from research universities and medical centers into products that we believe have the potential to dramatically improve patients' lives. Unlike many biotech companies, our success is not dependent on any one particular program or disease. Our current pipeline is already well-diversified and our access to innovations from academic and medical institutions allows us the flexibility to opportunistically develop product candidates, regardless of therapeutic area. We believe our sources of medical discoveries include not only research universities and medical centers but also companies with assets that are not core to their business model.

We use highly selective criteria and stringent due diligence for selecting assets for development. Picking the right assets requires unbiased and objective science/technology and market assessments that are not affected by institutional legacies, not blinded by research myopia or academic necessities, and not influenced by "herd mentalities." We seek to develop technologies that meet our stringent selection criteria and which are amenable to our controlled de-risking process that we believe can lead to clear and timely value inflection points and milestones. We intend to keep our focus on projects and technologies that demonstrate clear progress towards becoming commercially viable products. Our business model aims to diversify our approach away from a single vector of technology research or science, and instead to pursue a variety of promising research avenues simultaneously and cost effectively. As explained previously, we believe that we can address the resourcing challenges inherent in such diversity and that the diversity itself is an advantageous business strategy.

Our model for identifying, structuring and developing assets is based on the following tenets:

- We believe we have a disciplined process for identification, selection and prioritization of programs: We believe that only well-defined science can be monetized successfully. Independent analyses of pharmaceutical research and development productivity indicate that ill-defined science is a major cause of low success rates and eventual failure of programs. We believe that there is no substitute for a thorough science/technology assessment upfront as it is essential to have a clear understanding of the science and a clear vision of how a technology becomes a product before starting the development effort.

- Our approach to selecting programs is opportunistic: We seek opportunities based on solid science, well-characterized drug mechanisms of action, and targets with true disease-modifying potential that can address significant unmet medical needs. While many such opportunities may be found at leading universities and medical centers, we search for promising technologies wherever they can be found. We believe that such technologies can be located at institutions across the world. We are open to evaluating programs at any stage of development. We are purposely opportunistic and agnostic as to therapeutic area. Our strategy is to bring the appropriate and the most current expertise to bear as needed for each program.

- We aim for efficient therapeutic development operations: Once we select an asset for development, we leverage our years of experience in drug development to create appropriate development strategies. We aim to execute such strategies efficiently by leveraging CROs and other drug development experts and consultants. The development process is managed by our experienced team with support from leaders and experts in the relevant disease areas. We aim to rapidly and efficiently advance our product candidates to objective critical decision points. We direct resources toward the opportunities that we believe are the most promising, and we discontinue programs that do not meet performance thresholds. Each development program is carried forward with what we believe to be the right balance of effort from our centralized resources and personnel, through which we share certain support functions across various programs, combined with specialist external providers as appropriate. This combination is designed to ensure that each program has the appropriate level and type of resources required to execute its unique development strategy while minimizing fixed costs at the program level.

- We believe our structure supports our strategic aims: We are structured in a manner where Ocean Biomedical currently houses each program in a wholly-owned subsidiary. This structure is designed to leverage a main feature of our business model in which each program is derived from our acquisition of a license to assets from a research university or similar institution. This structure is intended to allow us to provide attractive economic incentives to the institution and its relevant investigators. We intend in the future, as new programs are licensed in by us, to grant a certain percentage of the ownership in the new subsidiaries we create for such programs, targeting 20% in aggregate, to the institution and to the researchers. This model is also designed to align our interests with those of our partners and to facilitate our access to the particular program's scientific expertise and know-how. We believe this approach will make us the partner of choice or licensee of choice for institutions and researchers because we aim to act with greater speed and to provide better potential upside when compared to pharmaceutical companies or venture-backed biotechnology companies with whom the institution might also consider partnering.

- We believe that our diversified pipeline approach provides us with meaningful advantages: Unlike biotechnology companies that are focused on a narrow set of assets, on a single platform, or on a particular therapeutic area, we are advancing a diverse portfolio of several programs in parallel. In so doing, we aim to avoid the duplication of resources, the extra costs and the lack of valuable cross-pollination that would likely exist if each program were pursued as independent assets. We are evidence-based and program agnostic, where deployment of program resources are driven strictly by program progress and milestone achievements. We believe that our diverse, multi-program business model and our access to a robust pipeline of opportunities helps us to remain focused on the most promising assets. We believe this focus differentiates us advantageously from biotech companies that, by purposely being focused, have bet their fortunes on a limited number of programs.

- We aim to create optionality for maximum impact and value creation in each program: Throughout the development of any program we continuously assess that program's potential paths to market and monetization. We anticipate that such paths may include: (a) taking a candidate all the way through to potential approval and product launch via internal funding; (b) externalizing development with a strategic partner that we believe is better suited to progress a program; and (c) spinning out or taking a candidate's subsidiary public. We believe that our structure and operational strategy enables us to objectively assess and choose the option that maximizes potential value for patients and for our shareholders.

Our Structure: Supporting Innovation

We are structured in a manner where Ocean Biomedical houses each program in a subsidiary. We currently house our programs in four wholly-owned subsidiaries and intend to grant a certain percentage of the ownership in future subsidiaries, typically 20% in aggregate, to the institution and to the relevant researchers. This anticipated organizational structure for future subsidiaries is unique in the market and we believe it will make us the partner of choice for institutions and inventors.

Currently, research universities and medical centers (institutions) have two primary options to commercialize their biomedical innovations and technologies: licensing to pharma, or licensing to startups that are usually founded or co-founded by the researchers (the inventors) behind the innovations. Most commonly, the IP policy of U.S. institutions specifies that economic value received from licenses is split equally among the institution, the individual inventor(s), and their department or school.

Licensing to a large pharmaceutical company is appealing due to the vast resources it may employ to pursue commercial development and the potential for large up-front and milestone payments. However, these companies often only license innovations later in their development. Therefore, licenses to large pharmaceutical companies are relatively rare.

Researchers often choose to license their innovations to startups because (i) they see greater economic upside (as compared to only receiving a fraction of what their institution receives), (ii) they view a startup as a way to retain more control over the development of their innovation and (iii) a startup may be the only option given the challenges of licensing to larger companies. The researcher typically takes a non-operating role as a scientific founder of the startup, and holds between a 10% and 20% equity stake in the enterprise, which will be subject to dilution over time.

We can provide the resources and capital of a pharma licensee while also providing the more compelling economic upsides of a startup. Each patent portfolio that we license in from an institution (capturing the discoveries of one or more researchers) are housed, or in the future will be housed in a separate unit or subsidiary which we title a 'program'. We can provide the institution and the researchers a share in the potential economic upside of that particular program regardless of how that economic upside comes about. The proposed share we envision is a 20% total in such subsidiaries – with approximately 10% to the institution and approximately 10% to the researchers, a significantly higher stake than they would typically be able to hold in a startup venture.

We believe institutions and their researchers will prefer Ocean Biomedical to launching a startup because Ocean Biomedical eliminates the challenge of needing to raise capital and hire a team, and provides a greater share in the upside. Likewise, we believe Ocean Biomedical will be a preferred choice as opposed to licensing to large pharmaceutical companies because receiving a percentage of any economic value, regardless of how it is derived, is often more attractive than relying on fixed milestone payments or single-digit royalties.

We believe our approach will give us preferred access to innovations at research universities and medical centers, and that this in turn will benefit our shareholders.

Our Pipeline Funnel Process

Our core competencies for acquiring and developing pipeline programs include: (1) identifying, assessing and selecting inventions and technologies (from research universities and medical centers) that we may directly or indirectly license and commercialize; (2) in-licensing selected inventions and technologies; and (3) developing those inventions and technologies into potential therapeutic products aimed at addressing unmet medical needs.

Step One: New Program Identification, Assessment and Selection

Our close relationships with research universities and medical centers, along with their individual researchers, technology transfer offices, accelerator programs and entrepreneurship centers, provide us with access to biomedical inventions and technologies that we may directly or indirectly license and commercialize. Our multi-disciplinary Opportunity Assessment Committee, or OAC, is responsible for new program identification, assessment and selection – and for ensuring adherence to our due diligence process. The OAC is comprised of Dr. Jonathan Kurtis (Scientific Co-founder), Michelle Berrey (Interim Chief Executive Officer), and Jolie Kahn (Chief Financial Officer). The OAC applies our disciplined and rigorous due diligence process to identify, assess quantitatively, and select those inventions and technologies based on criteria we believe ensures that each asset selected to enter our pipeline is consistent with our mission and commercialization objectives. Our criteria are listed below, and we score and weigh each criterion through a combination of data analytics, experience and judgment.

- Robust and verifiable science that can lead to predictable outcomes
- Well-characterized mechanisms with potential to be disease modifying
- Development path with timely and achievable milestones / value inflection points
- Solid and dominating intellectual property / patent position
- Knowledge transfer assuredness (inventors available and approachable)
- Potential for multiple products / applications
- Potential to address significant unmet medical needs
- Product advantages that are "must-haves" for patients, practitioners, and payors
- Manufacturing and scale-up feasibility
- Attractive market / competitive dynamics
- Favorable pricing and reimbursement with good gross margin potential

Step Two: Executing License Agreements

After a new program is selected via the process outlined above, or in some cases as part of the selection process, we endeavor to negotiate and execute a license agreement with the relevant university or medical center. Our team has negotiated and executed dozens of such license agreements, both as licensee and as licensor.

As mentioned previously, we believe our business model may make us the 'licensee of choice' for institutions and researchers because we aim to act with greater speed and to provide better potential upside when compared to the companies or spin-out startups to whom the institution might also consider licensing. In particular, by housing each program in a subsidiary, we can grant a certain percentage of that subsidiary's ownership (targeting 20% in aggregate) to the institution and to the relevant researchers. We believe that receiving such percentage of economic value, regardless of how it is derived, will be more attractive to the institution than relying on the fixed milestone payments and single-digit royalties that are customary in other license agreements. Additionally, we believe that individual researchers will find it more attractive to have a direct stake in a program's economic value as opposed to receiving a share (typically one third) of whatever economic value their institution would receive in customary license agreements. Lastly, we believe institutions and their researchers will prefer our approach over launching a startup because we eliminate the challenge of raising venture capital and securing a team, and because the percent equity ownership we can offer is likely to be higher than the single-digit figures that usually result after the typical dilution in startups.

By offering a percentage ownership in a program's subsidiary in lieu of the alternative license fees, milestone payments and royalties, we believe our license agreements (and the associated negotiation) will be greatly simplified while also being more attractive to our licensors and their individual researchers.

Step Three: Product Development, and Commercialization

We are an asset-focused company with an operating model designed for agile, capital efficient, and scalable therapeutic product development. We have a structure wherein Ocean Biomedical houses each drug development program or therapeutic platform in a subsidiary. Each of these programs may include multiple product candidates or assets. This structure helps to ensure that we align interests and that we gain access to the particular program's scientific expertise and know-how. The results and outcomes of one subsidiary do not directly affect others, and because our subsidiaries (or assets) are decoupled, success is not dependent on any one particular asset. We can thereby evaluate each asset's preclinical, translational and clinical development progress objectively, which we believe enables us to allocate resources and capital throughout our portfolio based on each asset's evidence-based progress and continued scientific and commercial merits. The continued merits of an asset are periodically assessed using some or all of the criteria outlined above which we use to assess potential new programs. We are agnostic as to which assets deliver success and believe this allows us to maintain focus on those which continue to show most potential.

Our product development and commercialization process reflects the disciplined and objective asset-centric philosophy described above. This process has the following features:

- Evidence-based and science-driven decision making at each stage of translational and clinical development: For each product candidate, key milestones or decision points are set based on their ability to validate technical and commercial viability, and feasibility, as viewed from industry and regulatory lenses. We support each product candidate with the interdisciplinary expertise and resources to reach these key decision points. We review progress on an on-going basis and constantly re-assess whether the program warrants continued investment – i.e., we recognize the dynamic nature of these product candidates and we re-evaluate them based on development progress, risk factors, and market dynamics.

- Lean and agile translational development operations: Each program is managed by our centralized team of experienced product development leaders who enlist the support of relevant external resources including CROs, CMOs, domain experts, consultants, etc. We believe this approach is most cost-effective for clinical and commercial development and that it allows us to minimize overhead while giving us the flexibility to tap into the most relevant and current talent for each program without having to rely on large teams of permanent hires.

In addition, our Research Review Committee, or RRC, which is expected to be comprised of Dr. Jack A. Elias (Scientific Co-founder), Dr. Jonathan Kurtis (Scientific Co-founder), and Dr. Inderjote Kathuria (Chief Strategy Officer) will be responsible for the research, translational and preclinical efforts leading to filing an IND and moving a product candidate into human clinical trials.

Our Development Review Committee, or DRC, which is expected to be comprised of Dr. Jonathan Kurtis (Scientific Co-founder), and Inderjote Kathuria (Chief Strategy Officer) will be responsible for managing all clinical development efforts, including progress monitoring, allocation of resources, and continuous re-evaluation of a product candidate's merits.

Both these committees will work in collaboration with our OAC described previously to ensure that each product candidate that enters our pipeline as well as existing ones continue to meet the criteria we have outlined above.

Our Therapeutic Programs

Oncology Product Candidates for NSCLC and GBM

Our oncology product candidates for NSCLC and GBM:

- OCX-253 anti-Chi3l1 Single-target mAb (NSCLC)
- OCX-410 anti-Chi3l1/PD-1 Bi-specific antibody (NSCLC)
- OCX-909 anti-Chi3l1/CTLA-4 Bi-specific antibody (GBM)

Our product candidates in our oncology program are based on a drug target pioneered by Dr. Elias. His research demonstrated that a protein called chitinase 3-like-1, or Chi3l1, is a key driver of multiple disease pathways in primary and metastatic tumor development demonstrating an 85-95% reduction in primary and metastatic tumor burden in multiple animal models. Animal models of lung cancer and glioblastoma, a type of brain cancer, showed that inhibition of Chi3l1 resulted in statistically significant tumor reduction – even more so when combined with immunotherapies to stimulate the body's own immune response against cancer. Our oncology development pipeline consists of: (a) an antibody therapeutic product candidate inhibiting Chi3l1; (b) a bi-specific antibody product candidate inhibiting Chi3l1 plus PD-1, a checkpoint inhibitor protein; and (c) a bi-specific antibody product candidate inhibiting Chi3l1 plus CTLA-4, another checkpoint inhibitor protein. These product candidates are targeting non-small cell lung cancer, or NSCLC, which accounts for about 85% of all lung cancers globally and affects about 460,000 people in the United States and 595,000 people in Europe, and glioblastoma multiforme, or GBM, a brain cancer that kills approximately 60% of patients within 12 to 18 months from the time of diagnosis and for which new treatment therapies are needed.

Non-Small Cell Lung Cancer

Lung cancer is the most common cancer worldwide, accounting for 2.1 million new cases and 1.8 million deaths in 2018. In the United States, lung cancer is the third most common and the deadliest malignancy. Approximately 541,000 people in the United States today have been diagnosed with lung cancer at some point in their lives. It is estimated that 229,000 new cases of lung cancer are diagnosed annually in the United States, representing about 13% of all cancer diagnoses. NSCLC is the most common type of lung cancer, accounting for approximately 85% of new lung cancer cases.

NSCLC continues to rank among the cancers with the lowest five-year survival rates and has one of the largest disease burdens in terms of disability-adjusted life years.

Staging is a way of describing the severity and extent of a cancer's growth and spread. The stage of NSCLC is based on a combination of several factors, including the size and location of the primary tumor and whether it has spread to the lymph nodes and/or other parts of the body.

There are five stages for NSCLC: stage 0 and stages I through IV. In general, an earlier stage of NSCLC is linked with a better outcome. Unfortunately, a significant proportion of patients, in the order of 40% to 50%, are still diagnosed with hard-to-treat stage IV disease.

There are currently five main ways to treat NSCLC: surgery, radiation therapy, chemotherapy, targeted therapy and immunotherapy. The use of these treatment options for NSCLC is based mainly on the stage of the cancer, but other factors, such as a person's overall health and lung function, as well as certain traits of the cancer itself, such as its molecular characteristics, are also important.

Treatment decisions often follow either formal or informal guidelines. Treatment options can be ranked or prioritized into lines of therapy: first-line therapy, second-line therapy, third-line therapy, and so on. First-line therapy, sometimes called induction therapy, primary therapy or front-line therapy, is the first therapy that will likely be attempted. If a first-line therapy either fails to produce sufficient antitumor response or produces intolerable side effects, additional therapies may be substituted or added to the treatment regimen, known as second-line or third-line treatments. Often, multiple therapies may be administered simultaneously, known as combination therapy or polytherapy.

Surgery is usually the first choice for early stage disease followed by radiation and chemotherapy. Targeted therapies and immunotherapy are the main options in advanced disease, in stages III and IV.

Targeted therapy is a treatment that targets the cancer's specific genes, proteins or the tissue environment that contributes to cancer growth and survival. This type of treatment blocks the growth and spread of cancer cells and limits damage to healthy cells.

Immunotherapy is designed to boost the body's natural antitumor immune defenses. Lung cancers often contain genetic mutations that are seen as "non-self" by the host's immune system because they are not seen in normal cells and tissues. The human immune system is designed to attack and eliminate cells and tissues that it detects as foreign or "non-self." However, in many patients with cancer these desired antitumor responses are suppressed by the tumor and surrounding cells. This is done by activating one of a number of immune checkpoint inhibitor pathways, or ICPI pathways.

An example of the multiple ICPI pathways that have been discovered that has received significant attention in lung cancer is the programmed death-1/ PD-ligand 1, or PD-1/PD-L1, pathway. In many patients with lung cancer, the immune cells and nearby cells, such as macrophages express, PD-1 and the tumor cells express its binding partner PD-L1. When PD-L1 binds PD-1, it activates pathways that suppress the host's antitumor immune response. On the other hand, therapeutics (usually antibodies) have been developed that prevent these PD-1/PD-L1 interactions. These therapies boost the host's antitumor responses which augments its ability to attack the tumor. Because there are multiple ICPI pathways, assays that determine which pathway(s) is activated in a given tumor have been and are being developed. This allows the therapeutic intervention to be directed to the ICPI pathway that is most important in a given individual.

Importantly, immunotherapy has been generally regarded as revolutionizing the treatment of NSCLC, with immunotherapies targeting the PD-1/PD-L1 pathway now emerging as standard-of-care in some settings. However, despite the advent of these new therapies for NSCLC, there continues to be a need for other therapeutic options because only approximately 15% of patients respond to these interventions. In addition, among those that initially improve, the responses are often not durable and diminish over time. In many cases, tumors evolve compensatory mechanisms that circumvent the beneficial effects of an individual immunotherapy. Thus, a significant unmet medical need in NSCLC are treatment options that either restore or complement, the efficacy of anti PD-1 / PD-L1 and other ICPI-based therapies.

A general overview of immunotherapy and antibodies is presented below under the caption "A Primer on Antibodies, Antigens and Targeted Therapies."

We believe that OCX-253, our mono-specific mAb against Chi3l1, if approved, will likely be used individually or in combination with immunotherapies, such as anti-PD-1 therapeutics. Our belief is based on the observation that OCX-253 modulates multiple oncogenic pathways, or signaling networks used by cancer cells to control the growth and progression of tumors, in addition to its ability to modulate ICPI pathways. Should OCX-253 become a marketed treatment, we would anticipate it being initially used primarily in later-stage cancers, as with most recently approved oncology therapeutics. OCX-253 may progress towards being used for earlier stage cancers, and/or in combination with other medications, as clinician and regulatory agency experience with the drug grows and as our understanding of the needs of individual patients deepens.

OCX-410, our bi-specific antibody, is designed to combine the mechanism of actions of OCX-253 and anti-PD-1 therapeutics. We believe this is a promising combination because studies by Dr. Elias have demonstrated that this bi-specific antibody recruits immune cells, such as CD8+ cytotoxic T cells that kill tumor cells, and the physical interaction of these activated T cells to tumor cell membranes. If approved, we anticipate that OCX-410 will likely enter the market as a second-line therapy in patients with stage III or IV lung cancer who have failed anti PD-1/PD-L1 immunotherapies. We believe that OCX-410 may eventually be used as a first-line treatment for patients with later stage NSCLC.

Glioblastoma Multiforme

GBM is an aggressive type of cancer that can occur in the brain or spinal cord, the components of the central nervous system, or CNS, and is the most common brain tumor in adults. GBMs are a type of astrocytoma, meaning that they arise from the star-shaped cells, known as astrocytes, in the CNS. Normally, these cells form a key component of the blood brain barrier, or BBB, a network of cells, proteins, and structural components that controls which substances can get into the central nervous system, or CNS, and which cannot. Astrocytes also normally help support nerve cells and carry nutrients to them.

Brain tumors are graded on an I to IV scale based on how fast they grow. Grade I brain tumors are the least aggressive. They grow very slowly and rarely spread into nearby tissues. Grade IV are the most aggressive. GBMs are grade IV astrocytomas. They grow quickly and often spread into nearby brain tissue. They rarely metastasize or spread to other parts of the body.

GBM is a rare disease, with a prevalence of 1-9 out of 100,000 individuals. The prevalence in the United States is estimated to be approximately 28,000 diagnosed individuals, and the annual incidence is estimated to be between 6,000 and 10,000. Primary GBM accounts for 90% of cases, mostly occurring in older individuals, while secondary GBM develops more slowly and occurs in relatively younger patients.

No curative therapies exist for GBM and the treatment landscape has not changed in recent years. A significant proportion, approximately 25%, of the GBM prevalent population is not actively treated due to rapid disease progression and an extremely poor prognosis. Surgery is standard-of-care followed by radiation and follow-up with chemo. If that does not work, then physicians may try a second line approach, such as switching chemo monotherapies. However, these second line therapies are rarely effective.

Our bispecific antibody candidate, OCX-909, is designed to combine the mechanism of actions of OCX-253 with an anti-CTLA-4 component. CTLA-4 is a protein receptor that functions as an immune checkpoint that binds to molecules called B7.1 and B7.2 to suppress antitumor immune responses in a manner similar to PD-1. We believe OCX-909 may produce antitumor response particularly in GBM because CTLA-4 is expressed in an exaggerated manner in many GBM tumors. If approved, we envision OCX-909 being potentially utilized as an alternative to surgery, or in the treatment regimen in both the neoadjuvant (before surgery) and adjuvant (after surgery) settings for patients with GBM.

A Primer on Antibodies, Antigens and Targeted Therapies

One way the body’s immune system attacks foreign substances is by making large numbers of antibodies. An antibody is a protein that binds to a specific antigen. An antigen is a molecule that is foreign to the human body; examples include viruses, bacteria, and tumor cells.

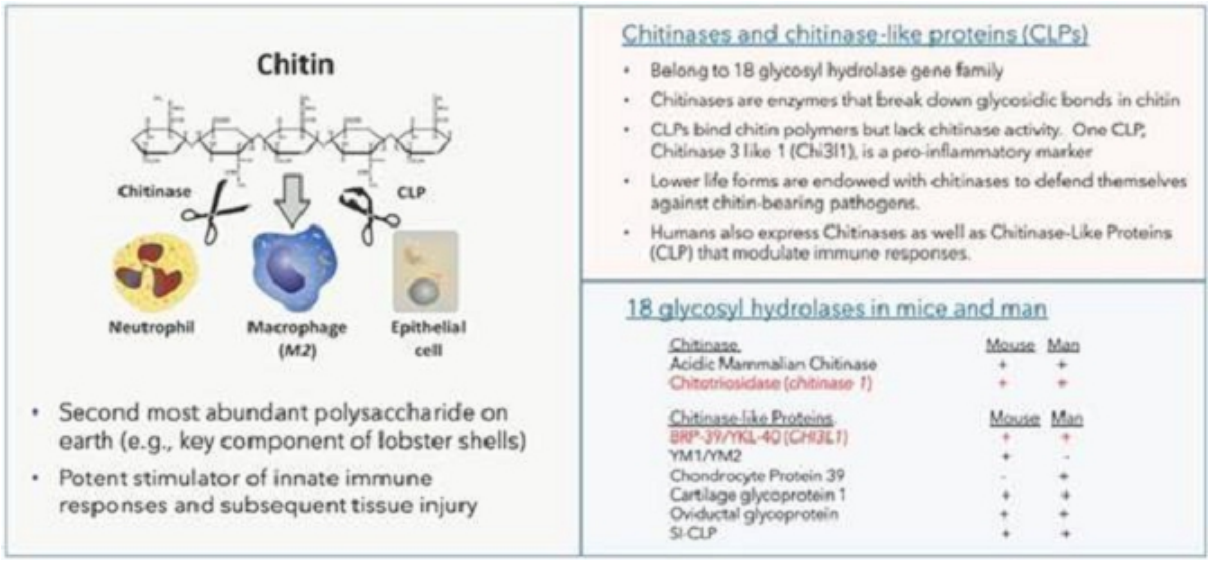
Antibodies have a distinct “Y” shape. Each upper arm of the “Y” is uniquely structured to bind to a specific part of a particular antigen, called an epitope. Once bound to the antigen, an antibody triggers other parts of the immune system to destroy the cells containing the antigen.

Monoclonal antibodies, or mAbs, are antibodies that are designed and made as therapeutics to bind to specific antigen targets such as those present in a particular type of cancer cell, virus, or other pathogen. When mAbs are used in this manner they are referred to as targeted therapies. Therapeutic antibodies can also be engineered to recognize two epitopes simultaneously, making them "bispecific." Bispecific antibodies, or BsAbs, can bind directly to surface antigens to kill the cells containing the antigens and they can also help ramp up the immune system to make it more effective against those cells.

The Chitinase Biology Behind Our Oncology Project Candidates

Dr. Elias has focused a significant amount of his research over the last decade on a gene family called the 18 glycosyl hydrolases and its chitinase and chitinase-like proteins, or CLP. The chitinases and CLP both bind chitin, a polysaccharide that is a major structural component of the exoskeletons of insects and other arthropods and the cell walls of fungi. The chitinases are true enzymes that cleave chitin into smaller saccharide units. In contrast, the CLPs bind to but do not cleave chitin.

Chitin, Chitinases, and Chitinase-Like-Proteins



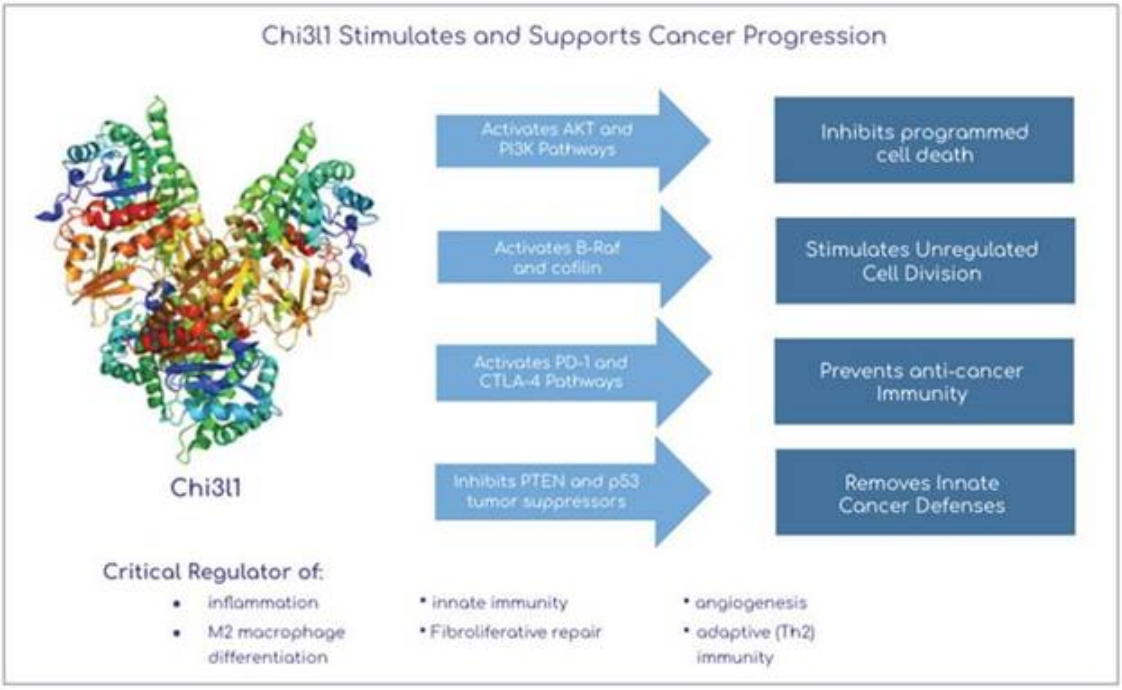
Chitinase-3-like-1, or Chi3l1, also known as YKL-40, the prototypic CLP, was initially described as a soluble product of an osteosarcoma cell line and has since been found in several different laboratory cell lines and animal tissues. In humans, Chi3l1 is found on the cell surface, inside cells and in the circulation. It plays a major role in tissue injury, inflammation, tissue repair and remodeling responses in healthy individuals. It is produced by a variety of cells including epithelial cells and macrophages in response to cytokines, lipids, oxidant injury and other stimuli. It then feeds back to inhibit tissue injury by inhibiting cell death and apoptosis while stimulating fibroproliferative repair.

The levels of circulating and tissue Chi3l1 are increased in many human visceral cancers and animal tumor models including lung cancer and glioblastoma. In visceral tumors elevated serum levels of Chi3l1 correlate with a poor prognosis and shorter disease-free intervals and survival. Studies in animal models have also demonstrated that the inhibition of Chi3l1 can dramatically reduce tumor burden. Consequently, Chi3l1 is now appreciated to be a sensitive biomarker and an attractive therapeutic target for these malignancies. We intend to take advantage of both of these properties because the inhibition of Chi3l1 is a major focus in OCX-253, —410 and —909, and we intend to use Chi311's properties as a biomarker to identify relevant populations for clinical trials of these product candidates.

Chi3l1 interacts with several different cell-surface proteins to mediate its cell and tissue responses. Studies by Dr. Elias and others have demonstrated that Chi3l1 binds to and signals via a number of cell surface receptors (proteins that pass signals between the outside and inside of cells) including the interleukin-13 receptor-α 2 and CRTH2. They have also demonstrated that IL-13Rα2 is the alpha subunit of multimeric receptor complexes that can include galectin 3 and CD44 as ß subunits. Chi3l1 can also interact with receptor tyrosine kinases, integrins αVß3 and αVß5 / syndecan 1 complexes, and the receptor for advanced glycation end products. These receptors activate a number of signaling pathways including MAPK kinases, Protein Kinase B/Akt and the Wnt/ß-catenin pathways and induce the production of VEGF intermediaries. As a result of these complex receptor-ligand interactions it is now known that Chi3l1 regulates oncogenesis via a number of mechanisms. Dr. Elias has demonstrated that Chi3l1 stimulates malignant responses by inhibiting tumor cell death, stimulating tumor cell proliferation, stimulating the B-Raf protooncogene, and stimulating the phosphorylation of cofilin. He has demonstrated that Chi3l1 also inhibits key antineoplastic pathways including those mediated by the tumor suppressors phosphatase and tensin homolog, or PTEN, and p53 thereby removing intracellular controls against unregulated cell growth. These molecules taken together form the tumor microenvironment, a localized set of conditions that supports the evolution and growth of tumors.

In summary, Chi3l1 contributes to neoplasia, or the uncontrolled and abnormal growth of cells or tissues that is the hallmark of cancer, by regulating various pro- and anti-oncogenic pathways as shown in the illustration below:

Chi3l1 and its Roles in Disease Biology



Dr. Elias and other investigators have also found a direct link between Chit1 and fibrotic diseases, such as IPF and HPS. This finding is the basis for our anti-Chit1 small molecule therapeutic product candidate, OCF-203, detailed later.

OCX-253—Anti-Chi3l1 mAb for Lung Cancer

Recent published studies have demonstrated that the levels of circulating Chi3l1 are elevated in many malignancies including cancers of the prostate, colon, rectum, ovary, kidney, breast, as well as GBM and malignant melanoma. In these diseases, the levels of Chi3l1 frequently correlate directly with disease progression and inversely with disease-free interval and survival. This is particularly striking in lung cancer where preclinical and clinical studies demonstrated that the serum and tissue levels of Chi3l1 are increased and are associated with adverse outcomes, such as poor prognosis and shorter survival. Dr Elias and colleagues have found that Chi3l1 plays a critical role in the pathogenesis of primary and metastatic lung cancer in murine models that have the same genetic mutations that are seen in human disease including activating mutations of the K-Ras oncogene. In murine models primary lung cancer is induced in mice that have activating mutations of Kras (the G12 D mutation) and null mutations of the tumor suppressor p53. Dr Elias and colleagues have additionally demonstrated that Chi3l1 is able to replace null mutations of p53 in the generation of primary lung cancer in murine models that only have activating mutations of the K-Ras oncogene. They also demonstrated that Chi3l1 is induced during pulmonary melanoma and pulmonary breast cancer metastasis in murine models of these diseases and that Chi3l1 induction is required for the generation of a metastasis permissive pulmonary microenvironment. As shown below, both primary tumor growth and metastatic spread were both significantly inhibited via immune inhibition of Chi3l1 using therapeutic antibodies (Fig. 1). These antibody findings are the basis for Ocean Biomedical's OCX-253 program in NSCLC. We plan to initially focus on a subset of patients who exhibit elevated levels of circulating Chi3l1 as they are anticipated to be the patient population most likely to respond to this product candidate. However, the treatable patient population may eventually expand as a consequence of the many critical pathways OCX-253 appears to impact (as described and shown in the figure above) and as our understanding of chitinase biology grows.

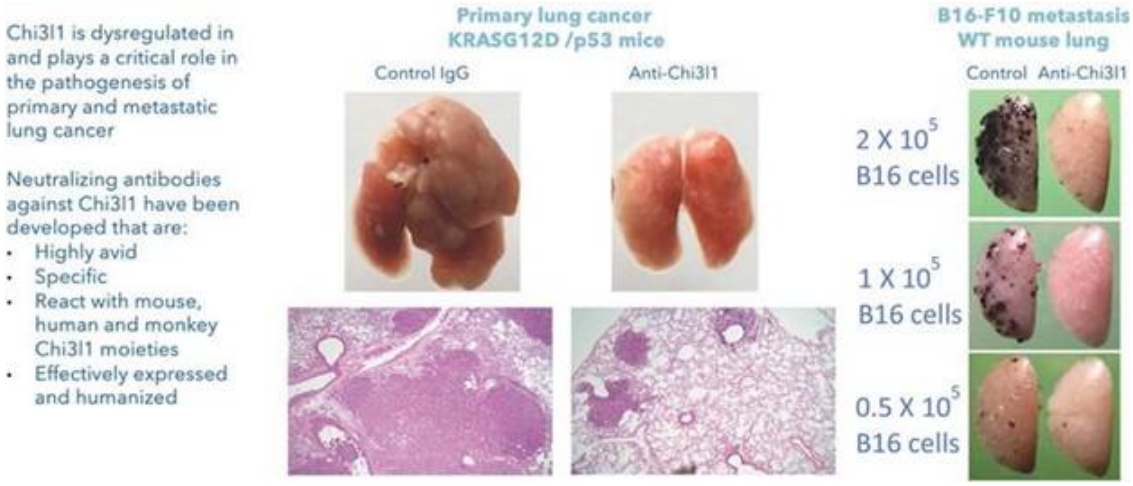


Figure 1: In Animal Models, Antibodies Against Chi3l1 Show Reduction in Primary and Metastatic Tumors

OCX-410 and OCX-909—Anti-Chi3l1/PD-1 and Anti-Chi3l1/CTLA-4 Bispecific Antibodies for NSCLC and GBM

Novel immunotherapeutic approaches have improved the prognosis for a number of cancers over the past decade. Cancer cells have unstable genomes and as a result accumulate genetic mutations that are not seen in normal cells and tissues. These non-self mutations generate non-self proteins that can be recognized and reacted to by the immune system. Normal white blood cells, particularly T lymphocytes, learn to recognize these novel antigens and kill the cells that express them. Under normal circumstances, immune responses are activated to deal with pathogens and non-self antigens but are then inhibited to prevent overexuberant, injury-inducing, immune responses. This immune inhibition is often mediated by immune checkpoint inhibitor pathways. Unfortunately, some tumors evolve to take advantage of these regulatory pathways to evade endogenous antitumor immune responses. For example, tumor cells may produce the regulatory protein cell death ligand 1, or PD-L1 or cluster of differentiation proteins 80 or 86. These proteins interact with their corresponding receptors on T cells, PD-1 and CTLA-4, respectively, to turn off the immune system response to the cancer. Multiple approved immunotherapies disrupt the connection between PD-1 or CTLA-4 and their ligands to restore immune activity against susceptible cancers.

Dr. Elias has demonstrated in widely accepted mouse models of cancer that PD-1 and its ligands, PD-L1 and PD-L2, are induced in melanoma metastases by Chi3l1, and that Chi3l1 can stimulate these checkpoint inhibitors, thereby encouraging tumor growth. Further work by Dr. Elias has demonstrated that bispecific antibodies that bind to both Chi3l1 and PD-1 (or CTLA-4) dramatically improve the responses seen in cocultures of T cells and tumor cells with more tumor cells undergoing cell death when treated with the bispecific antibody than cells treated with mono-specific antibodies against the same targets, either individually or in combination (Fig. 2). These studies also demonstrated that these effects were mediated by an enhanced induction of CD8+ cytotoxic T cells that kill the tumor cells and an enhanced ability of these cytotoxic cells to bind to tumor cell membranes in cultures treated with the bispecific antibody compared to cultures treated with mono-specific antibodies against the same targets, administered either individually or in combination. These observations suggest that the proximity of the Chi3l1 and PD-1 (or CTLA-4) targets in the tumor microenvironment play a role in their vulnerability to this precision immunotherapy 9 (Fig. 3). Thus, we hypothesize that even patients whose tumors have been resistant to anti-PD-1 or anti-CTLA-4 antibody therapy may benefit from our bi-specific antibody product candidates that are designed to bind both Chi3l1 and immune checkpoint targets simultaneously. These bi-specific antibodies against Chi3l1 and PD-1 or CTLA-4 are the basis for our OCX-410 and OCX-909 programs, respectively.

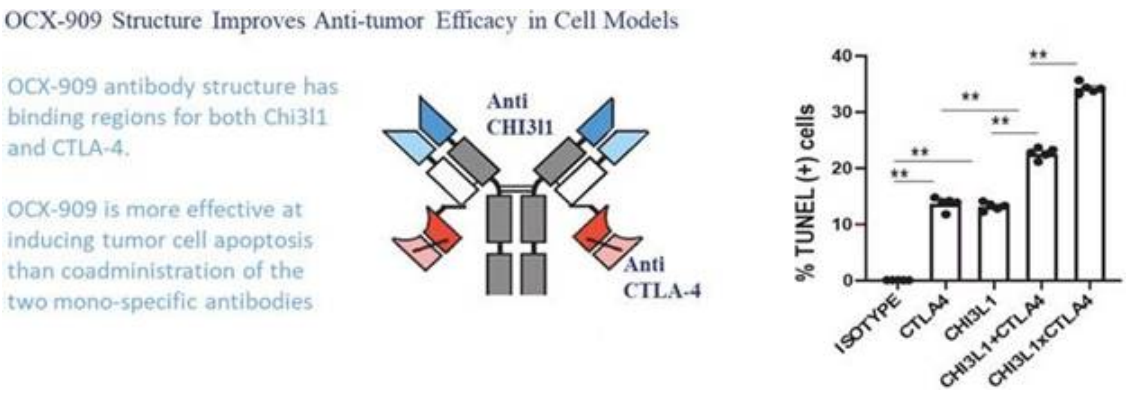


Figure 2: In vitro Experiments Show Improved Killing of Glioblastoma Tumor Cells with OCX-909 Bi-Specific Anti-Chi3l1 / Anti-CTLA-4 Antibody. **=p<0.01

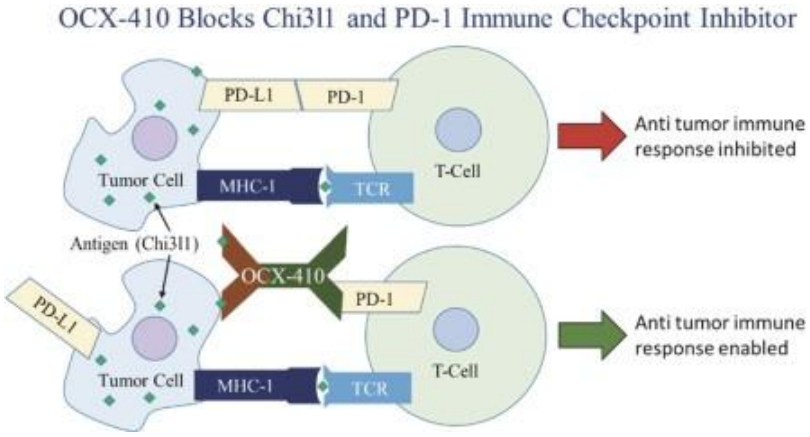


Figure 3: Mechanism of Action of OCX-410

We are planning to initially target checkpoint inhibitor positive NSCLC with OCX-410 and GBM with OCX-909 due to the previously published importance of these checkpoint inhibitors for these tumor types as well as Dr. Elias' supporting data in preclinical models of these diseases. We intend to evaluate whether checkpoint inhibitor upregulation is critical for the activity of OCX-410 and OCX-909 in humans, and we intend to evaluate the response seen in checkpoint inhibitor negative patients as well. The outcome of these studies may help us to better identify our potential target patient population.

Oncology Product Candidates Clinical Development Plan

All three therapeutic antibody product candidates, OCX-253, OCX-410, and OCX-909, have been optimized against their respective targets, and we are beginning efforts to develop, through the establishment of manufacturing and supply relationships with third parties, a production system capable of supporting clinical use. A critical step in production is the creation of a master cell bank, or MCB, a depository where genetically identical antibody-producing cells are stored, by a CMO. The MCB is critical for production of consistent therapeutics through clinical development and, potentially, commercial production. We have collaborated on the first steps of MCB production for OCX-253 with Lonza Group AG, a global contract manufacturing organization and have completed development of 8 research cell lines that produce OCX-253 in February 2021. Initial assessments indicate that any of these cell lines could possibly be used to generate clinical and commercial grade OCX-253. Additional evaluations are under way to determine which of the 8 cell lines is preferred for the generation of the cGMP MCB and the generation of clinical drug material. The OCX-410 and OCX-909 programs are expected to begin MCB generation in 2H 2023/1H 2024. We anticipate filing IND applications with the FDA for product candidates within 18 months of raising sufficient capital to fund such IND projects.

We intend to model our Phase 1/2 clinical trials of OCX-253 and OCX-410 after Merck's pembrolizumab KEYNOTE-001 trial (NCT01295827). This design is expected to allow for combined initial safety and efficacy endpoints using a single ascending dose, or SAD, strategy followed by a repeat dose regimen to identify tumor responses through generally accepted Response Evaluation Criteria in Solid Tumors, or RECIST, criteria and time to tumor progression. Using RECIST criteria as the primary endpoint of the initial clinical trial will measure whether tumors shrink in response to treatment and allows for a relatively quick determination of whether our product candidates are likely to provide benefit in a larger, more extensive pivotal trial. The time to the tumor progression endpoint will likely be a secondary endpoint in these first trials but is the generally accepted primary endpoint for registrational trials in NSCLC.

GBM

The OCX-909 program for GBM has the additional challenge of successfully delivering the protein therapeutic product candidate to the brain where the Blood Brain Barrier or BBB has questionable permeability. The BBB is a stretch of less-permeable blood vasculature in the CNS, as compared to the rest of the body. Its purpose is to carefully screen the entry and exit of molecules between the CNS and bloodstream. The BBB is a difficult hurdle to cross using small molecules delivered to the periphery, and consistent peripheral delivery of protein-based therapeutics, such as antibodies, to the brain has so far been elusive. Patients suffering from GBM may have a partially disrupted BBB due to changes in the vasculature associated with the tumors or their recent surgery, but the inconsistency of these disruptions may add considerable challenge to the development of a peripherally delivered medicament.

We plan to bypass the BBB using a number of approaches, alone or in combination. The first approach is intracerebral-ventricular, or ICV, delivery of OCX-909. We intend to make use of a port-reservoir system, such as an Ommaya reservoir, which is a small, plastic, coin-shaped device placed under the scalp and connected to a catheter placed in one of the brain's ventricles. This would allow direct delivery of OCX-909 into the cerebral spinal fluid, or CSF, pool in the ventricles at the center of the brain. The size of the ICV space changes throughout the day, particularly during sleep, effectively pumping CSF, and the drug it contains, throughout the brain. Though placement of an Ommaya reservoir is somewhat invasive, it is frequently used in patients suffering from brain cancers, and we anticipate many of our patients will likely already have one in place.

We intend to model our Phase 1/2 clinical trial after the Phase 1/2 clinical trial of Johnson and Johnson's Zarnestra sponsored by M.D. Anderson Cancer Center (NCT00050986). The envisioned clinical trial plan involves a dose escalation SAD/multiple ascending dose, or MAD, strategy followed by continued assessments of safety parameters and efficacy using six-month progression free survival as the primary endpoint. We anticipate also monitoring tumor size during this trial using radiology techniques in the interest of acquiring efficacy data more rapidly than the primary endpoint is likely to provide.

Our Phase 3 clinical trial for OCX-909 is tentatively planned to follow the example of Merck's CENTRIC trial of Cilengitide (NCT00689221). The CENTRIC trial used overall survival as the approval endpoint leading to a study duration over five years. We intend to continue to work with the oncology community to develop novel validated biomarkers, which could allow for accelerated trials in GBM. We are optimistic that these novel tools may allow for accelerated trials in the GBM space which could speed the transition of OCX-909 to the market. We intend to seek orphan drug designation for OCX-909 in GBM and may also request priority review.

Fibrosis Product Candidate for IPF and HPS:

- OCF-203 anti-Chit1 Small Molecule

Overview of Fibrotic Diseases

An important protective mechanism for tissue regeneration and wound healing is the formation of extracellular matrix, or ECM, a non-cellular portion of a tissue produced and secreted by cells and functions mainly to provide support for tissues.

Fibrosis is a pathologic condition where an excessive accumulation of ECM leads to organ disfunction and failure. Fibrotic diseases constitute a major health problem worldwide and encompass a wide spectrum of clinical entities including systemic fibrotic diseases such as systemic sclerosis, or SSc, scleroderma and nephrogenic systemic fibrosis, as well as numerous organ-specific disorders including pulmonary, cardiac, liver and kidney fibrosis.

The United States government estimates that 45% of deaths in the United States can be attributed to fibrotic disorders. Fibrosis is a factor in various tissue and organ diseases as shown in the figure below.

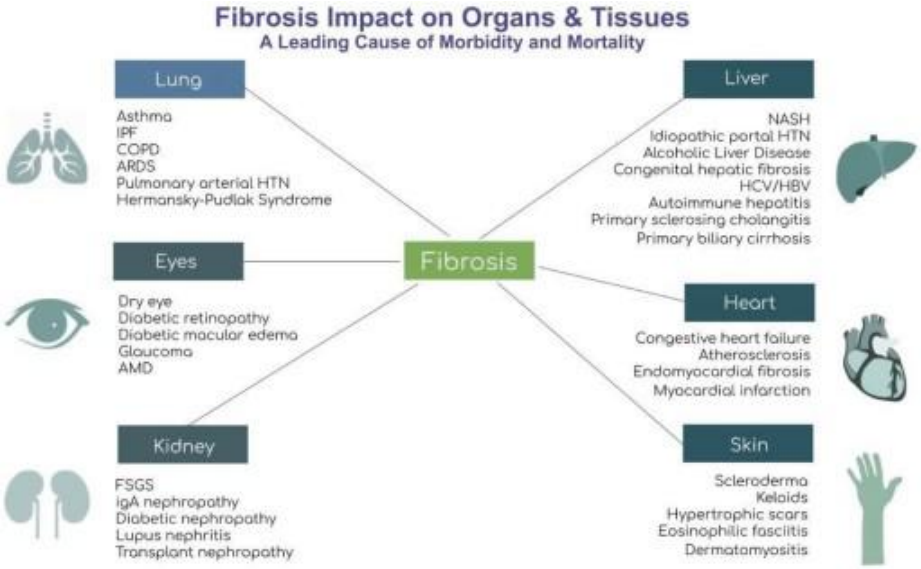


Figure 4

Idiopathic Pulmonary Fibrosis

IPF is a chronic, progressive, and fibrotic interstitial lung disease of unknown cause, which occurs primarily in older adults. It results in irreversible loss of lung function with high morbidity and mortality rates. Median survival is three-to-five years following diagnosis.

IPF is a rare disease with an estimated prevalence ranging from 10-to-60 per 100,000 in the United States and 1.3 to 32.5 per 100,000 in Europe depending on country, age, and risk factors. There is an estimated prevalence of approximately 160,000 in the United States, with most cases occurring in individuals over the age of 50 years. The United States incidence rate is approximately 55,000 cases per year, and the incidence is rising due to a growing elderly population and increased disease awareness and detection.

In practice, patients are diagnosed and categorized into three categories, as shown below, based on disease severity: mild, moderate, and severe. Their disease may be characterized based on two lung function measures: FVC, or forced vital capacity, and diffusing capacity of the lung for carbon monoxide, or $DL_{CO,}$

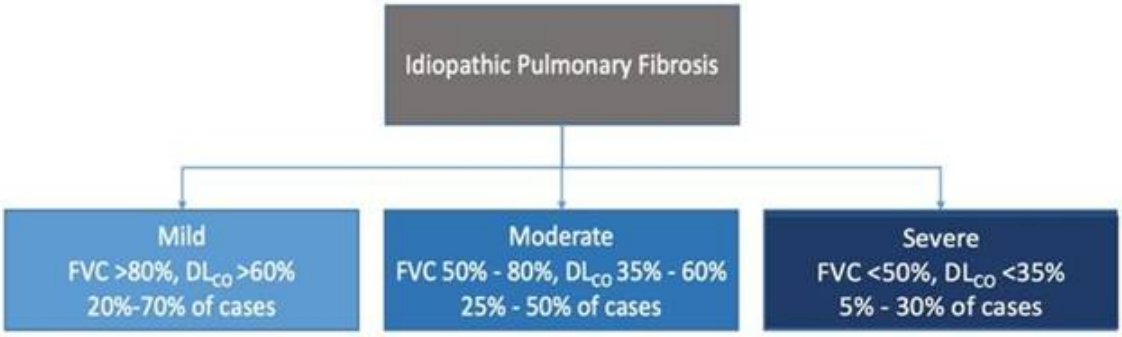


Figure 5

Current therapeutic standard-of-care utilizes Roche's Esbriet (pirfenidone) or Boehringer's Ofev (nintedanib). Pirfenidone and nintedanib slow pulmonary function loss with only modest deceleration of disease progression and no reversal, and their severe side effects (e.g., nausea, vomiting, diarrhea) cause many patients to avoid or discontinue these therapies. These drugs are primarily used in the moderate patient segment—both mild and severe patients view the negative side effect profile as outweighing the benefits. Despite the side effects, it is estimated that approximately 58% of patients diagnosed with IPF take one of these therapeutics and, together, they generated global sales of approximately $3.0 billion in 2019. We believe that a therapy with even a modest improvement in side effect profile would likely see more utilization.

Hermansky-Pudlak Syndrome

HPS is a rare, inherited genetic disorder which occurs when a child inherits defective genes from both parents. Although HPS is ultra-rare from a worldwide perspective, it has a much higher prevalence in Puerto Rico – where the prevalence is roughly 1 in 1,800 in the northwest region of the island, or an estimated 1,500 patients, accounting for more than 50% of the worldwide HPS population. HPS effects approximately 1 to 9 people per 1 million individuals worldwide outside of Puerto Rico. The disease onset occurs as early as age 30, and the lifespan of patients with some of the most severe disease subtypes usually does not exceed 40 to 50 years. HPS is diagnosed through a combination of identifying signs of albinism, evaluation of patient blood, and/or genetic testing; however, early diagnosis of PF in HPS patients presents the same challenges as IPF diagnosis.

There is an unmet need for therapeutics to treat HPS-related pulmonary fibrosis, or HPS-PF, patients. There is no approved drug therapy, and no treatment except potential lung transplantation. The only pharmacological option for patients is off-label use of Esbriet, which may slow disease progression but only in patients who retain significant residual lung function. Published clinical studies of Esbriet and Ofev suggest that bleeding is more likely with Ofev, so its use is generally avoided in the HPS patient population.

We believe that OCF-203, if approved, has potential to address the need for a HPS therapeutic due to its novel therapeutic approach. It is also our belief that developing this product candidate for HPS may allow us to enter the broader fibrotic disease space in an expedited manner by pursuing an ultra-rare disease indication before potentially broadening to adjacent indications.

The Chitinase Biology Behind Our Fibrosis Product Candidate

Previously, we described Dr. Elias' research on chitinase enzymes and CLP, and his discovery of the key role that a CLP called Chi3l1 plays in cancer. Dr. Elias also discovered that a chitinase called Chit1, also known as chitotriosidase, plays a central role in inflammation and in fibrotic diseases such as IPF and HPS. Chit1 is expressed in an exaggerated manner in IPF where it correlates inversely with Smad 7. Chit1 is also a critical biomarker and therapeutic target in Scleroderma-associated interstitial lung disease. This finding is the basis for our anti-Chit1 small molecule therapeutic product candidate, OCF-203.

OCF-203—Small Molecule Candidate for IPF and HPS

In animal models, Dr. Elias and his colleagues showed that Chit1 is a master regulator of transforming growth factor beta 1, an extensively-published biochemical pathway relevant to inflammation, tissue modeling, and fibrosis, and that it mediated fibrosis response through various mechanisms described below. Animal models of IPF exhibit similar pathology to that of humans, allowing for relevant testing of molecular mechanisms and potential therapeutics in these models. Transgenic laboratory animals developed in the Elias laboratory to over-express Chit1 were shown to be far more susceptible to lung fibrosis than their wild type counterparts, which further demonstrates the role of Chit1 as a factor in IPF.

Using high throughput screening, Dr. Elias identified a small molecule candidate for the OCF-203 program that prevented and reduced inflammation and fibrosis in the bleomycin mouse model of IPF (Fig. 5). Importantly, the molecular mediators of fibrosis, fibronectin, Col1A1, and Col3A1, were also substantially reduced in the IPF model animals that had received the OCF-203 candidate. Results were similar in a mouse model of HPS (Fig. 6), suggesting that the OCF-203 molecule could benefit this patient population as well. The biochemical pathways known to be impacted by Chit1 inhibition imply that there may be benefit of this product candidate for the potential treatment of other fibrotic diseases such as non-alcoholic-steatohepatitis, or NASH, and lysosomal storage disorders.

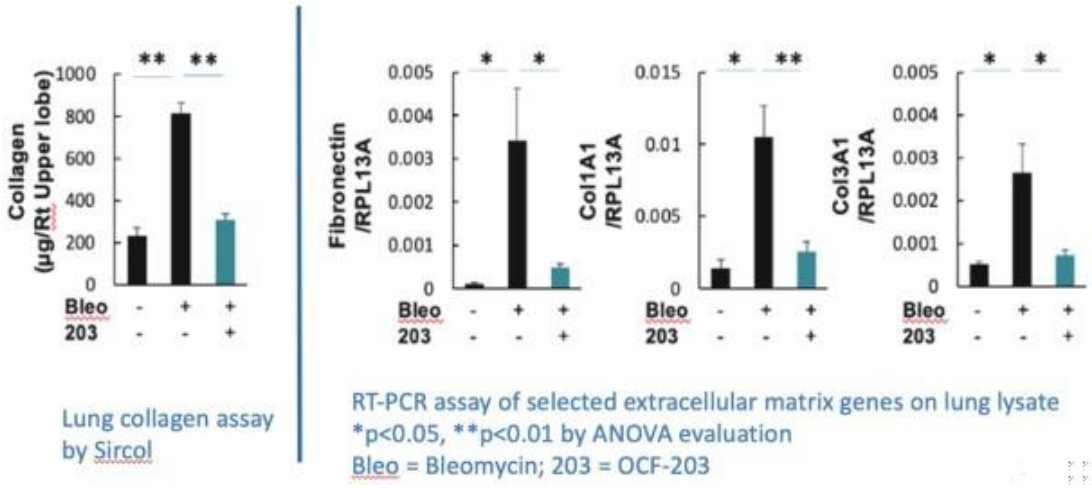


Figure 6: OCF-203 Lead Candidate Treatment Reduces Observed Markers of Fibrosis in an Animal Model of IPF

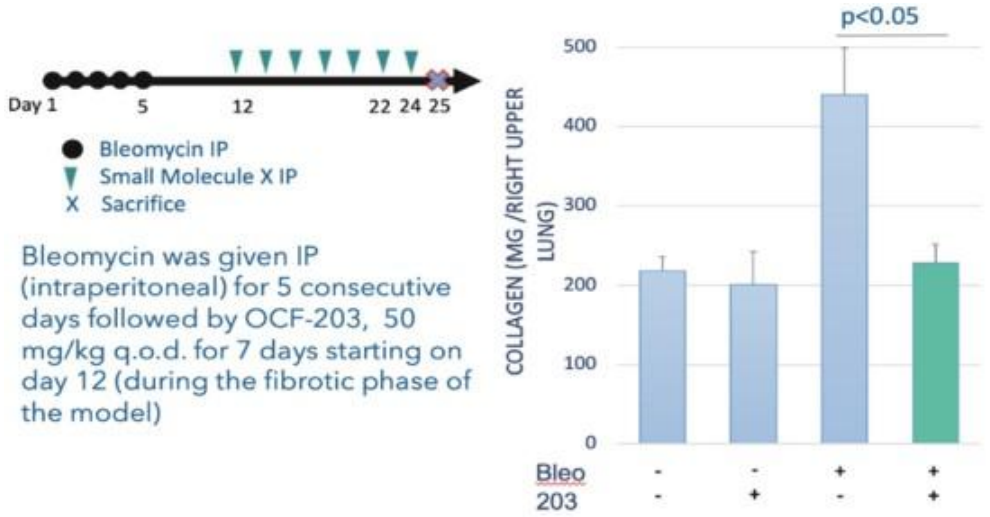


Figure 7: OCF-203 Lead Candidate Treatment of the Bleomycin HPS-1 Mouse Model results in Normalized Levels of Fibrotic Markers

No significant toxicity has been observed at therapeutic doses in the animal studies with the OCF-203 lead to date. This candidate molecule has been previously evaluated (by unrelated parties) in Japan in the mid-1960s for potential use as an antibiotic – though approval was never pursued. While the clinical data from these studies is not suitable for current regulatory filings, we believe it may support the safety observations seen in Dr. Elias' recent animal studies and also provides invaluable information as to the behavior of this molecule and its derivatives that we can potentially use in the design of future clinical development work. Additionally, we believe OCF-203's safety observations in animal studies may be further supported by past published literature which estimates that 6% of humans do not produce Chit1 and, though they may be more susceptible to infection by chitin-containing parasites, this deficiency may provide greater longevity and reduced age-related disease burden as compared to people who produce Chit1 normally. Taken together, these findings suggest that therapies that focus on inhibiting Chit1 may be well tolerated in patients. This is of import to IPF and HPS given that there are no currently approved drug therapies for HPS, and the currently approved therapies for IPF, pirfenidone and nintedanib, both carry a significant risk of severe side effects, as described previously.

Fibrosis Programs Clinical Development Plan

We have identified opportunities in the structure of OCF-203 that we believe may be able to improve the expected risk/benefit ratio for patients. We intended to embark on a limited structure-activity-relationship, or SAR, study and planned to begin IND enabling studies in 2023. We plan to submit our IND application to the FDA within 18 months of raising sufficient capital to fund such IND projects.

Clinical Development

Clinical development of OCF-203 is expected to initiate with a single Phase 1/2 clinical trial in IPF that we plan will be followed by later stage clinical development for IPF and HPS in parallel. We intend to conduct a Phase 1/2 SAD/MAD trial in patients with IPF that is modeled after the Phase 2 portion of the Galapagos PINTA trial (NCT03725852). Our Phase 1/2 clinical trial is expected to be designed to provide human proof of concept data demonstrating the cessation of fibrosis progression, which would allow for the initiation of Phase 3 clinical trials in both IPF and HPS. The Phase 3 clinical trial of OCF-203 for the prevention of fibrotic progression in IPF will likely be modeled after the Genentech ASCEND trial (NCT01366209), while the Phase 3 clinical trial of OCF-203 for the prevention of fibrotic progression in HPS will likely be modeled after the National Human Genome Research Institute, or NHGRI, trial in HPS patients (NCT00001596). Both the Genentech and NHGRI trials were evaluating pirfenidone. We intend to seek orphan drug designation for OCF-203 in HPS.

Infectious Diseases Product Candidates for Malaria

- ODA-570 Vaccine for the Prevention of P. falciparum Infection
- ODA-611 anti-PfGARP mAb for the Treatment of Symptomatic P. falciparum Infection
- ODA-579 anti-PfGARP Small Molecule for the Treatment of Symptomatic P. falciparum Infection

Infectious diseases, caused by infection with viruses, bacteria, fungi or parasites are the primary cause of more than 12.5% of all deaths worldwide. Efforts to reduce this death toll are hampered by drug resistant pathogens and, for many pathogens, a lack of effective vaccines. As detailed below, our infectious disease program is designed to address this significant unmet medical need and will initially focus on malaria, the greatest single agent killer of children worldwide. Please see the section entitled “Description of Business – Our Therapeutic Programs – Malaria Background: Epidemiology and Lifecycle” below.

ODA-570—malaria vaccine

Using the WPDS platform, Dr. Kurtis has identified PfGARP and PfSEA-1 as parasite antigens that are recognized by antibodies in the plasma of children who are relatively resistant—but not in those who are susceptible—to malaria caused by P. falciparum.

PfSEA-1 is a parasite antigen with a mass of 244 kilodaltons, which has no significant similarity to proteins of known function. PfSEA-1 displays minimal sequence variation in the region we cloned (amino acids 810 to 1083) across hundreds of parasite strains. Antibodies made in mice immunized with recombinant PfSEA-1 have been shown to inhibit parasite growth by 58% to 74% across three parasite strains compared with controls (Fig 8). Similarly, purified human antibodies to PfSEA-1 have also been shown to significantly inhibit parasite growth in laboratory studies. In both cases, anti-PfSEA-1 antibodies trapped parasites within the red cell, preventing their egress, and led to parasite death.

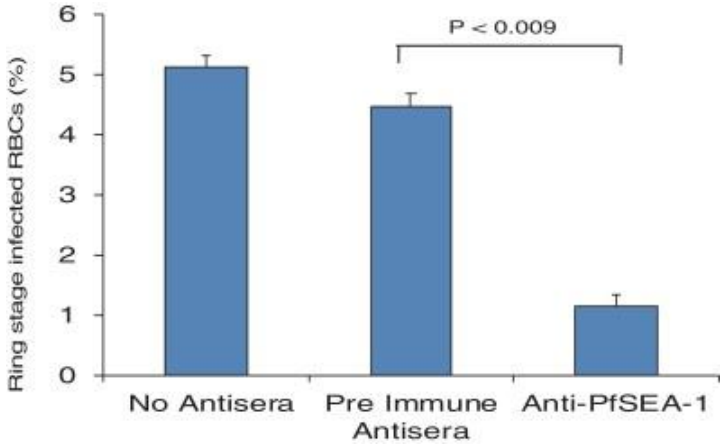


Figure 8. Antibodies to PfSEA-1 kill parasites. Polyclonal anti-PfSEA-1 antibodies in mice inhibit parasite growth by 74% in vitro. Ring stage 3D7 parasites were cultured in the presence of anti-PfSEA-1 mouse sera at 1:10 dilution. Negative controls included no anti-sera and pre-immune mouse sera. Red blood cells (RBC).

In vaccine challenge experiments in mouse models of malaria infection, immunization with a recombinant protein encoding the P. berghei ANKA (a lethal mouse malaria strain) ortholog of PfSEA-1, or PbSEA-1, or antibodies to PbSEA-1 conferred marked protection against a lethal P. berghei ANKA challenge as evidenced by up to a 75% reduction in parasitemia seven days after challenge. In all five experiments performed, by day seven to eight after challenge, control mice had high parasitemia with associated morbidity, whereas none of the vaccinated mice had high parasitemia or overt morbidity. In experiments with long-term follow-up, both active immunization with rPbSEA-1 and passive transfer of antibodies to PbSEA-1 significantly reduced parasitemia and delayed mortality.

In human observational studies conducted in Tanzania, individuals with naturally acquired antibodies to PfSEA-1 were associated with significant protection from severe malaria, with no cases occurring while children had detectable antibodies to PfSEA-1 (Fig 9). In a second longitudinal Kenyan cohort, anti–PfSEA-1 antibodies were associated with significant protection against parasitemia in adolescents and young adults. Individuals with detectable IgG anti–rPfSEA-1 antibodies had 50% lower parasite densities over 18 weeks of follow-up compared with individuals with no detectable IgG anti-rPfSEA-1A antibodies.

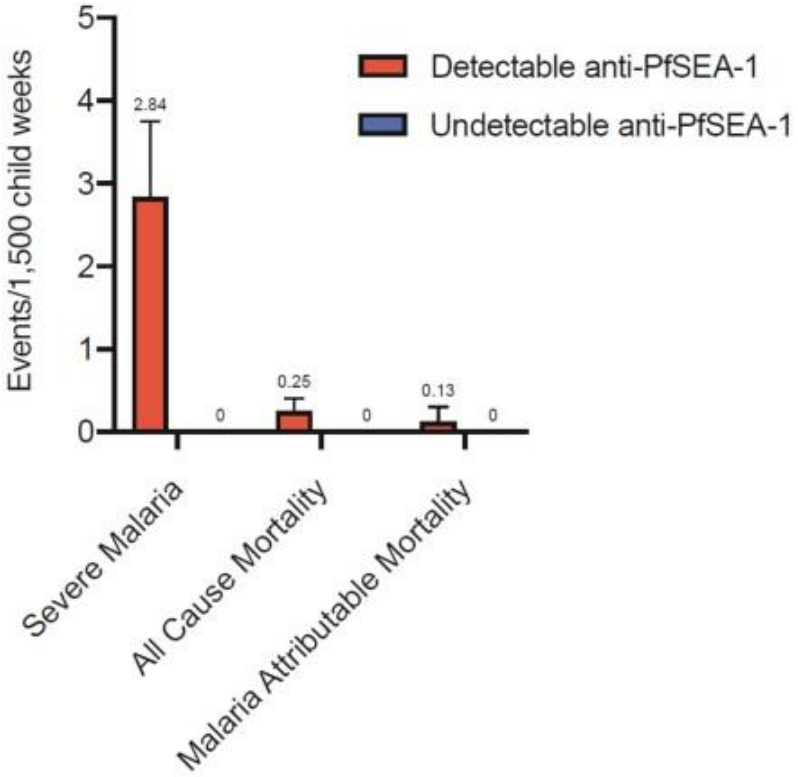


Figure 9. Antibodies to rPfSEA-1A predict reduced malaria severity and parasitemia. Incidence of severe malaria and death in Tanzanian children aged one and a half to three and a half years during intervals with detectable and undetectable antibodies to PfSEA-1 (1688 and 23,806 weeks, respectively). No cases of severe malaria or death occurred during intervals with detectable antibodies to rPfSEA-1A. Error bars represent 95% CI.

Based on these data, we hypothesize that vaccination of humans with PfSEA-1 could generate antibodies that trap parasites within a red cell and lead to parasite death.

PfGARP is a parasite antigen with a mass of 80 kilodaltons that is expressed on the external surface of erythrocytes (red blood cells) infected by early-to-late-trophozoite-stage parasites.

Antibodies against PfGARP kill trophozoite-infected erythrocytes in culture by inducing programmed cell death in the parasites (see Fig 10). Vaccinating non-human primates with PfGARP has been shown to protect against a challenge with P. falciparum (see Fig 11). Furthermore, longitudinal cohort studies have shown that, compared to individuals who had naturally occurring anti-PfGARP antibodies, Tanzanian children without anti-PfGARP antibodies had a 2.5-fold-higher risk of severe malaria, and Kenyan adolescents and adults without these antibodies had a 2-fold-higher parasite density.

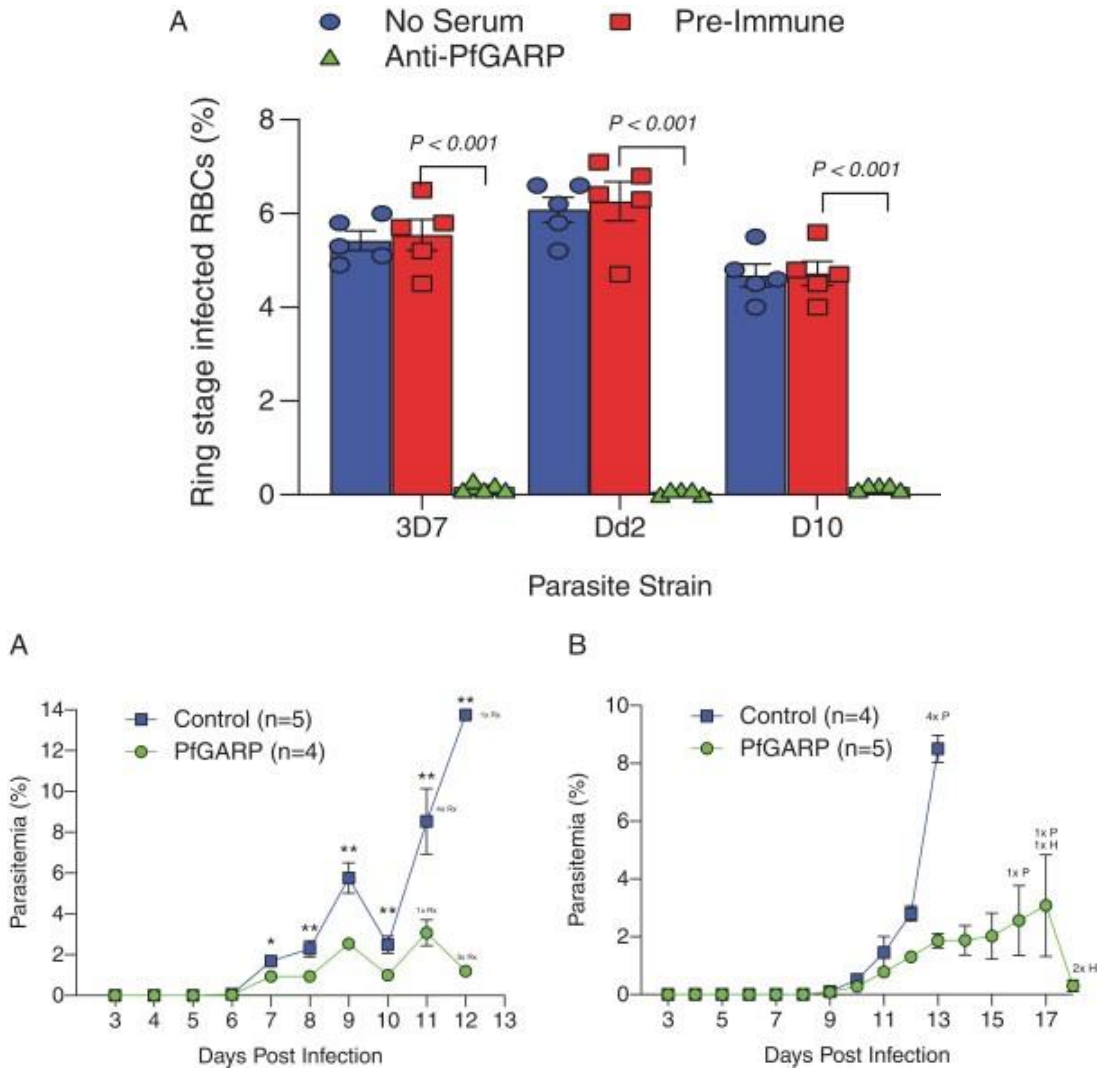


Figure 11. Vaccination with PfGARP-A protects monkeys from challenge with P. falciparum. A) Animals were vaccinated with PfGARP-A mRNA-LNP (n=5 monkeys) poly(C) RNA-LNP (negative control, n=4 monkeys) and challenged IV with 10^4 P. falciparum FVO strain infected RBC. Parasitemia was followed daily. Points represent means, error bars represent SEM.) B) Animals were vaccinated with rPfGARP-A protein (n=5 monkeys) or control (n=4 monkeys) and challenged IV with 10^4 P. falciparum FVO strain infected RBC. Parasitemia was followed daily. Points represent means, error bars represent SEM. * indicates $P < 0.05$. ** indicates $P < 0.01$ in two-sided t-Tests.

We hypothesize that killing of trophozoite-infected erythrocytes by targeting PfGARP will kill P. falciparum malaria parasites before they cause disease. We also hypothesize that a vaccine targeting PfGARP could synergize with vaccine antigens, like PfSEA-1, that target parasite egress from erythrocytes.

Importantly, PfGARP and PfSEA-1 are novel targets with no homology, or similarity, to any human proteins and when these genes have been sequenced in thousands of parasite strains, they have minimal sequence variation in the region that is contained in our vaccine formulations. Based on these data, we believe that vaccination with PfGARP and/or PfSEA-1 is unlikely to generate immunologic toxicity in humans and further suggest that the parasite may likely not be able to mutate to escape the killing effect of the vaccine induced antibodies.

It is important to note that, unlike the target of the RTS,S vaccine (circumsporozoite protein), PfSEA-1 and PfGARP antigens are expressed in the host for 8 to 24 hours which allows sufficient time for them to be targeted by vaccine induced antibodies. This is in stark contrast to the circumsporozoite protein, which is only expressed during the sporozoite stage of the P. falciparum lifecycle and thus only available for intervention during the first five minutes of infection. Furthermore, P. falciparum disease progression is dependent upon repeated rounds of schizont formation, merozoite egress, and infection of new erythrocytes (see lifecycle description above), and each time the cycle repeats the parasite again becomes vulnerable to anti-PfSEA-1 or anti-PfGARP antibodies. In contrast, parasites that escape the small window of intervention induced by the RTS,S vaccine are not prevented from further growth and replication. The subsequent unimpeded progression through the parasite lifecycle is likely a primary contributor to the relatively low immunization success rate seen with RTS,S.

We are currently evaluating whether a vaccine targeting PfSEA-1, PfGARP or a combination of the two antigens would present the best opportunity to protect patients from P. falciparum infection.

ODA-611—Anti-PfGARP mAbs

We produced a series of mAbs in mice that were immunized with laboratory generated recombinant PfGARP. Of the 16 mAbs that reacted with PfGARP in an enzyme-linked immunosorbent assay, or ELISA, only one mAb killed parasites in culture (see Fig 12). We sequenced and expressed the heavy-chain and light-chain variable regions (the genes that encode the mAb), and the resulting recombinant mAb had a dissociation constant, or Kd, of 2.9 nM, (indicating strong binding of the monoclonal to its target PfGARP) and killed parasites in culture. A monovalent antigen-binding fragment, or Fab, of this antibody also killed parasites in culture. These data confirmed that anti-PfGARP-mediated killing occurs in the absence of complement, cellular effector functions, or antigen cross-linking. We expect that a humanized version of this antibody will form the basis for our ODA-611 program.

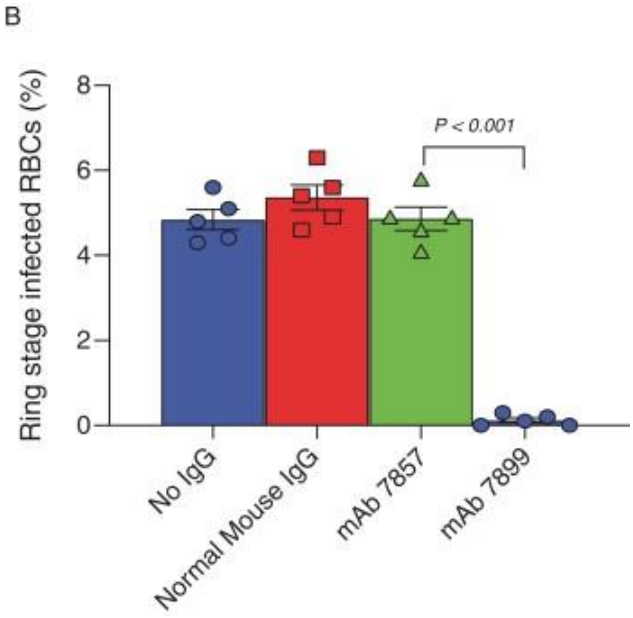


Figure 12. Monoclonal anti-PfGARP kill parasites. Anti-PfGARP mAb kills parasites. Ring stage 3D7 parasites were cultured in the presence of media alone, normal mouse IgG (1 mg/ml) or anti-PfGARP mAbs (mAb 7857 or mAb 7899, at 1 mg/ml).

ODA-579—small molecule targeting PfGARP

Our belief that PfGARP is a high value druggable target for anti-malarial drug development is based on PfGARP's surface expression on infected RBCs, the absence of any significant amino acid homology with human host proteins, and the ability of antibody binding to PfGARP to kill parasites in vitro within 12-24 hours by activating parasite programed cell suicide.

To develop a drug based on PfGARP binding, Dr. Kurtis screened a small molecule library to identify compounds that inhibit the binding of anti-PfGARP antibody to PfGARP protein. Dr. Kurtis reasoned that compounds which bind to the same region of PfGARP that is targeted by the parasite-lethal anti-PfGARP antibodies would be enriched for effective anti-malarials. Dr. Kurtis screened 6,400 compounds using an assay that detects inhibition of binding of anti-PfGARP antibodies to immobilized PfGARP protein. Dr. Kurtis identified one compound as having anti-parasite activity.

Dr. Kurtis then conducted a limited Structure Activity Relationship, or SAR, campaign, evaluating 33 additional compounds with similarity to the structure of the first compound identified. Dr. Kurtis identified one compound with enhanced parasite killing activity compared to the original compound. This molecule has an IC_{50} (concentration of drug that results in half of the maximal killing effect) of between 1 and 4.8 uM in wild type parasites (3D7 strain) and no activity in a parasite strain that has had the PfGARP gene deleted (3D7 PfGARP KO) (see Fig 13). This result demonstrates both the specificity of drug activity for PfGARP, as well as the lack of general toxicity to eukaryotic cells. Toxicity assessments show no loss of viability in multiple mammalian cell lines at up to 400 uM, which was the highest concentration tested. These data are consistent with a selectivity index (ratio of IC_{50} for mammalian cells/IC_{50} for parasites) greater than 100.

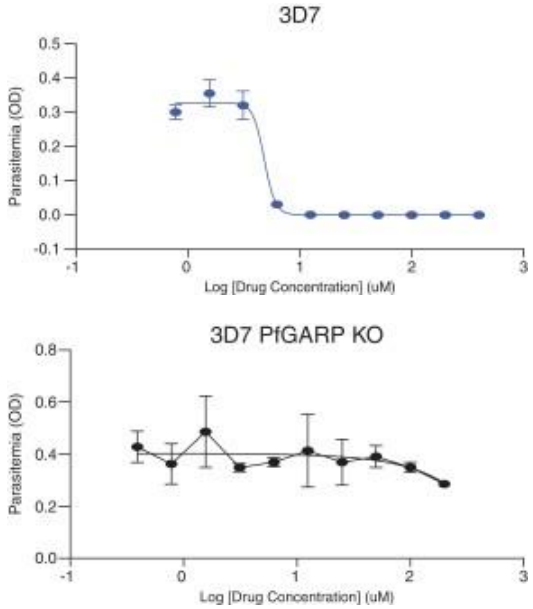


Figure 13. Molecule kills P. falciparum parasites. 3D7 (top) or 3D7 PfGARP KO (bottom) parasites were synchronized to the ring stage and incubated with a dilution series of compounds or media control for 48 hours followed by quantification of parasitemia by pLDH assay. Each dilution was evaluated in quadruplicate and error bars represent SD. The IC_{50} = 4.8 uM for killing of 3D7 parasites. Results representative of two independent experiments.

Our Whole Proteome Differential Screening Platform for Antigen Discovery

Our infectious disease product candidates are the result of decades of NIH-funded work by our co-founder, Dr. Kurtis and his team. Dr. Kurtis developed the WPDS platform and used this platform to identify our two vaccine candidate antigens for malaria: Plasmodium falciparum Schizont Egress Antigen-1, or PfSEA-1, and Plasmodium falciparum Glutamic Acid Rich Protein, or PfGARP. The WPDS platform was first described by Dr. Kurtis in 2005, and later used to identify PfSEA-1 (published in Science, the peer-reviewed academic journal of the American Association for the Advancement of Science and one of the world's top academic journals) in 2014. Dr. Kurtis has since perfected the WPDS platform to discover PfGARP as described in his Nature (the world's leading multidisciplinary science journal), 2020 publication.

The WPDS platform differs markedly from standard vaccine discovery approaches, which rely on the identification of immunodominant antigens (protein targets that generate large quantities of antibody) recognized by antibodies in animal models of human pathogens. Unfortunately, these animal models are often poor models of the complex human host-pathogen relationship and the immunodominant antigens are often decoys deployed by the pathogen to evade protective immune responses. Identifying the critical antigens that are the targets of protective antibodies on the pathogen is further complicated by the fact that susceptible humans make essentially the same antibody repertoire (i.e., recognize the same pathogen antigens) as resistant humans, thus masking the identity of the key, protective targets.

Dr. Kurtis designed the WPDS platform to specifically identify pathogen antigens that are only recognized by antibodies expressed by resistant, but not by susceptible, humans. The successful implementation of the WPDS platform requires blood samples from well characterized longitudinal cohort studies of individuals exposed to the pathogen, high quality gene libraries from the pathogen, and one-to-three months of experimental effort.

The WPDS platform identifies the pathogen antigens that are recognized by antibodies made by resistant individuals and then, importantly, removes, or excludes as vaccine targets, any antigens that are also recognized by susceptible individuals. This removal phase is essential as any antigen that is recognized by antibodies made by susceptible individuals cannot possibly be involved in providing protection.

We believe that the WPDS platform may be applicable to any human pathogen for which a subset of humans develops antibody-mediated resistance to infection/reinfection while a subset of humans remains susceptible. We believe that the platform may also enable us to identify targets against other infectious diseases.

The WPDS platform led to the discovery of novel targets against malaria, which are the basis for our anti-PfGARP therapeutics programs (ODA-611 and ODA-579) and for our vaccine program targeting PfGARP and PfSEA-1 (ODA-570).

Malaria Background: Epidemiology and Lifecycle

Plasmodium falciparum malaria is a leading cause of morbidity and mortality in developing countries, infecting 200-300 million individuals and killing nearly 500,000 children in sub-Saharan Africa each year. Nearly half of the world's population, consisting of more than three billion individuals, is at risk of malaria infection. Recent estimates indicate that even these staggering figures significantly underestimate the actual disease burden. In addition, people from the United States and Europe (including military personnel) who travel to malaria endemic regions are also at risk of contracting malaria.

Human malaria is caused by infection with one of five species of protozoan parasite of the genus Plasmodium. Infection with just one of these species, P. falciparum, accounts for more than 95% of all malaria-related deaths. Plasmodium parasites have a complex lifecycle (Fig. 14), which begins when humans become infected following the bite of an infected anopheline mosquito. During blood feeding, an infected female mosquito (only female mosquitos feed on blood, which is necessary for egg laying) injects a parasite stage called a sporozoite into the human blood stream. These sporozoites leave the blood stream and rapidly (within 5 minutes) infect liver cells. Within the liver cells, the sporozoites multiply asexually with each sporozoite giving rise to up to 10,000 merozoites. These merozoites rupture out of the liver cell and each merozoite rapidly infects (within 140 microseconds) an individual red blood cell. Within the red blood cell, the merozoite undergoes an approximately 48-hour developmental cycle. Each merozoite sequentially develops into a ring stage parasite, a trophozoite stage parasite, a schizont stage parasite and then the schizont stage parasite segments into approximately 20 daughter merozoites, which rupture from the red blood cell. Each of these twenty daughter merozoites infect new red blood cells. This blood stage infection expands exponentially until the red blood cell loss become sufficient to cause disease. In addition, the trophozoite- and schizont-stage infected red blood cells become very sticky, leading to clogged blood vessels and tissue damage to the infected human. Ultimately, some of the parasites differentiate into sexual stages, which are referred to as gametocytes, which can be taken up by a mosquito during a blood meal. Within the mosquito, these gametocytes develop into sporozoites, which can be injected into a new host when the mosquito takes her next bloodmeal.

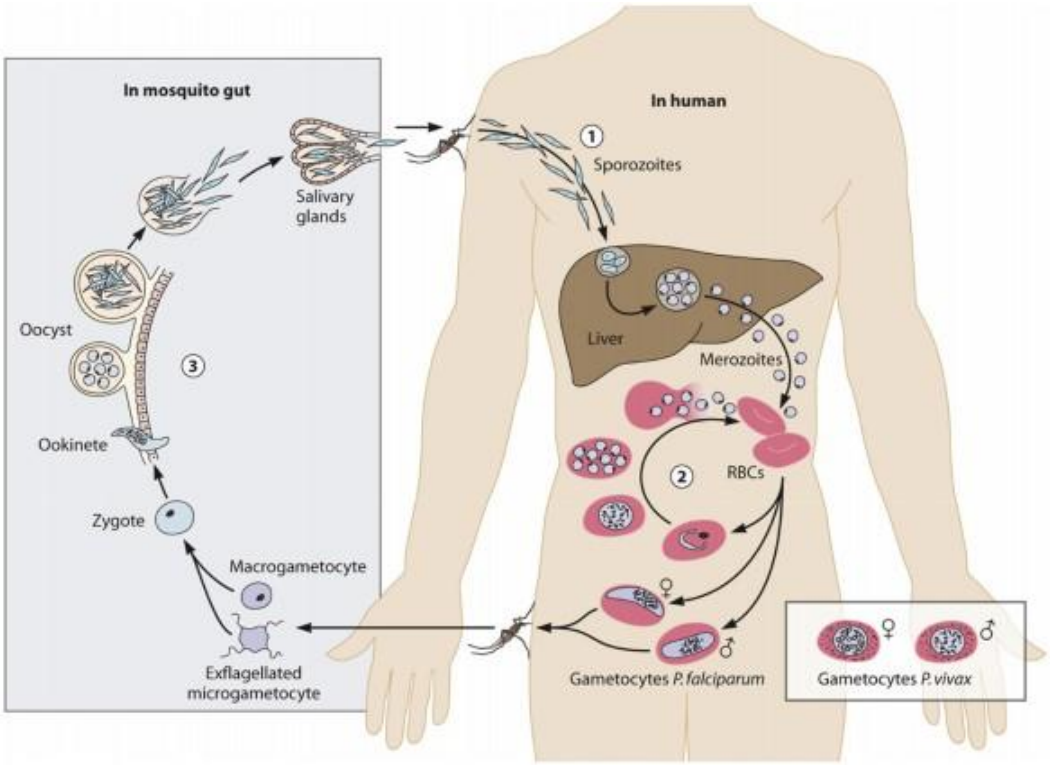


Figure 14. Lifecycle of Plasmodium falciparum (source: Clinical Microbiology Reviews, Apr. 2011, p. 379)

Limitations of Current Malaria Control Efforts

There are currently three approaches to control malaria, including insecticides to kill mosquitoes, bed nets to limit human-mosquito contact, and anti-malarial drugs used to treat infected individuals. While these interventions have some impact, each has significant limitations. Insecticides are expensive, difficult to apply, and harmful to the environment. More concerning is the emergence of widespread resistance of mosquitos to the insecticides which has led to the search for ever more lethal, and ecologically damaging, insecticides. Nevertheless, application of insecticides remains an important component of many national malaria control programs.

Bed nets have seen widespread distribution over the past 15 years based on data demonstrating that sleeping under an insecticide-impregnated bed net results in a low, but still significant, 16% reduction in child mortality. Bed nets suffer from issues of cost, maintenance (they must be repaired and re-dipped in insecticide), and compliance.

Given the low efficacy of bed nets and insecticides, the cornerstone of malaria control programs remains the treatment of symptomatic cases with anti-malarial drugs. Unfortunately, malaria parasites are particularly good at developing resistance to anti-malarial drugs and have done so for every anti-malarial drug ever developed. Currently, the most effective antimalarial drug is artemisinin and its derivatives. The recent development of artemisinin resistance in south east Asia, coupled with its detection in sub-Saharan Africa, threatens to reverse the reductions in malaria-attributed mortality seen in the past decade. Given the socio-ecological context of malaria, delayed access to drug treatment, with its consequent increased mortality, remains a major challenge to control programs.

The world continues to experience a high burden of malaria and we believe this calls for the development of new drugs and vaccines.

Current Landscape of Malaria Vaccines

A broadly effective malaria vaccine represents the holy-grail of malaria control efforts and has been pursued by scientists for decades without success. The most advanced malaria vaccine candidate, RTS,S, has publicly reported relatively low efficacy (17% and 32% protection from severe malaria in infants and young children, respectively). More concerning, RTS,S reports two significant safety signals: a ten-fold increased risk of bacterial meningitis and two-fold increased risk of mortality in girls. These safety signals had resulted in a decision in 2016 by the European Medicines Agency, or EMA, under recommendation by the World Health Organization, or WHO, to limit release of the RTS,S vaccine to a pilot introduction in three African countries (Kenya, Malawi, and Ghana) with detailed follow-up of safety outcomes that would then be used to decide whether to proceed with broad release. In October 2021 the WHO recommended broader roll-out of the RTS,S / Mosquirix vaccine after concluding it was safe based on studies from its pilot introduction, though of note these studies were not clinical trials and did not include a control group.

The RTS,S vaccine seeks to generate antibodies that prevent the sporozoite from entering the liver cell, a process that takes less than five minutes. The high antibody levels necessary to block this rapid event are very difficult to achieve and even harder to maintain. Parasites which escape the RTS,S antibodies and invade a liver cell will give rise to a full-blown malaria infection as the vaccine has no impact on the red blood cell stages of the malaria life cycle. These fundamental properties of the RTS,S vaccine result in the vaccine's poor efficacy and create a significant unmet medical need that our vaccine will endeavor to address.

Indications and Addressable Market for Malaria Programs

The target indication for our malaria vaccine ODA-570, is malaria in all at risk populations. This includes individuals living in malaria-endemic areas, as well as travelers to these areas. Based on the epidemiology, the addressable market for a malaria vaccine is more than three billion individuals.

Based on the immunology of malaria, we expect that the initial course of vaccination would entail three doses over a three-month period, with subsequent booster doses required every one-to-two years. In the developing world, we expect that our vaccine, if approved for marketing, will likely be included in the WHO-expanded program in immunization, or EPI, which currently achieves greater than 85% coverage for eligible children worldwide.

We believe that our malaria antibody, ODA-611, may have both therapeutic and prophylactic applications. The target indication for ODA-611 is the prevention of malaria in short-term travelers to malaria endemic areas, including tourists, government employees and military personnel.

We expect the target indication for our malaria drug, ODA-579, if approved, to be the treatment of mild to moderately severe malaria infection. There are 200-300 million malaria infections per year. We estimate the addressable market for our anti-malarial drug to be more than 200 million persons per year.

In addition to this prophylactic indication, we believe that our anti-PfGARP antibody could have therapeutic use in individuals with severe malaria, who are typically unable to take oral medicines. While data on the incidence of severe malaria is difficult to obtain, more than 500,000 people die each year due to malaria, each of which, by definition, represented a severe malaria case. Thus we believe this represents a reasonable estimate of the addressable worldwide market for our anti-PfGARP antibody and small molecule for severe malaria.

Infectious Disease Programs Clinical Development Plan

The ODA-570 Plasmodium falciparum vaccine is completing optimization efforts and, when completed, we plan to begin IND-enabling studies with an expected IND filing date in the second half of 2023. Clinical development will likely be modeled after the GlaxoSmithKline, or GSK, trials of their RTS, S vaccine (Mosquirix). We plan to conduct the Phase 1 clinical trial in two stages in a population of healthy volunteer adults, with the Phase 1a goal being to establish the safety of ODA-570 and Phase 1b goals to demonstrate the generation of antibodies following a ODA-570 administration and to find a preferred dosing regimen for the vaccine. The Phase 1a/b design is intended to allow for cost-effective and rapid assessment of ODA-570 on a preliminary basis. We anticipate that our Phase 2 clinical trial would proceed with the GSK RTS, S model (NCT00197041), comparing the efficacy of ODA-570 to standard of care. We expect that our Phase 3 clinical trial of ODA-570 will likely have a similar design to the Phase 2 clinical trial, although in a greater geographic area and with a participation of more volunteers, such as was done by GSK in the development of their RTS, S vaccine (NCT00866619). We expect the ODA-570 program to qualify for priority NDA review based on the neglected tropical diseases qualification and, if approved, may be eligible for a tropical disease priority review voucher.

The ODA-611 and ODA-579 Plasmodium falciparum therapeutic product candidates are also in the optimization stage, with ODA-611 anticipated to begin IND-enabling studies (including antibody humanization) within 18 months of raising sufficient capital to fund such IND projects.

The chemical structure of ODA-579 allows for the possibility of further refinement, so we plan for limited SAR work to be conducted prior to the initiation of IND-enabling studies. However, we believe that the relatively short manufacturing development period for small molecules, such as ODA-579, should allow for the filing of IND applications for both ODA-579 and ODA-611 within 18 months of raising sufficient capital to fund such IND projects.

It is our intention that the ODA-611 and ODA-579 Plasmodium falciparum therapeutic product candidates will initially follow the clinical development example of Takeda and AbbVie's DSM265 (ACTRN12613000522718 and ACTRN12613000527763). The Phase 1a portion of the trial of ODA-611 will likely be a single-ascending dose, or SAD, trial based on the expected long half-life of this antibody, that is aimed at evaluating safety and pharmacokinetics. The Phase 1a portion of ODA-579 will likely begin with a SAD study, and an additional MAD may be added depending on the pharmacokinetics observed. Both drugs are expected to proceed into a Phase 1b trial that will likely consist of a small number of volunteers testing the efficacy of the product candidates following a challenge with P. falciparum. This design is intended to allow us to observe any early signs of efficacy on a preliminary basis that could help guide future development and further refine the dosing strategy. The Phase 2 clinical trials of ODA-611 and ODA-579 are modeled after that of Novartis' KAE607 (NCT03334747). This trial design allows for assessment of the impact of different dose levels and treatment regimens of the molecules in the treatment of P. falciparum infected patients in a region where malaria is endemic. The registration trials of ODA-611 and ODA-579 are aimed at assessing the safety and efficacy of these treatments in combination with standard of care and are modeled after the National Institute of Allergy and Infectious Diseases', or NIAID, past work exploring combinations with chloroquine (NCT00379821). While the NIAID's chloroquine trial was primarily focused on children, we anticipate recruiting both adults and children because we believe this may maximize the treatable population should our therapeutic candidate receive regulatory approval.

Intellectual Property

We seek to protect the intellectual property ("IP") and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We likewise seek to protect the IP to which we obtain rights through direct and indirect licenses (e.g., from universities and research institutions) and work collaboratively with our licensors to ensure (and if possible be the driver of) patent prosecution and protection. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and IP positions. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position(s) for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and patent cooperation treaty, or PCT, patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology in relation to the commercialization of our products. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future.

Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. For example, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent.

The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. Additionally, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA. In the future, if our product candidates receive approval by the FDA, we expect to apply for patent term extensions on any issued patents covering those products, depending upon the length of the clinical studies for each product and other factors.

There can be no assurance that our pending provisional or PCT patent applications will issue or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

As of November 24, 2024, we exclusively license 16 allowed or issued patents and 36 pending patent applications. The issued patents and pending patent applications have nominal expiration dates ranging from 2032 to 2041, without accounting for any available patent term adjustments or extensions. We have further exclusively sublicensed our rights and obligations under our licenses with Elkurt, Inc. to three subsidiaries that house the applicable program: Ocean Chitorx, Inc. (for oncology), Ocean Sihoma, Inc. (for malaria) and Ocean Chitofibrorx, Inc. (for fibrosis).

These issued patents and patent applications include:

- With respect to OCX-253, OCX-410, and OCX-909, our Ocean Chitorx, Inc. subsidiary obtained an exclusive sublicense from Elkurt, Inc., or Elkurt, under Elkurt's exclusive license from Brown University. Specifically, the Elkurt license includes four issued U.S. methods and compositions utility patents and twenty pending utility patent applications including applications in the United States, Canada, Europe, and Hong Kong. The issued patents have expected expiration dates in 2038, without accounting for any available patent term adjustments or extensions. Elkurt is a company formed by our scientific co-founders and members of our board of directors, Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., Ph.D., Chair of the Department of Pathology and Laboratory Medicine at Brown.

- With respect to OCF-203, our Ocean Chitofibrorx, Inc. subsidiary obtained an exclusive sublicense from Elkurt under Elkurt's exclusive license from Brown University. Specifically, this Elkurt license includes one issued U.S. methods and compositions utility patent and three pending utility patent application including applications in the United States, Canada, and Europe.

- With respect to ODA-570, our Ocean Sihoma, Inc. subsidiary obtained an exclusive sublicense from Elkurt under Elkurt's exclusive license from Rhode Island Hospital. Specifically, this Elkurt license includes eight issued patents including four U.S. patents, one European patent validated in seven countries, one South African patent, one African Regional Intellectual Property Organization, or ARIPO, patent; one Indian patent; and six pending utility patent applications including applications in the United States, Brazil, Europe, India, AIRPO, and Thailand. The issued patents have expected expiration dates in 2032, without accounting for any available patent term adjustments or extensions.

- With respect to ODA-611 and ODA-579, our Ocean Sihoma, Inc. subsidiary also obtained an exclusive sublicense from Elkurt under Elkurt's exclusive license from Rhode Island Hospital. Specifically, this Elkurt license includes eight pending utility patent applications in the United States, Canada, Brazil, Europe, South Africa, India, Thailand, and ARIPO.

Licensing Agreements

Exclusive License Agreement with Elkurt for (FRG) Antibody

On July 31, 2020, we entered into an exclusive license agreement, or the FRG License Agreement, with Elkurt, Inc., or Elkurt, for OCX-253. We further sub-licensed this program to our Ocean Chitorx, Inc. subsidiary on February 25, 2021. We amended the FRG License Agreement on March 21, 2021, August 31, 2021, March 25, 2022, July 1, 2022, July 2, 2022, August 25, 2022, November 1, 2023 and June 13, 2024. Pursuant to the FRG License Agreement, we obtained from Elkurt an exclusive, royalty-bearing license under certain patent rights, or the FRG Patents, and a nonexclusive, royalty-bearing license under certain data, expression and purification methods, information and other know-how, or the FRG Know-How, relating to anti-Chi311 antibodies, or FRG Antibodies. Under such licenses that we obtained from Elkurt, or the FRG Licenses, we have the right to make, have made, market, offer for sale, use and sell in all fields of use on a worldwide basis any products or services that are either covered by the FRG Patents or incorporates or otherwise utilizes any FRG Know-How, or any materials that are sold in conjunction with any such products or services, in each such case an FRG Product. On January 29, 2020, Elkurt obtained from Brown University, or Brown, the licenses, with the rights to sublicense, under the FRG Patents and the FRG Know-How, to grant us the FRG Licenses as described above, or the Upstream Brown FRG License. Brown and Elkurt, on behalf of Brown, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings. Elkurt is a company formed by our scientific co-founders and members of our board of directors, Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., Ph.D., Chair of the Department of Pathology and Laboratory Medicine at Brown.

The FRG License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The FRG License Agreement sets forth the following future development milestones: the filing of an IND within one year after commencing IND-enabling studies; completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and completion of a Phase 3 clinical trial within three and a half years following completion of a Phase 2 clinical trial. Elkurt may also terminate the agreement if we do not complete a $10 million equity or debt financing by 2025.

In consideration for the rights conveyed by Elkurt under the FRG License Agreement and amendments, we are obligated to pay to Elkurt a non-refundable, annual license maintenance fee. Beginning January 1, 2022, we are obligated to pay Elkurt an annual license maintenance fee of (a) $3,000 until January 1, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any FRG Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the FRG Licenses, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% and 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of an FRG Product. We are also required to pay certain milestone payments on an FRG Product-by-FRG Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each FRG Product. To the extent net sales or non-royalty sublicense income are generated from any FRG Products that are commercialized by us or our sublicensees that incorporates or otherwise utilizes the FRG Know-How but is not covered by any FRG Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to Brown under the Upstream Brown FRG License Agreement, except that Elkurt is not obligated to pay any annual maintenance fee amounts to Brown.

Under the FRG License Agreement, Brown retains control of the preparation, filing, prosecution and maintenance of the FRG Patents. We are responsible for reimbursing Elkurt for all documented, out-of-pocket expenses incurred in performing such patent-related activities during the term of the FRG License Agreement. We are also obligated to reimburse Elkurt for all documented, out-of-pocket expenses incurred prior to the effective date of the FRG License Agreement with respect to the preparation, filing, prosecution and maintenance of the FRG Patents.

Unless earlier terminated, the FRG License Agreement, including the royalty bearing license, will terminate in its entirety upon the later of (a) the expiration of the last to expire valid claim of the FRG Patents covering any FRG Product, or (b) ten years. We may terminate the FRG License Agreement in its entirety at any time for convenience. Either party may terminate the FRG License Agreement in its entirety for the other party's uncured material breach after an opportunity for the other party to cure such material breach. Elkurt may terminate the FRG License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the FRG License Agreement for our insolvency. If the FRG License Agreement is terminated by either party for any reason, the FRG Licenses will terminate and all rights thereunder will revert to Elkurt.

Exclusive License Agreement with Elkurt for Bi-Specific Antibody Anti-CTLA4

On July 31, 2020, we entered into an exclusive license agreement, or the Anti-CTLA4 License Agreement, with Elkurt, for OCX-909. We further sub-licensed this program to our Ocean Chitorx, Inc. subsidiary on February 25, 2021. We amended the Anti-CTLA4 License Agreement on March 21, 2021, August 31, 2021, March 25, 2022, July 1, 2022, July 2, 2022, August 25, 2022, November 1, 2023 and June 13, 2024. Pursuant to the Anti-CTLA4 License Agreement, we obtained an exclusive, royalty-bearing license under certain patents rights, or the Anti-CTLA4 Patents, and a nonexclusive, royalty-bearing sublicense under certain data, expression and purification methods, information and other know-how, or the Anti-CTLA4 Know-How, relating to anti-CTLA4 bi-specific antibodies, or Anti-CTLA4 Antibodies. Under such licenses that we obtained from Elkurt, or the Anti-CTLA4 Licenses, we have the right to make, have made, market, offer for sale, use and sell in the field of cancer on a worldwide basis any products or services that are either covered by the Anti-CTLA4 Patents or incorporates or otherwise utilizes any Anti-CTLA4 Know-How, or any materials that are sold in conjunction with any such products, in each such case an Anti-CTLA4 Product. On January 29, 2020, Elkurt obtained from Brown, the licenses, with the rights to sublicense, under the Anti-CTLA4 Patents and the Anti-CTLA4 Know-How, to grant us the Anti-CTLA4 Licenses as described above, or the Upstream Brown Anti-CTLA4 License. Brown and Elkurt, on behalf of Brown, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings.

The Anti-CTLA4 License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The Anti-CTLA4 License Agreement sets forth the following future development milestones: the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and the completion of a Phase 3 clinical trial within approximately three years following the completion of a Phase 2 clinical trial. Elkurt may also terminate the agreement if we do not complete a $10 million equity financing by November 1, 2023.

In consideration for the rights conveyed by Elkurt under the Anti-CTLA4 License Agreement, we are obligated to pay to Elkurt a non-refundable, annual license maintenance fee. Beginning January 1, 2022, we are obligated to pay Elkurt an annual license maintenance fee (a) of $3,000 until January 1, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any Anti-CTLA4 Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the Anti-CTLA4 License Agreement, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% or 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of an Anti-CTLA4 Product. We are also required to pay certain milestone payments on an Anti-CTLA4 Product-by-Anti-CTLA4 Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each Anti-CTLA4 Product. To the extent net sales or non-royalty sublicense income are generated from any Anti-CTLA4 Products that are commercialized by us or our sublicensees that incorporate or otherwise utilizes the Anti-CTLA4 Know-How but not covered by any Anti-CTLA4 Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to Brown under the Upstream Brown Anti-CTLA4 License Agreement, except that Elkurt is not obligated to pay Brown any annual maintenance fees.

Under the Anti-CTLA4 Agreement, Brown retains control of the preparation, filing, prosecution and maintenance of the Anti-CTLA4 Patents. We are responsible for reimbursing Elkurt for all documented, out-of-pocket expenses during the term of the Anti-CTLA4 License Agreement. We are also obligated to reimburse Elkurt for all documented, out-of-pocket expenses incurred prior to the effective date of the Anti-CTLA4 License Agreement with respect to the preparation, filing, prosecution and maintenance of the Anti-CTLA4 Patents licensed by us.

Unless earlier terminated, the Anti-CTLA4 License Agreement, including the royalty bearing license, will expire upon the later of (a) the expiration of the last to expire valid claim of an Anti-CTLA4 Patents covering any Anti-CTLA4 Products in any country, or (b) ten years. We may terminate the Anti-CTLA4 License Agreement in its entirety at any time for convenience. Either party may terminate the Anti-CTLA4 License Agreement in its entirety for the other party's uncured material breach after an opportunity by the other party to cure such material breach. Elkurt may terminate the Anti-CTLA4 License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the Anti-CTLA4 License Agreement for our insolvency. If the License Agreement is terminated by either party for any reason, the Anti-CTLA4 Licenses will terminate and all rights thereunder will revert to Elkurt.

Exclusive License Agreement with Elkurt for Bispecific (FRG)xAnti-PD-1 (FRGxPD-1)

On July 31, 2020, we entered into an exclusive license agreement, or the FRGxPD-1 License Agreement, with Elkurt, for OCX-410. We further sub-licensed this program to our Ocean Chitorx, Inc. subsidiary on February 25, 2021. We amended the FRGxPD-1 License Agreement on March 21, 2021, August 31, 2021, March 25, 2022, July 1, 2022, July 2, 2022, August 25, 2022, November 1, 2023 and June 13, 2024. Pursuant to the FRGxPD-1 License Agreement, we obtained from Elkurt an exclusive, royalty-bearing license under certain patent rights, or the FRGxPD-1 Patents, and a nonexclusive, royalty-bearing license under certain data, expression and purification methods, information and other know-how, or the FRGxPD-1 Know-How, relating to (FRG)xAnti-PD-1 bispecific antibodies, or FRGxPD-1 Antibodies. Under such licenses that we obtained from Elkurt, or the FRGxPD-1 Licenses, we have the rights to make, have made, market, offer for sale, use and sell in all fields of use worldwide any products or services that are either covered by the FRGxPD-1 Patents or incorporates or otherwise utilizes any FRGxPD-1 Know-How, or any materials that are sold in conjunction with any such products, in each such case an FRGxPD-1 Product. On January 29, 2020, Elkurt obtained from Brown, the licenses, with the rights to sublicense, under the FRGxPD-1 Patents and the FRGxPD-1 Know-How, to grant us the FRGxPD-1Licenses as described above, or the Upstream Brown FRGxPD-1 License. Brown and Elkurt, on behalf of Brown, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings.

The FRGxPD-1 License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The FRGxPD-1 License Agreement sets forth the following future development milestones: the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and the completion of a Phase 3 clinical trial within three years following the completion of a Phase 2 clinical trial. Elkurt may also terminate the agreement if we do not complete a $10 million equity financing by November 1, 2023.

In consideration for the rights conveyed by Elkurt under the FRGxPD-1 License Agreement, we must pay to Elkurt a non-refundable, annual license maintenance fee. Beginning January 1, 2022, we are obligated to pay Elkurt an annual license maintenance fee (a) of $3,000 on each until January 1, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any FRGxPD-1 Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the FRGxPD-1 Licenses, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% or 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of an FRG Product. We are also required to pay certain milestone payments on an FRGxPD-1 Product-by-FRGxPD-1 Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each FRGxPD-1 Product. To the extent net sales or non-royalty sublicense income are generated from any FRGxPD-1 Products that are commercialized by us or our sublicensees that incorporate or otherwise utilizes the FRGxPD-1 Know-How but not covered by any FRGxPD-1 Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to Brown under the Upstream Brown FRGxPD-1 License Agreement, except that Elkurt is not obligated to pay Brown any annual maintenance fees.

Under the FRGxPD-1 Agreement, Brown retains control of the preparation, filing, prosecution and maintenance of the FRGxPD-1 Patents. We are responsible for reimbursing Elkurt for all documented, out-of-pocket expenses during the term of the FRGxPD-1 License Agreement. We will also reimburse Elkurt for all documented, out-of-pocket expenses incurred prior to the effective date of the FRGxPD-1 License Agreement with respect to the preparation, filing, prosecution and maintenance of the FRGxPD-1 Patents licensed by us.

Unless earlier terminated, the FRGxPD-1 License Agreement, including the royalty bearing license, will expire upon the later of (a) the expiration of the last to expire valid claim of an FRGxPD-1 Patent covering any FRGxPD-1 Products in any country or (b) ten years. We may terminate the FRGxPD-1 License Agreement in its entirety at any time for convenience. Either party may terminate the FRGxPD-1 License Agreement in its entirety for the other party's uncured material breach after an opportunity by the other party to cure such material breach. Elkurt may terminate the FRGxPD-1 License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the FRGxPD-1 License Agreement for our insolvency. If the License Agreement is terminated by either party for any reason, the FRGxPD-1 Licenses will terminate and all rights thereunder will revert to Elkurt.

Exclusive License Agreement with Elkurt for (Chit1) Small Molecule Antifibrotic

On July 31, 2020, we entered into an exclusive license agreement, or the Chit1 License Agreement, with Elkurt, for OCF-203. We further sub-licensed this program to our Ocean Chitofibrorx, Inc. subsidiary on February 25, 2021. We amended the Chit1 License Agreement on March 21, 2021, August 31, 2021, March 25, 2022, July 1, 2022, July 2, 2022, August 25, 2022, November 1, 2023 and June 13, 2024. Pursuant to the Chit1 License Agreement, we obtained from Elkurt an exclusive, royalty-bearing license under certain patent rights, or the Chit1 Patents, and a nonexclusive, royalty-bearing license under certain protocols, data, expression and purification methods, information and other know-how, or the Chit1 Know-How, relating to Chit1 small molecules, or Chit1 Molecules. Under such licenses that we obtained from Elkurt, or the Chit1 Licenses, we have the worldwide rights to make, have made, market, offer for sale, use and sell in the field of pulmonary fibrosis and other fibrotic conditions any products or services that are either covered by the Chit1 Patents or incorporates or otherwise utilizes any Chit1 Know-How, or any materials that are sold in conjunction with any such products or services, in each such case an Chit1 Product. On January 29, 2020, Elkurt obtained from Brown the necessary licenses, with the rights to sublicense, under the Chit1 Patents and the Chit1 Know-How, or the Upstream Brown Chit1 License, to grant us the Chit1 Licenses as described above. Brown and Elkurt, on behalf of Brown, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings.

The Chit1 License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The Chit1 License Agreement sets forth the following future development milestones: the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1/2 clinical trial within two years following the filing of an IND; and the completion of a Phase 3 clinical trial within approximately three years following the completion of a Phase 1/2 clinical trial. Elkurt may also terminate the agreement if we do not complete a $10 million equity financing by November 1, 2023.

In consideration for the rights conveyed by Elkurt under the Chit1 License Agreement, we must pay to Elkurt a non-refundable, annual license maintenance fee. Beginning January 1, 2022, we are obligated to pay Elkurt an annual license maintenance fee (a) of $3,000 until January 1, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any Chit1 Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the Chit1 Licenses, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% to 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of a Chit1 Product. We are also required to pay certain milestone payments on a Chit1 Product-by-Chit1 Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each Chit1 Product. To the extent net sales or non-royalty sublicense income are generated from any Chit1 Products that are commercialized by us or our sublicensees that incorporate or otherwise utilizes the Chit1 Know-How but not covered by any Chit1 Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to Brown under the Upstream Brown Chit1 License Agreement, except that Elkurt is not obligated to pay Brown any annual maintenance fees.

Under the Chit1 Agreement, Brown retains control of the preparation, filing, prosecution and maintenance of the Chit1 Patents. We are responsible for reimbursing Elkurt for all documented, out-of-pocket expenses during the term of the Chit1 License Agreement. We will also reimburse Elkurt for all documented, out-of-pocket expenses incurred prior to the effective date of the Chit1 License Agreement with respect to the preparation, filing, prosecution and maintenance of the Chit1 Patents licensed by us under this agreement.

Unless earlier terminated, the Chit1 License Agreement, including the royalty bearing license, will expire upon the later of (a) the expiration of the last to expire valid claim of a Chit1 Patent covering any Chit1 Products in any country or (b) ten years. We may terminate the Chit1 License Agreement in its entirety at any time for convenience. Either party may terminate the Chit1 License Agreement in its entirety for the other party's uncured material breach after an opportunity to cure such material breach. Elkurt may terminate the Chit1 License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the Chit1 License Agreement for our insolvency. If the License Agreement is terminated by either party for any reason, the Chit1 Licenses will terminate and all rights thereunder will revert to Elkurt.

Exclusive License Agreement with Elkurt for Malaria Small Molecules

On January 25, 2021, we entered into an exclusive license agreement, or the PfGARP/PfSEA License Agreement, with Elkurt, for ODA-570, ODA-611 and ODA-579. We further sub-licensed this program to our Ocean Sihoma, Inc. subsidiary on February 25, 2021. We amended the PfGARP/PfSEA License Agreement on April 1, 2021, September 10, 2021, March 25, 2022, July 1, 2022, August 26, 2022 and July 18, 2024. Pursuant to the PfGARP/PfSEA License Agreement, we obtained from Elkurt an exclusive, royalty-bearing license under certain patent rights, or the PfGARP/PfSEA Patents, and a nonexclusive, royalty-bearing license under certain protocols, data, expression and purification methods, information and other know-how, or the PfGARP/PfSEA Know-How, relating to PfGARP-1 vaccines and antibodies to Pfgarp. Under such licenses that we obtained from Elkurt, or the PfGARP/PfSEA Licenses, we have the worldwide rights to make, have made, market, offer for sale, use and sell in the field of malaria any products or services that are either covered by the PfGARP/PfSEA Patents or incorporates or otherwise utilizes any PfGARP/PfSEA Know-How, or any materials that are sold in conjunction with any such products or services, in each such case a PfGARP/PfSEA Product. On February 1, 2020, Elkurt obtained from Rhode Island Hospital, or RIH, the necessary licenses, with the rights to sublicense, under the PfGARP/PfSEA Patents and the PfGARP/PfSEA Know-How, or the Upstream RIH License, to grant us the PfGARP/PfSEA Licenses as described above. RIH and Elkurt, on behalf of RIH, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings.

Under the PfGARP/PfSEA License Agreement, we must use commercially reasonable efforts to develop and commercialize products in accordance with the development and commercialization plan, to introduce PfGARP/PfSEA Products into the commercial market and to market PfGARP/PfSEA Products after such introduction in the market, and we must meet certain development and commercialization milestones or else failure to do so will be considered a material breach of the PfGARP/PfSEA License Agreement.

In consideration for the rights conveyed by Elkurt under the PfGARP/PfSEA License Agreement, we must pay to Elkurt a non-refundable, annual license maintenance fee. Beginning January 1, 2022 we are obligated to pay Elkurt an annual license maintenance fee (a) of $3,000 until January 1, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any PfGARP/PfSEA Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the PfGARP/PfSEA Licenses, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% or 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of a PfGARP/PfSEA Product. We are also required to pay certain milestone payments on a PfGARP/PfSEA Product-by-PfGARP/PfSEA Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each PfGARP/PfSEA Product. To the extent net sales or non-royalty sublicense income are generated from any PfGARP/PfSEA Products that are commercialized by us or our sublicensees that incorporate or otherwise utilizes the PfGARP/PfSEA Know-How but not covered by any PfGARP/PfSEA Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to RIH under the Upstream RIH PfGARP/PfSEA License Agreement, except that Elkurt is not obligated to pay RIH any annual maintenance fees.

The PfGARP/PfSEA License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The PfGARP/PfSEA License Agreement sets forth the following future development milestones for the malaria vaccine program: the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1/2 clinical trial within one and a half years following the filing of an IND; and the completion of a Phase 3 clinical trial within three years following completion of a Phase 1/2 clinical trial. Elkurt may also terminate the agreement if we do not complete a $10 million equity financing by November 1, 2023.

Unless earlier terminated, the PfGARP/PfSEA License Agreement, including the royalty bearing license will expire upon the later of (a) the expiration of the last to expire valid claim of a PfGARP/PfSEA Patent covering any PfGARP/PfSEA Products in any country or (b) ten years. We may terminate the PfGARP/PfSEA License Agreement in its entirety at any time for convenience. Either party may terminate the PfGARP/PfSEA License Agreement in its entirety for the other party’s uncured material breach after an opportunity to cure such material breach. Elkurt may terminate the PfGARP/PfSEA License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the PfGARP/PfSEA License Agreement for our insolvency. If the PfGARP/PfSEA License Agreement is terminated by either party for any reason, the PfGARP/PfSEA Licenses will terminate and all the rights thereunder will revert to Elkurt.

Exclusive License Agreement with Elkurt for Malaria Antibodies

On September 13, 2022, we entered into an exclusive license agreement, or the Brown Anti-PfGARP Small Molecules License Agreement, with Elkurt. Pursuant to the Brown Anti-PfGARP Small Molecules License Agreement, we obtained from Elkurt an exclusive, royalty-bearing license under certain patent rights, or the Brown Anti-PfGARP Small Molecules Patents, and a nonexclusive, royalty-bearing license under certain protocols, data, expression and purification methods, information and other know-how, or the Brown Anti-PfGARP Small Molecules Know-How, relating to anti-PfGARP small molecules. Under such licenses that we obtained from Elkurt, or the Brown Anti-PfGARP Small Molecules Licenses, we have the worldwide rights to make, have made, market, offer for sale, use and sell in the field of malaria any products or services that are either covered by the Brown Anti-PfGARP Small Molecules Patents or incorporates or otherwise utilizes any Brown Anti-PfGARP Small Molecules Know-How, or any materials that are sold in conjunction with any such products or services, in each such case a Brown Anti-PfGARP Small Molecules Product. Elkurt obtained from Brown University the necessary licenses, with the rights to sublicense, under the Brown Anti-PfGARP Small Molecules Patents and the Brown Anti-PfGARP Small Molecules Know-How, or the Upstream Brown Anti-PfGARP Small Molecules License, to grant us the Brown Anti-PfGARP Small Molecules Licenses as described above. Brown University and Elkurt, on behalf of Brown University, retained the rights to practice the intellectual property rights sublicensed to us for academic research, educational and scholarly purposes, and to publish resulting scientific findings.

Under the Brown Anti-PfGARP Small Molecules License Agreement, we must use commercially reasonable efforts to develop and commercialize products in accordance with the development and commercialization plan, to introduce Brown Anti-PfGARP Small Molecules Products into the commercial market and to market Brown Anti-PfGARP Small Molecules Products after such introduction in the market, and we must meet certain development and commercialization milestones or else failure to do so will be considered a material breach of the Brown Anti-PfGARP Small Molecules License Agreement.

In consideration for the rights conveyed by Elkurt under the Brown Anti-PfGARP Small Molecules License Agreement, we must pay to Elkurt a non-refundable, annual license fee. Beginning September 13, 2023 we are obligated to pay Elkurt an annual license maintenance fee equal to (a) $3,000 until September 13, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. We are also obligated to pay to Elkurt low, single-digit royalties, on net sales of any Brown Anti-PfGARP Small Molecules Products that are commercialized by us or our sublicensees. If we grant any sublicenses under the Brown Anti-PfGARP Small Molecules Licenses, we are obligated to pay to Elkurt an initial sublicense fee that is either 10% or 25% depending, respectively, on whether we execute the sublicense after or before the first commercial sale of a Brown Anti-PfGARP Small Molecules Product. We are also required to pay certain milestone payments on a Brown Anti-PfGARP Small Molecules Product-by-Brown Anti-PfGARP Small Molecules Product basis upon the achievement of specified clinical and regulatory milestones, totaling up to $0.7 million for each Brown Anti-PfGARP Small Molecules Product. To the extent net sales or non-royalty sublicense income are generated from any Brown Anti-PfGARP Small Molecules Products that are commercialized by us or our sublicensees that incorporate or otherwise utilizes the Brown Anti-PfGARP Small Molecules Know-How but not covered by any Brown Anti-PfGARP Small Molecules Patents, we may reduce the applicable royalty rates and non-royalty income rates by half. These payment amounts are identical to the amounts owed by Elkurt to Brown University under the Upstream Brown Anti-PfGARP Small Molecules License, except that Elkurt is not obligated to pay Brown University any annual maintenance fees. We also are required to pay Elkurt $0.1 million in the event that we or one of sublicensees sublicenses this technology to a major pharmaceutical company or if the license agreement or any sublicense agreement for this technology is acquired by a major pharmaceutical company. A major pharmaceutical company is one that is publicly traded, with market capitalization of at least $5 billion and has been engaged in drug discovery, development, production and marketing for no less than 5 years.

The Brown Anti-PfGARP Small Molecules License Agreement requires us to achieve future development milestones by certain dates. Recognizing the unpredictability of clinical development, the agreement allows us to request amendments and/or extensions to these milestones by providing Elkurt with a reasonable explanation for such requests along with plans for achieving the extended and/or amended milestones. Although Elkurt is obliged to reasonably extend or amend those milestones, it may terminate the agreement for failure to achieve development milestones after giving us reasonable opportunity to cure. The Brown Anti-PfGARP Small Molecules License Agreement sets forth the following future development milestones for the malaria small molecules program: the filing of an IND in 2027; the commencement of Phase 1/2 clinical trials in 2027; and the commencement of a Phase 3 clinical trial in 2029. Elkurt may also terminate the agreement if we do not complete a $10 million equity financing by November 1, 2023.

Unless earlier terminated, the Brown Anti-PfGARP Small Molecules License Agreement, including the royalty bearing license will expire upon the later of (a) the expiration of the last to expire valid claim of a Brown Anti-PfGARP Small Molecules Patent covering any Brown Anti-PfGARP Small Molecules Products in any country or (b) ten years. We may terminate the Brown Anti-PfGARP Small Molecules License Agreement in its entirety at any time for convenience. Either party may terminate the Brown Anti-PfGARP Small Molecules License Agreement in its entirety upon the other party's uncured material breach after an opportunity to cure such material breach. Elkurt may terminate the Brown Anti-PfGARP Small Molecules License Agreement in its entirety immediately upon notice for failure by us to meet certain milestones or the failure to achieve a certain amount of financing. Elkurt may also terminate the Brown Anti-PfGARP Small Molecules License Agreement for our insolvency. If the Brown Anti-PfGARP Small Molecules License Agreement is terminated by either party for any reason, the Brown Anti-PfGARP Small Molecules Licenses will terminate and all the rights thereunder will revert to Elkurt.

Competition in our Industry

Competition for New Product Candidates

Our industry is intensely competitive and subject to rapid and significant technological change. While we believe that our knowledge, experience, scientific resources and business model provide us with competitive advantages and may make us a partner of choice to research universities and medical centers, we face substantial competition from pharmaceutical companies as well as established and venture-backed biotechnology companies worldwide. For example, other companies such as BridgeBio similarly target research universities and medical centers to identify and develop therapeutic candidates that may or may not overlap with the inventions or technologies that we may seek to develop. As a result, we may face competition from other companies that are seeking to gain access to the types of institutions that we may seek to partner with. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Competition for Existing Product Candidates

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If our current product candidates or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

In addition, we may likely need to develop certain of our product candidates in collaboration with diagnostic companies, and we will face competition from other companies in establishing these collaborations. Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable treatments. Some of these competitive drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Oncology

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them.

In oncology, two of our programs, OCX-253 and OCX-410, are targeting NSCLC as their initial indication. For NSCLC, currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to immune checkpoint inhibitors targeting PD-1/PDL-1, such as Bristol Myers Squibb's, or BMS', Opdivo, Merck's Keytruda, Genentech's Tecentriq, Regeneron's Libtayo, Astra Zeneca's Imfinzi, and targeting CTLA- 4, such as BMS' Yervoy. There are also numerous compounds in clinical development for the potential treatment of NSCLC including Roche's tiragolumab which targets TIGIT. Our OCX-909 is targeting GBM, for which there are no currently approved therapies that are effective in treating this disease.

Fibrosis

Our program OCF-203 in fibrotic diseases is targeting IPF and HPS. For the treatment of IPF, we are aware of two approved products: Esbriet (pirfenidone), marketed by Roche Holding AG, and Ofev, marketed by Boehringer Ingelheim GmbH. Novartis launched a generic version of pirfenidone in May 2022. Roche and Boehringer Ingelheim are both developing next-generation IPF therapies. Companies currently developing product candidates in IPF in late-stage Phase III trials include Fibrogen, United Therapeutics, and Roche. Companies with IPF candidates in early-stage trials include BMS, Horizon, Pliant, Galecto Biotech, and Endeavor Biomedicines. For HPS, there are no marketed therapeutics and only one investigational program from Roche, which is targeting HPS patients who have an associated interstitial lung disease.

Infectious Disease

The infectious disease programs address both prophylactic and therapeutic treatment of malaria. Our malaria vaccine program, ODA-570, currently has only one marketed competitor, GSK's Mosquirix. Companies with the next most advanced vaccines are Sanaria with PfSPZ (beginning Phase 3 clinical trials) and VLP therapeutics (Phase 2 clinical trials). Additionally, there are several additional early-stage vaccine candidates in development. One application of our malaria antibody program, ODA-611, targets short-term prophylaxis. Several generic short-term prophylactic treatments are currently available, such as Atovaquone/Proguanil, chloroquine, doxycycline, mefloquine, primaquine, tafenoquine. Additionally, prophylactic anti-malarial therapies in pre-clinical or early stage development are being explored by Medicines for Malaria Venture (MMV), Merck, Lyndra Therapeutics, and Titan Pharmaceuticals. The NIH is currently conducting a Phase 1 clinical trial, mAb CIS43LS, which is the only direct analogous competitor to our program.

Programs ODA-611 and ODA-579 have target indications for the treatment of symptomatic malaria infection. Currently favored treatment classes include quinoline-related compounds, antifolates, artemisinin derivatives, and antimicrobials. There are a variety of treatment options within these classes available and currently marketed by MMV, Novartis, Leadiant Biosciences, GSK, Millennial Hope, Roche, Takeda, and most recently IV Artesunate from Amivas. Additionally, MMV, Merck, J&J, and Eisai have severe malaria therapeutic candidates in early stage clinical trials.

Manufacturing

We do not have any manufacturing facilities or personnel at this time. We currently rely, and expect to continue to rely, on CMOs for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacturing if our product candidates receive marketing approval.

Our product candidates include small molecules, vaccines, and monoclonal and bispecific antibodies. Several contract manufacturing facilities exist that have expertise in each product type and we anticipate that our product candidates can be produced by them at scale and in a cost-effective manner. As needed, we also expect to rely on CMOs for the manufacturing of companion diagnostics, which are assays or tests to identify an appropriate patient population. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

Commercialization

We will objectively assess and choose each program's commercialization option that maximizes potential value for patients and for our shareholders. We anticipate optimizing its commercial value through various options, including internal advancement, partnerships with established companies, and spin-outs or IPOs. If we opt to commercialize a particular candidate ourselves, we anticipate assembling a focused sales and marketing organization to sell our products. We will aim for such organization to address the community of relevant medical practitioners who are the key specialists in treating the patient populations for which our product candidates are being developed. We may also enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, as well as diagnostics. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized, or cleared by the applicable regulatory authority.

United States Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and its implementing regulations and biologics under the FD&C Act and the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Our product candidates must be approved by the FDA through either an NDA or a BLA before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each human trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval or pre-license inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with Current Good Manufacturing Practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any drug or biologic product candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry, stability and formulation, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin in the United States. 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 trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin in the United States. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Additionally, the review of information in an IND application may prompt FDA to, among other things, scrutinize existing INDs or marketed products and could generate requests for information or clinical holds on other product candidates or programs.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple geographically dispersed clinical trial sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for approval and product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product 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 the required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which 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 and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require the applicant to obtain additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and/or to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor’s product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Tropical Disease Priority Review Voucher Program

The FDA has authority to award priority review vouchers, or PRVs, to sponsors of certain tropical disease product applications. The FDA's Tropical Disease Priority Review Voucher Program is designed to encourage development of new drug and biological products for the prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Under this program, a sponsor who receives an approval for a drug or biologic for the prevention or treatment a tropical disease that meets certain criteria may qualify for a PRV that can be redeemed to receive priority review of a subsequent NDA or BLA for a different product. The sponsor of a topical disease drug product receiving a PRV may transfer (including by sale) the voucher to another sponsor of an NDA or BLA. The FD&C Act does not limit the number of times a PRV may be transferred before the voucher is used.

For a product to qualify for a PRV, (i) the sponsor must request approval of the product for the prevention or treatment of a "tropical disease" listed in Section 524 of the FD&C Act, (ii) the product must otherwise qualify for priority review, and (iii) the product must contain no active ingredient (including any salt or ester of an active ingredient) that has been approved by the FDA in any other NDA or BLA. Applications also must contain reports of one or more new clinical investigations (other than bioavailability studies) that were essential to the approval of the application and conducted or sponsored by the sponsor. In addition, the sponsor must provide in the application an attestation that such report(s) were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the development, FDA review and approval of new drugs and biologics that meet certain criteria. For example, the FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that are intended to treat a serious or life threatening disease or condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

A product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review and accelerated approval. Priority review means that, for a new molecular entity or original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A product is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review. If criteria are not met for priority review, the application for a new molecular entity or original BLA is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act, or PREA, certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FD&C Act to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, PREA generally does not apply to a drug or biologic for an indication for which orphan designation has been granted.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted if a sponsor submits pediatric data that fairly responds 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 trial is deemed to fairly respond to the FDA's request, the additional protection is granted.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include limitations on industry-sponsored scientific and educational activities and restrictions on promoting products for unapproved uses or patient populations (known as "off-label use"). Although physicians may in their independent medical judgment prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, 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 trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. 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. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FD&C Act also can delay the submission or the approval of certain applications. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FD&C Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Biosimilars and Exclusivity

Certain of our product candidates will be regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the Affordable Care Act, or ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product 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 biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, the Office of Inspector General and the Office for Civil Rights, as well as other divisions of the U.S. Department of Health & Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Other Healthcare Laws in the United States

Healthcare providers, and third party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and physicians and any future arrangements with third party payers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and the federal Health Insurance Portability and Accountability Act, or HIPPA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. The Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, or collectively the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Our operations, including the future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, 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 product candidates, are subject to scrutiny under this law.

HIPAA created new 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, knowingly and willfully embezzling or stealing from a healthcare benefit program, 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 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.

The Civil Monetary Penalties Statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans, and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity and their covered subcontractors. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians, and teaching hospitals and to report annually certain ownership and investment interests held by physicians, certain other healthcare professionals, and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. 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.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with state laws that require the registration or licensure 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. Several states have enacted legislation 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 trials 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. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions"(i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.

- imposed a requirement on manufacturers of branded drugs to provide a 70% point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.

- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.

- expanded the entities eligible for discounts under the 340B Drug Discount Program.

- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.

- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a United States District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The case was argued in the United States Supreme Court on November 10, 2020. On February 10, 2021, the Biden administration informed the Supreme Court that the government had withdrawn its support of a nationwide repeal of the ACA. On June 17, 2021, the Supreme Court held that states did not have standing to challenge the ACA and that the individual plaintiffs could not show sufficient injury to have standing, therefore avoiding having to make a substantive determination on the constitutionality of the law. While the litigation was pending, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how future litigation and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach the required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013, following passage of the Bipartisan Budget Act of 2013, and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, followed by a period of 1% payment adjustment April 1 - June 30, 2022, followed by a 2% payment adjustment beginning July 1, 2022. Further, in January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. 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 United States Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. On September 24, 2020, HHS and FDA issued a final rule under Section 804 of the Food, Drug, and Cosmetic Act allowing commercial importation of certain prescription drugs from Canada without the manufacturer's authorization. The validity of the final rule has been challenged in federal court by the Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines and the Council for Affordable Health Coverage. Further, on November 30, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Infrastructure Investment and Jobs Act to January 2026. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed. On November 20, 2020, CMS issued an interim final rule implementing a new payment model, the Most Favored Nation Model, which would have tied Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. CMS withdrew the rule on December 27, 2021.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Further, products must meet applicable child-resistant packaging requirements under the United States Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

Other United States Environmental, Health and Safety Laws and Regulations

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

European Drug Development

In the European Union, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014 (the "Regulation"), which is set to replace the current Clinical Trials Directive 2001/20/EC. The European Commission confirmed January 31, 2022 as the date of entry into application of the Regulation and the go-live of the Clinical Trials Information System ("CTIS") by publishing a notice in the Official Journal of the European Union on July 31, 2021. The new Regulation will be directly applicable in all Member States (and so does not require national implementing legislation in each Member State), and aims at simplifying and streamlining the approval of clinical studies in the EU, for instance by providing for a streamlined application procedure via a single point and strictly defined deadlines for the assessment of clinical trial applications.

European Drug Marketing

Much like the Anti-Kickback Statue prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to induce or reward improper performance generally is usually governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. There are two main types of marketing authorizations.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under the centralized procedure the maximum timeframe for the evaluation of a MA application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MA application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MA application under the accelerated assessment procedure is of 150 days, excluding stop-clocks, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this national MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMSs) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the CMSs).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized MAs (under the Northern Irish Protocol, centralized MAs will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required.

European Data and Marketing Exclusivity

In the EEA, innovative medicinal products qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

European Orphan Designation and Exclusivity

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions which either affect not more than 5 in 10,000 persons in the European Union, or where it is unlikely that the marketing of the medicine would generate sufficient return to justify the necessary investment in its development. In each case, no satisfactory method of diagnosis, prevention or treatment must have been authorized (or, if such a method exists, the product in question would be of significant benefit to those affected by the condition).

In the EEA, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing approval for the orphan product. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, marketing authorization may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Pediatric Investigation Plan

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval). In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as Brexit). Thereafter, in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and the UK formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical law remained applicable to the UK, which ended on December 31, 2020. Since the regulatory framework in the UK covering the quality, safety and efficacy of medicinal products, clinical trials, marketing authorization, commercial sales and distribution of medicinal products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the UK, as UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the UK in the long-term. The MHRA, the UK medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the UK's regulatory position on medicinal products evolves over time.

European Data Collection

The collection and use of personal health data in the European Economic Area, or the EEA, is governed by the GDPR, which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the European Union. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

The Rest of the World Regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products 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 drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States.

In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to United States government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Employees and Human Capital

As of October 31, 2024, we had seven full-time employees, including three with Ph.D. or M.D. degrees and two who are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants.

Facilities

Our research and development efforts have taken place in state-of-the-art facilities at our academic partners, principally at Brown University, which are being used under the Sponsored Research Agreements. Consistent with our lean and agile operating philosophy, we anticipate relying on these facilities going forward through sponsored research arrangements with Brown and with other university partners. In addition, we expect to access laboratory facilities and resources through various CRO partners such as Lonza with whom we are currently engaged.

We believe that our access to preclinical and clinical research facilities are adequate for our current needs and that suitable facilities at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this Annual Report on Form 10-K, we were not a party to any material legal matters or claims except as set forth in our audited financial statements for the year ended December 31, 2023, as included in this Annual Report.

In the future, we may become party to legal matters and claims in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows except as set forth in our audited financial statements for the year ended December 31, 2023, as included in this Annual Report.

Status as a Public Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. As such, we 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, 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 our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the prices of our securities may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this extended transition period.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (i.e., December 31, 2026), (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Additionally, we are a "smaller reporting company" as defined in Rule 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock held by non-affiliates equals or exceeds $250 million as of the end of the prior June 30th, or (2) our annual revenues equaled or exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30th.

Available Information

We file annual reports, quarterly reports, current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). Our SEC filings are available to the public through the "Investors" portion of our website as soon as practicable after we have electronically filed such material with, or furnished it to, the SEC. In addition, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Our internet address is www.oceanbiomedical.com. The information on our website is not, and shall not be deemed to be, part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC, except as shall be expressly set forth by specific reference in any such filings. All website addresses in this report are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS.

In the course of conducting our business operations, Ocean Biomedical is exposed to a variety of risks. Any of the risk factors we describe below have affected or could materially adversely affect our business, financial condition and results of operations. The market price of shares of our common stock could decline, possibly significantly or permanently, if one or more of these risks and uncertainties occurs. Certain statements in this Item 1A are forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements."

The risk factors below reflect our business after the Closing of the Business Combination. Unless otherwise noted or the context otherwise requires, the disclosures in this Item 1A refer to Ocean Biomedical, Inc. and its subsidiaries following the consummation of the Business Combination.

The risks discussed below are not exhaustive and are based on certain assumptions made by us. 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, financial condition or results of operations. The following discussion should be read in conjunction with our financial statements and the notes thereto.

Risk Factors

Risks Related to Our Common Stock

We have incurred significant net losses since inception and we are expected to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception and have financed our operations principally through personal payments made by our executive chairman and founder and through financings with an institutional investor. We anticipate that we will continue to incur significant research and development and other expenses related to our ongoing operations, and do not expect to generate income, profits, or positive cash flow for the foreseeable future. For the years ended December 31, 2022 and 2023, Ocean reported a net loss of $17.4 million and $114.7 million, respectively. As of December 31, 2022 and 2023, Ocean had an accumulated deficit of $81.6 million and $196.1 million, respectively. We are still in the early stages of development of our product candidates and have not yet completed any clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we:

- advance the development of our current product candidates (OCX-253, OCX-410, OCX-909, OCF-203, ODA-570, ODA-611, and ODA-579) through preclinical and clinical development, and, if successful, later-stage clinical trials;
- identify, in-license, invest in, or discover and develop new product candidates;
- advance our preclinical development programs into clinical development;
- experience delays or interruptions with our preclinical studies or clinical trials, our receipt of services from our third-party service providers on whom we rely, our supply chain or other regulatory challenges, including those due to the COVID-19 pandemic or to other unforeseen global events;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize any one or more of our product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to identify and develop product candidates;
- hire additional clinical development, quality control, scientific and management personnel, including personnel to support our clinical development and manufacturing efforts and our operations as a public company;
- expand our operational, financial and management systems and establish office, research and manufacturing space;
- establish a business development, partnering, sales, marketing, medical affairs and/or distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and
- maintain, expand and protect our intellectual property portfolio.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Such failure could result in the loss of all or part of your investment.

Ocean's independent registered public accounting firm included an explanatory paragraph in its audit report on Ocean's consolidated financial statements as of December 31, 2023, stating that Ocean's working capital deficit and anticipated losses from operations and Ocean's need to obtain additional capital raised substantial doubt about Ocean's ability to continue as a going concern.

Risks Related to Our Corporate Structure

We may not be successful in our efforts to use our differentiated business model to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use our differentiated business model to form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties for programs, product candidates, technologies or intellectual property that we believe are novel, employ differentiated mechanisms of action, are more advanced in development than competitors, or have a combination of these attributes. We face significant competition in seeking appropriate strategic partners and licensing and acquisition opportunities, and the negotiation process is time-consuming and complex. We may not be successful in our efforts in building a pipeline of product candidates through acquisitions, licensing or through internal development or in progressing these product candidates through clinical development. Although our research and development efforts to date have resulted in our identification, discovery and preclinical and clinical development of certain of our product candidates, these product candidates may not be safe or effective as cancer treatments, and we may not be able to develop any other product candidates. Although we analyze whether we can replicate scientific results observed prior to our acquisition or investment in a product candidate, we may not be successful in doing so after our investment. Our differentiated business model is evolving and may not succeed in building a pipeline of product candidates. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of unacceptable toxicity or other characteristics that indicate that they are unlikely to receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. While we believe our subsidiary model offers an attractive platform for these transactions and for potential partners, our model is unique and we may not be able to attract or execute transactions with licensors or collaborators who may choose to partner with companies that employ more traditional licensing and collaboration approaches. Identifying, selecting, and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring, and developing products that ultimately do not provide a return on our investment. We expect to terminate programs in the future if they do not meet our criteria for advancement.

Our subsidiaries are party to certain agreements that provide our licensors, collaborators or other shareholders in our subsidiaries with rights that could delay or impact the potential sale of our subsidiaries or could impact the ability of our subsidiaries to sell assets, or enter into strategic alliances, collaborations or licensing arrangements with other third parties.

Each of our subsidiaries directly or indirectly licenses intellectual property from third parties and, future subsidiaries may be partially owned by third party investors. These third parties may have certain rights that could delay collaboration, licensing or other arrangement with another third party, and the existence of these rights may adversely impact the ability to attract an acquirer or partner.

We may form additional subsidiaries and enter into similar agreements with future partners or investors, or our subsidiaries may enter into further agreements, that in each case may contain similar provisions or other terms that are not favorable to us.

Our ability to realize value from our subsidiaries may be impacted if we reduce our ownership to a minority interest or otherwise cede control to other investors through contractual agreements or otherwise.

We currently wholly own all of our subsidiaries, and plan to remain majority owners of future subsidiaries. However, in the event that any of our subsidiaries require additional capital and its respective board of directors authorizes the transaction, our equity interest in our subsidiaries may be reduced to the extent such additional capital is obtained from third party investors rather than from us. Such transactions would still need to be approved by the board of directors of our respective subsidiary over which we maintain full control.

However, if we do not wish to or cannot provide additional capital to any of our subsidiaries, we may approve of an issuance of equity by a subsidiary that dilutes our ownership and may lose control over the subsidiary. In addition, if the affairs of such minority-owned subsidiaries were to be conducted in a manner detrimental to the interests or intentions of us, our business, reputation, and prospects may be adversely affected. For example, other shareholders in a minority-owned subsidiary could take actions without our consent, which could have an adverse impact on our investment in the subsidiary.

A single or limited number of subsidiaries may comprise a large proportion of our value.

A large proportion of our value may at any time reside in one or two of our subsidiaries, including intellectual property rights and the value ascribed to the product candidate or program that it is developing. Our consolidated financial condition and prospects may be materially diminished if the clinical development or potential commercialization prospects of a subsidiary's product candidate or program or one or more of the intellectual property rights held by a specific subsidiary becomes impaired. Furthermore, a large proportion of our consolidated revenue may at any time be derived from one, or a small number of, licensed technologies, and termination or expiration of licenses to these technologies would likely have a material adverse effect on our consolidated revenue. Any material adverse impact on the value of a particular subsidiary, including its intellectual property rights or the clinical development of its product candidate or program, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential, or fail to recognize or acquire assets that may be more promising than those we acquire. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future identification, discovery, and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

Our reliance on a central team consisting of a limited number of employees who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

Some of our officers and directors may serve as directors or officers of our subsidiaries, and, as a result, have and may continue to have, fiduciary and other duties to our subsidiaries causing conflicts of interest with respect to their duties to us and their duties to our subsidiaries and in determining how to devote themselves to our affairs and the affairs of our subsidiaries. Our subsidiaries' partners may also disagree with the sufficiency of resources that we provide to each subsidiary.

Certain of our officers, including our Executive Chairman and Director, Chirinjeev Kathuria, are also directors and/or officers of one or more of our subsidiaries and, as a result, have fiduciary or other duties both to us and our subsidiaries. The conflicts of interest that arise from such duties could interfere with the management of our subsidiaries and their programs and product candidates, or result in disagreements with our subsidiaries' partners. For example, an individual who is both our director and a director of one of our subsidiaries, owes fiduciary duties to the subsidiary and to us as a whole, and such individual may encounter circumstances in which his or her decision or action may benefit the subsidiary while having a detrimental impact on us, or vice versa, or on another subsidiary, including one for which he or she also serves as a director. Further, our officers and directors who are also officers and directors of our subsidiaries will need to allocate his or her time to responsibilities owed to us and each of the subsidiaries for which he or she serves as an officer or director, and will make decisions on behalf of one entity that may negatively impact others. In addition, while most of our subsidiaries have waived any interest in or expectation of corporate opportunities that are presented to, or acquired, created or developed by, or which otherwise come into possession of any director or officer who is also our director or officer, disputes could arise between us and our subsidiary's partners regarding a conflict of interest. These partners also may disagree with the amount and quality of resources that our officers and employees devote to the subsidiary in which they are invested. Any such disputes or disagreements could distract our management, interfere with our relations with our partners, and take significant time to resolve, which could disrupt the development of our product candidates, delay our potential commercialization efforts, result in increased costs or make it less likely that other third parties will choose to partner with us in the future.

We currently outsource, and intend to continue to outsource, nearly all our discovery, clinical development, and manufacturing functions to third-party providers or consultants. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business, results of operations, and financial condition.

Our business model relies upon the use of third parties, such as vendors and consultants, to conduct our drug discovery, preclinical testing, clinical trials, manufacturing, and all other aspects of clinical development. While our reliance on third parties allows us to purposely employ a small number of full-time employees, we may not effectively manage and oversee the third parties that our business depends upon and we have less control over our operations due to our reliance on third parties. While we believe our business model significantly reduces overhead cost, we may not realize the efficiencies of this arrangement if we are unable to effectively manage third parties or if our limited number of employees are unable to manage the operations of each of our subsidiaries, including the development of their programs and product candidates. The failure to successfully and efficiently outsource operational functions or appropriately manage the operations of our subsidiaries could materially adversely affect our business, results of operations, and financial condition.

Risks Related to Raising Additional Capital

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts and/or other operations.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We have sufficient committed sources of additional capital to fund our operations for more than a limited period of time. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our preclinical and clinical development programs, seek regulatory approvals for our product candidates, and launch and commercialize any products for which we receive regulatory approval. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

Our actual capital requirements may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and the activities associated with development of our product candidates are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, immediate, near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for our current and future product candidates, including whether and when to advance our diverse portfolio of product candidates;
- the development requirements of other product candidates that we may pursue;
- the clinical development plans we establish for our product candidates;
- the timelines of our clinical trials and the overall costs to finish the clinical trials;
- the impact on timelines and costs due to the COVID-19 pandemic or other unforeseen events;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the extent to which we enter into additional collaboration agreements with regard to product discovery or acquire or in-license products or technologies;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the timing and amounts of any milestone or royalty payments we may be required to make or may be entitled to receive under license agreements;
- the costs of building out our infrastructure including hiring additional clinical, quality control and manufacturing personnel;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. This additional funding may not be sufficient for us to fund any of our products through regulatory approval.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility and unforeseen events, such as the COVID-19 pandemic and the conflict between Russia and Ukraine, could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

The Backstop Agreement could impose cash constraints on us in the long-term.

Pursuant to the OTC Equity Prepaid Forward Transaction (the "Backstop Agreement") with Vellar Opportunity Fund SPV LLC – Series 3, Meteora Special Opportunity Fund I, LP, Meteora Capital Partners, LP, Meteora Select Trading Opportunities Master, LP, and Polar Multi-Strategy Master Fund (the "Backstop Providers"), the Backstop Providers purchased shares of Aesther Class A common stock from shareholders of Aesther including those that elected to exercise their option to redeem their shares. However, no later than three years after the Closing of the Business Combination, we may be required to repurchase shares purchased by the Backstop Providers from Aesther's redeeming shareholders, which could create a significant constraint on our cash and significantly reduce the amount of shares that are outstanding in the long-term. As a result, we may lack sufficient cash to exploit lucrative business opportunities and may need to resort to financing on burdensome terms.

The issuance of our common stock to the Backstop Providers pursuant to the Backstop Agreement could cause substantial dilution, which could materially affect the trading price of our common stock.

Pursuant to the Backstop Agreement, on the maturity date of the Backstop Agreement, the Backstop Providers will be entitled to consideration of $2.50 per share of our common stock sold back to us, which is payable in shares of our common stock. The number of shares of our common stock that will be issued to the Backstop Providers will depend on the number of shares owned by the Backstop Providers at the maturity date and the trading price of our common stock at that time. The issuance of such common stock in connection with the payment of such consideration could result in substantial dilution and decreases to our stock price.

In addition, purchases pursuant to the Backstop Agreement may reduce the public "float" of our common stock and the number of beneficial holders of our common stock, possibly making it difficult to maintain the quotation, listing or trading of our securities on Nasdaq.

If our common stock does not trade above the floor set in the Backstop Agreement we may never receive cash from the Backstop Providers.

The Backstop Agreement prohibits the Backstop Providers from selling our shares of common stock that are subject to the restrictions set forth in the Backstop Agreement unless our common stock is trading above $10.34 per share, which means that no cash will be returned to us pursuant to any sales under the Backstop Agreement unless and until our common stock is trading above $10.34 and our Backstop Providers are otherwise able to sell their shares. Therefore, we may never receive cash from the Backstop Providers during the term of the Backstop Agreement.

The issuance of our common stock in connection with the Common Stock Purchase Agreement could cause substantial dilution, which could materially affect the trading price of our common stock.

The Common Stock Purchase Agreement, by and between us and White Lion Capital, LLC ("White Lion"), dated as of September 7, 2022 (the "Common Stock Purchase Agreement"), grants us the right, but not the obligation, to require White Lion to purchase, from time to time, up to $75.0 million of newly issued shares of our common stock. To the extent that we exercise our right to sell such shares under the Common Stock Purchase Agreement, we will need to issue new shares to White Lion. Although we cannot predict the number of shares of common stock that would actually be issued in connection with any such sale, such issuances could result in substantial dilution and decreases to our stock price.

It is not possible to predict the actual number of shares of common stock, if any, we will sell under the Common Stock Purchase Agreement to White Lion or the actual gross proceeds resulting from those sales.

Subject to the satisfaction of certain customary conditions including, without limitation, the effectiveness of a registration statement to be filed with the SEC registering the shares to be sold to White Lion for resale, our right to sell shares to White Lion will commence on the effective date of that registration statement and extend for a period of two years thereafter. During such term, subject to the terms and conditions of the Common Stock Purchase Agreement, we may notify White Lion when we exercise our right to sell shares.

We generally have the right to control the timing and amount of any sales of our shares of common stock to White Lion under the Common Stock Purchase Agreement. Sales of our shares of common stock, if any, to White Lion under the Common Stock Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to White Lion all, some or none of the shares of common stock that may be available for us to sell to White Lion pursuant to the Common Stock Purchase Agreement.

Because the purchase price per share of common stock to be paid by White Lion for the shares of common stock that we may elect to sell to White Lion under the Common Stock Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we elect to sell shares of common stock to White Lion pursuant to the Common Stock Purchase Agreement, if any, it is not possible for us to predict, prior to any such sales, the number of shares of common stock that we will sell to White Lion under the Common Stock Purchase Agreement, the purchase price per share that White Lion will pay for shares of common stock purchased from us under the Common Stock Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by White Lion under the Common Stock Purchase Agreement.

The number of shares of common stock ultimately offered for sale by White Lion is dependent upon the number of shares of common stock, if any, we ultimately elect to sell to White Lion under the Common Stock Purchase Agreement. However, even if we elect to sell shares of common stock to White Lion pursuant to the Common Stock Purchase Agreement, White Lion may resell all, some or none of such shares at any time or from time to time in its sole discretion and at different prices.

We are not required or permitted to issue any shares of common stock under the Common Stock Purchase Agreement if such issuance would breach our obligations under the rules or regulations of Nasdaq. Further, White Lion will not be required to purchase any shares of our common stock if such sale would result in White Lion's beneficial ownership exceeding 9.99% of our outstanding shares of common stock. Our inability to access a part or all of the amount available under the Common Stock Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

The sale and issuance of shares of common stock to White Lion will cause dilution to our existing securityholders, and the resale of the shares of common stock by White Lion, or the perception that such resales may occur, could cause the price of our securities to fall.

The purchase price per share of common stock to be paid by White Lion for the shares of common stock that we may elect to sell to White Lion under the Common Stock Purchase Agreement, if any, will fluctuate based on the market prices of our shares of common stock at the time we elect to sell shares of common stock to White Lion pursuant to the Common Stock Purchase Agreement. Depending on market liquidity at the time, resales of such shares of common stock by White Lion may cause the trading price of our shares of common stock to fall.

If and when we elect to sell shares of common stock to White Lion, sales of newly issued shares of common stock by us to White Lion could result in substantial dilution to the interests of existing holders of our shares of common stock. Additionally, the sale of a substantial number of shares of common stock to White Lion, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We may use proceeds from sales of our common stock made pursuant to the Common Stock Purchase Agreement in ways with which you may not agree or in ways which may not yield a significant return.

We will have broad discretion over the use of proceeds from sales of our shares of common stock made pursuant to the Common Stock Purchase Agreement and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. However, we have not determined the specific allocation of any net proceeds among these potential uses, and the ultimate use of the net proceeds may vary from the currently intended uses. The net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our securities.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

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

- our ability to complete preclinical studies and successfully submit Investigational New Drug, or IND, applications or comparable applications for our product candidates;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including the COVID-19 pandemic;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions, natural disasters, the conflict between Russia and Ukraine, and/or the COVID-19 pandemic;
- the changing and volatile U.S. and global socio-economic and political environments; and
- future accounting pronouncements or changes in our accounting policies or changes in tax laws.

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

Risks Related to Clinical Development

We are a biopharmaceutical company with a limited operating history, and many of our development programs are in early stages of development. This may make it difficult to evaluate our prospects and likelihood of success.

We are an early-stage biopharmaceutical company with a limited operating history, have no products approved for commercial sale and have not generated any revenue. All of our product candidates are in the preclinical stages of development and will require additional preclinical studies or clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. In addition, our product candidates will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to initiate or progress any product candidate through clinical trials. We are still in preclinical development and may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug and biological products.

Our business is dependent on the success of our product candidates that we advance into the clinic. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. If one or more of our product candidates encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business could be significantly harmed. Before we can generate any revenue from sales of any of our product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- timely completion of our preclinical studies and clinical trials;
- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- the prevalence, duration and severity of potential product-related side effects experienced by subjects receiving our product candidates in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;

- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact of recessions, man-made and/or natural disasters, pandemics, and/or any other such events;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Our underlying technology is unproven and may not result in marketable products.

Our approach is designed to discover and develop targeted treatments for non-small cell lung cancer, or NSCLC, glioblastoma, or GBM, and possibly other visceral cancers, by targeting the prototypic chitinase-like protein Chi3l1 which we have found is induced in human cancers including in primary lung cancer formation, in pulmonary melanoma metastasis, and in pulmonary breast cancer metastasis. These findings are the basis for our OCX-253, OCX-410 (PD-1), and OCX-909 (CTLA-4) programs. However, although multiple preclinical studies are currently underway, to date, our approach has not been tested in clinical trials for the treatment of NSCLC, GBM or other cancers.

Our approach to drug discovery and development in the area of fibrosis, with initial focus on targeting chitinase 1, or Chit1, is unproven and may not result in marketable products. Our approach is designed to discover and develop targeted treatments for idiopathic pulmonary fibrosis, or IPF, Hermansky-Pudlak Syndrome, or HPS, and possibly other fibrotic diseases, by targeting Chit1 which we have found to be a master regulator of the TGF-ß1 mediated fibrosis response through various mechanisms. These findings are the basis for our OCF-203 program. However, although multiple preclinical studies are currently underway, to date, our approach has not been tested in clinical trials for the treatment of IPF, HPS, or other fibrotic conditions.

Our approach to therapeutics discovery and development in the area of malaria, with initial focus on targeting P. falciparum glutamic-acid-rich protein, or PfGARP, and P. falciparum schizont egress antigen, or PfSEA-1, is unproven and may not result in marketable products. Our approach is designed to discover and develop therapeutics for the treatment of malaria infections and short-term malaria prophylaxis, and to develop vaccines for immunization against malaria, by targeting PfGARP and PfSEA-1, as applicable. Our findings regarding PfGARP and PfSEA-1 form the basis for our ODA-611, ODA-579 and OCF-203 programs. However, although multiple preclinical studies are currently underway, to date, our approach has not been tested in clinical trials for the treatment of malaria infections, to provide malaria prophylaxis or to provide immunization against malaria.

Our approach to the discovery and development of product candidates based on our Whole Proteome Differential Screening target discovery platform represents a novel approach to product candidate development, which creates significant challenges for us.

Our future success depends on the successful development of our product candidates, some of which may be discovered or developed by our Whole Proteome Differential Screening target discovery program, or WPDS. WPDS is a new technology, and as such, it is difficult to predict whether WPDS will enable us to successfully identify or develop product candidates. It is also difficult to accurately predict the developmental challenges we may incur for our product candidates as they proceed through product discovery or identification, preclinical studies and clinical trials. It is difficult for us to predict the time and cost of the development of product candidates identified by WPDS, and we cannot predict whether the application of our technology, or any similar or competitive technologies, will result in the identification, development, and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved at all. Any of these factors may prevent us from completing our preclinical studies and clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Due to our business model, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We may forego or delay pursuit of opportunities with respect to additional research programs or product candidates or for indications other than those we are currently targeting. To the extent we allocate resources to any particular product candidate, our ability to pursue development of another product candidate may be hindered. Some of these opportunities may later prove to have greater commercial potential or a greater likelihood of success. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

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

Although our business model relies in part on a plan to harness breakthrough inventions at research universities and medical centers and develop them into therapeutics that can address unmet medical needs, there can be no assurance that we will ever be able to identify additional candidate opportunities at these institutions or others. Even if we were able to identify such opportunities, there can be no assurance that we will be able to in-license them or otherwise acquire rights to them on terms that are beneficial to us. Furthermore, we could face competition for such opportunities from other companies and from venture capital firms.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, such as:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

We may not be able to file INDs or IND amendments or comparable applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA or other regulatory authorities may not permit us to proceed.

We may not be able to file INDs or other comparable applications for our product candidates on the timelines we expect. For example, we or our third party collaborators may experience manufacturing delays or other delays with preclinical studies or FDA or other regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we cannot be sure that submission of an IND or other comparable application will result in the FDA or other regulatory authorities allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by institutional review boards or independent ethics committees, or by the FDA or other regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if FDA or other regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or comparable application, we cannot guarantee that they will not change their requirements or expectations in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or other comparable application. Any failure to file INDs or other comparable applications on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Preclinical and clinical development involves a lengthy, complex and expensive process, with an uncertain outcome and results of earlier studies and trials may not be predictive of future preclinical studies or clinical trial results.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new product is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development in any of our product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including but not limited to:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary and/or secondary endpoint(s)) or to have unacceptable side effects or toxicities, or unexpected adverse drug-drug interactions;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to execute the clinical trials caused by slow enrollment or subjects dropping out;
- failure to receive the necessary regulatory approvals;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, some of our trials may be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, such as "patient bias" where patients in open-label clinical trials perceive their symptoms to have improved merely due to their awareness of receiving treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. The standards are also different for the development of small molecule drug products and for the development of biological products, both of which we are undertaking through our programs. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays and/or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. If data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

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

We may experience delays in initiating or completing clinical trials. Clinical trials can be delayed or terminated for a variety of reasons, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may need to address any subject safety concerns that arise during the course of a clinical trial;
- we may experience delays and interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- logistical issues relating to any future clinical trials we may operate in developing countries;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Our product development costs will increase if we experience additional delays in preclinical or clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in our clinical trials, we may be required to abandon the trials or our development efforts altogether. In addition, we may encounter unexpected drug-drug interactions in our planned trials, and may be required to further test those candidates, including in drug-drug interaction studies, which may be expensive, time-consuming and result in delays to our programs. Some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- reporting of the preliminary results of any of our clinical trials;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

For example, we are initially developing OCF-203 for the treatment of IPF, a rare disease. In the United States, IPF is estimated to affect approximately 160,000 patients. As a result, we may encounter difficulties enrolling subjects in our clinical trials of OCF-203 due in part to the small size of the patient population. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. If any of our product candidates is shown to have undesirable side effects, some patients may decline or drop out of our clinical trials. Additionally, certain of our planned clinical trials may also involve invasive procedures which may lead some patients to decline or to drop out of trials.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. If patients are unable to follow the trial protocols or if our trial results are otherwise disrupted due to the effects of a pandemic or actions taken to mitigate its spread, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

The design or execution of our clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. It is possible that we may need to amend our clinical trial designs, which would require us to resubmit our clinical trial protocols to IRBs and FDA for reexamination and approval, and may impact the costs, timing or successful completion of such clinical trials.

Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

We intend to develop OCX-253 and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop OCX-253 and potentially other product candidates in combination with one or more approved or unapproved therapies to treat cancer or other diseases. Even if any product candidate we develop were to receive marketing approval for use in combination with other approved therapies, the FDA or comparable foreign regulatory authorities outside of the United States could still revoke approval of the therapy used in combination with our product. If the therapies used in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

If we are unable to successfully validate, develop and obtain regulatory approval for any required companion diagnostic tests for our product candidates or experience significant delays in doing so, we may fail to obtain approval or may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we intend to engage third parties to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates, as we are targeting certain genetically defined populations for our treatments. For example, in the OCX-253 program, we may develop a diagnostic tool for measuring the circulating Chi3l1 as a method of stratifying patients for particular clinical studies. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are subject to regulation by the FDA and other regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

Given our limited experience in developing and commercializing diagnostics, we intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

We may in the future seek orphan drug designation for our product candidates, but we may be unable to obtain orphan drug designation and, even if we obtain such designation, we may not be able to realize or maintain the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate products intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug or biologic product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a marketing application. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. 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 does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes the same drug treating the same indication for a period of seven (7) years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

We may seek orphan drug designation for OCF-203 for IPF and HPS, and some of our other future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. We may be unable to obtain and maintain orphan drug designation and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition in the United States. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We will face an inherent risk of product liability as a result of testing any of our other product candidates in clinical trials, and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;

- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

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 products we develop. We will need to obtain additional insurance for clinical trials as our product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, venture capital firms, hedge funds, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large biopharmaceutical and biotechnology companies that are currently pursuing the development of products, or already have products in the market, for the treatment of cancer, fibrosis, and malaria. Although we believe that our approaches are unique, there is no assurance that they will demonstrate advantages or even parity against competitive products from other companies, including those with significant financial resources such as BristolMyersSquibb, Merck, Genentech, AstraZeneca/Daiichi Sankyo, Roche, Boehringer Ingelheim, GSK, AbbVie, Novartis, United Therapeutics and Horizon, as well as emerging biotechnology companies such as Fibrogen, Pliant, Galecto Biotech and Endeavor Biomedicines, to name a few. For additional information on our competitors please see Item 1 of this Annual Report on Form 10-K.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of fibrosis as well, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Risks Related to Manufacturing

Because we rely on third-party manufacturing and supply vendors, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of a contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may 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. We will also need to verify, such as through a manufacturing comparability or bridging study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

To the extent that we enter into future manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;

- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

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

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

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

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

Risks Related to Commercialization

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if a product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the price we pay or any of our future collaborators charge for our products;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- The size and effectiveness of our sales, marketing and distribution support.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

The market opportunities for our product candidates may be relatively small since the patients who may potentially be treated with our product candidates are those who are ineligible for or have failed prior treatments, and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized by line of therapy (first line, second line, third line, fourth line, etc.), and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. In our oncology program, we may initially seek approval of certain of our product candidates as a second or third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receive regulatory approval, we expect to establish either an internal or external marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and, to the extent we establish such organization in house, time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in establishing or managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal or external sales, marketing and distribution capabilities would adversely impact the commercialization of these products. If we choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. 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 are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Risks Related to Our Reliance on Third Parties For Our Product Development

We rely on third parties to conduct all or certain aspects of our preclinical studies and clinical trials. 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 of or commercialize any potential product candidates.

We depend upon third parties to conduct all or certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, CMOs, strategic collaborators and others. We expect to continue to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our preclinical studies and clinical trials, and, as a result, we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we relied entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP and cGMP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP and cGMP requirements through periodic inspections of trial sponsors, clinical investigators, manufacturers and trial sites. If we or any of these third parties fail to comply with applicable GCP or cGMP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP or cGMP requirements.

Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies, clinical trials or manufacturing process will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism due to the COVID-19 pandemic or other such crises they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs, CMOs or others terminate, we may not be able to enter into arrangements with alternative CROs, CMOs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs or CMOs involves additional cost and requires extensive time and focus of our management. In addition, there is a natural transition period when a new CRO or CMO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

Though we carefully manage our relationships with our CROs and CMOs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties for blood and other tissue samples and other materials required for our research and development activities, and if we are unable to reach agreements with these third parties our research and development activities would be delayed.

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of blood and other tissue samples, clinical and laboratory supplies and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we expect to enter into agreements with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources and there is no guarantee that we will be able to enter into or renew such agreements on commercially reasonable terms, if at all. If we were unable to enter into or renew such agreements, we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and our ability to implement a key part of our development strategy will be compromised.

We are a party to sublicense agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events. The sublicense agreements may be terminated in their entirety immediately upon notice for failure by us to meet certain milestone events by certain dates.

We are a party to various sublicense agreements that are important to our business and to our current and future product candidates. For example, we sublicense all of the technologies forming our oncology, fibrosis and infectious disease programs from Elkurt, Inc. ("Elkurt"), a company formed by our scientific co-founders Jack A. Elias, M.D. and Jonathan Kurtis, M.D., Ph.D., both of whom also serve on our board of directors. Elkurt licenses such technologies from Brown University and Rhode Island University. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved.

All of our current product candidates are being developed through sublicense agreements from Elkurt. Our rights to use currently licensed intellectual property from Elkurt are subject to the continuation of and our compliance with the terms of our sublicense agreements with Elkurt. In spite of our efforts, Elkurt might conclude that we have materially breached our obligations under one or more of such sublicenses and might therefore terminate any of such agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. For example, our sublicense of the FRG Antibody from Elkurt (which licenses such technology from Brown University on substantially parallel terms) is subject to termination by Elkurt in the event of a default by us that is not cured within 30 days. If any of our existing sublicense agreements were to be terminated, our business and prospects could be substantially harmed.

Additionally, the sublicense agreements may be terminated in their entirety immediately upon notice for failure by us to meet certain milestone events by certain dates. Each of the below listed sublicense agreements may be terminated if we do not complete a $10 million equity or debt financing by 2025. In addition, the license agreements set forth the following milestone events and deadlines. Failure by us to meet such milestone events by the listed deadlines trigger a termination right by the licensing party upon notice:

- The FRG License Agreement (BROWN ID 2465, 2576, 2587): the filing of an IND within one year after commencing IND-enabling studies; completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and completion of a Phase 3 clinical trial within three and a half years following completion of a Phase 2 clinical trial.

- The Anti-CTLA4 License Agreement (BROWN ID 3039): the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and the completion of a Phase 3 clinical trial within approximately three years following the completion of a Phase 2 clinical trial.

- The FRGxPD-1 License Agreement (BROWN ID 2613): the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1 clinical trial within one year following the filing of an IND; completion of a Phase 2 clinical trial within approximately four years following completion of a Phase 1 clinical trial; and the completion of a Phase 3 clinical trial within three years following the completion of a Phase 2 clinical trial.

- The Chit1 License Agreement (BROWN ID 2502): the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1/2 clinical trial within two years following the filing of an IND; and the completion of a Phase 3 clinical trial within approximately three years following the completion of a Phase 1/2 clinical trial.

- The PfGARP/PfSEA License Agreement (RIH #154): the filing of an IND within two years after commencing IND-enabling studies; the completion of a Phase 1/2 clinical trial within one and a half years following the filing of an IND; and the completion of a Phase 3 clinical trial within three years following completion of a Phase 1/2 clinical trial.

- The Brown Anti-PfGARP Small Molecules License Agreement (BROWN ID 3085J): the filing of an IND in 2027; the commencement of Phase 1/2 clinical trials in 2027; and the commencement of a Phase 3 clinical trial in 2029.

A core element of our business strategy also includes continuing to acquire or in-license additional technologies or product candidates. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

Collaborations are and will be important to our business. If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to maximize the value of our product candidates by evaluating partnerships where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have and may in the future enter into collaborations with other organizations to provide us with important technologies and funding for our programs and technology.

The collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and

- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If the collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators.

Additionally, if one of our existing or future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected. In addition, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and a material and adverse effect on our business, financial condition, results of operations and prospects.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. We currently license or sublicense all of the intellectual property underlying our product candidates from universities and from other institutions such as for example, Elkurt and Rhode Island Hospital, and as such do not currently and solely maintain patents regarding the intellectual property we use. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we or our licensors may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license or sublicense from or license to third parties and are reliant on our licensors, sublicensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we in-license or may own in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;

- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;

- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights;

- the patents of others may have an adverse effect on our business; or

- given that all of the preclinical developments of our oncology, fibrosis and malaria programs have, to date, been funded through grants totaling more than $110 million (prior to in-licensing our product candidates), which include grants from the federal government, it is possible that the federal government could invoke its march-in rights under 35 U.S.C. § 203 if it deems that it is necessary for it, or for third parties it designates, to practice our patent rights in order to address a national public safety or national security threat.

The intellectual property that we have in-licensed has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

All of the intellectual property rights that we have in-licensed to date were discovered through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights, pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations, to the intellectual property embodied in our current product candidates, all of which are derived from our existing in-licensed intellectual property. These U.S. government rights in certain inventions developed under a government-funded program include a nonexclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). All of our product candidates pursuant to the license agreements are subject to such march-in rights. The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, such as that involved in our WPDS platform, and we intend to enter into non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we expect to try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. For example, the way in which we use our WPDS platform is proprietary and confidential. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Risks Related to Third Party Intellectual Property

We have entered into and may enter into license, sublicense or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such agreements with third parties, we could lose license or sublicense rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we have entered into and may enter into certain licenses, sublicenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed or sublicensed intellectual property.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license or sublicense agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license or sublicense agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

We are currently party to various sublicense agreements that we depend on to operate our business, and our rights to use currently licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. In spite of our efforts, our sublicensors might conclude that we have materially breached our obligations under such sublicense agreements and might therefore terminate the sublicense agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by such agreements. In the event that we breach any of our sublicense agreements, or if any of the parties from whom we have sublicensed intellectual property breach the underlying license agreements, we may not be entitled to the intellectual property that we sublicense. Moreover, in the event that our sublicensors terminate such agreements, we may be unable to successfully prove that we have not materially breached our obligations if we disagree with the assertion, and we may be required to expend significant resources to protect our rights to the intellectual property even if our efforts to do so are ultimately unsuccessful.

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

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our sublicensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is sublicensed to us. It is possible that such infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of blood and other tissue samples and other materials required for our research and development activities, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do may not cover all instances of medical development that are researched by the counterparty. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator’s materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator’s samples, or data developed in a collaborator’s study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or sublicense or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license or sublicense may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license or sublicense to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license or sublicense, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed or sublicensed 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, sublicense, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses or sublicenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license or sublicense would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses or sublicenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses or sublicenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees, consultants or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we collaborate with and/or employ and intend to collaborate with and/or employ individuals who were previously affiliated with universities or other biotechnology or biopharmaceutical companies, including those that operate in the same indications we do. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. We may be unable to sustain the costs of such litigation or proceedings as a result of our currently limited financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our drug substance and pre-existing biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license or sublicense, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we currently collaborate and intend to continue collaborating with academic institutions to facilitate and/or complement our preclinical research and/or clinical development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such options, if we are granted one, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and institutions, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established institutions may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Risks Related to Intellectual Property Litigation

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;

- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be nonexclusive, which could result in our competitors gaining access to the same intellectual property; and

- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a nonexclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Risks Related to Intellectual Property Laws

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any of our patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

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

Likewise, without taking into account any possible patent term adjustments or extensions, our current sublicensed patents sublicensed from Brown University and Rhode Island Hospital may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We also have rights to pending patent applications covering our proprietary technologies or our product candidates, but we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

Changes in patent law in the U.S. and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

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

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

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Risks Related to Managing Our Business and Operations

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such a material system failure, accident or security breach could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from an of our clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, during the COVID-19 pandemic, there have been a number of security breaches relating to companies providing or developing treatments or vaccines related to COVID-19. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. The development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, as well as occurrences of civil unrest, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters and civil unrest.

Our operations may be adversely affected by fire, climate events, or other manmade or natural disasters or incidents, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster or event. Such incidents or events may result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, or of our collaborators, and thus may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and may have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural or manmade disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage, fire or other event occurred that prevented us from using all or a significant portion of our critical infrastructure, such as our research facilities or the research or manufacturing facilities of our third-party collaborators, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

Our disaster recovery and business continuity plans may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery, insurance coverage, and business continuity plans, which could have a material adverse effect on our business.

Risks Related to Growing Our Organization

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

As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our pre-clinical and clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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.

The estimates of market opportunity and forecasts of market growth included in this Annual Report on Form 10-K may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Market opportunity estimates and growth forecasts included in this Annual Report on Form 10-K are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this Annual Report on Form 10-K relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included in this Annual Report on Form 10-K, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

We may engage in strategic transactions, which could impact our liquidity, increase our expenses, and present significant distractions to our management.

We may consider engaging in a variety of different business arrangements, including mergers and acquisitions, spin-outs, strategic partnerships, joint ventures, co-marketing, co-promotion, distributorships, development and co-development, restructurings, divestitures, business combinations and investments on a global basis. Any such transaction(s) may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures, grow and expand rapidly putting pressure on current resources and capabilities, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could expose us to liability, delays, and implementation obstacles that could harm our business, financial condition, operating results, and prospects. We have no current commitment or obligation to enter into any transaction described above other than ones to which we are already committed.

Risks Related to Employee Matters

If we lose key management or scientific personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, including our scientific and medical personnel, including Dr. Elias and Dr. Kurtis. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we intend to provide restricted stock awards and stock options that vest over time. The value to employees of restricted stock awards and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. In addition, we do not maintain key person insurance. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We adopted a code of ethical business conduct, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, 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 actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, 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, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

Risks Related to Tax and Accounting Matters

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

We may from time to time generate net operating loss carryforwards that would be available to reduce future U.S. federal and state taxable income. Certain of these carryforwards may be carried forward indefinitely for U.S. federal tax purposes. It is possible that we will not generate taxable income in time to use all or a portion of these net operating loss carryforwards before their expiration or at all. Under legislative changes made in December 2017, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but may only offset 80% of our taxable income in any given year. In addition, our net operating loss carryforwards are subject to review and possible adjustment by the IRS, and state tax authorities. The federal and state net operating loss carryforwards and certain other attributes, such as research tax credits, may be subject to significant limitations under Section 382 and Section 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), respectively, and similar provisions of U.S. state law. Under those sections of the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change attributes to offset its post-change income or tax may be limited. In general, an "ownership change" would occur if the percentage of our equity interests held by one or more of our "5-percent shareholders" (as such term is used in Section 382 of the Code) increased by more than 50 percentage points over the lowest percentage of our equity held by such 5-percent shareholders at any time during the relevant testing period (usually three years). Similar rules may apply under state tax laws. Our ability to utilize our net operating loss carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of future ownership changes.

We identified a material weakness in the Company's internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

In connection with Legacy Ocean's preparation and the audits of its historical financial statements, and the Company's preparation and the audit of its financial statements as of December 31, 2023, the Company identified a material weakness as defined under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and by the Public Company Accounting Oversight Board (United States) in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's financial statements will not be prevented or detected on a timely basis.

Specifically, the Company's material weakness was that its management does not have adequate staffing in its accounting department and has not yet designed and implemented the appropriate processes and internal controls to support accurate and timely financial reporting.

The Company is working to remediate the material weakness and is taking steps to strengthen its internal control over financial reporting such as the Company's hiring of Jolie Kahn as its Chief Financial Officer in the first quarter of 2024. Additionally, the Company plans to further develop and implement formal policies, processes and documentation procedures relating to financial reporting, including the oversight of third-party service providers. The actions that the Company is taking are subject to ongoing executive management review. If the Company is unable to successfully remediate the material weakness, or if in the future, we identify further material weaknesses in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by Nasdaq, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, because no such evaluation has been required. Had an independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses might have been identified.

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404, however they will not be required to do so for so long as we are an EGC. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Government Regulatory Compliance

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a 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 products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

Changes to currently applicable laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors, health care providers and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, or AKS, and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign 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 or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; 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 often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, 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 requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA may impose consent decrees or 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

The FDA and other regulatory agencies strictly regulate the post-approval marketing, labeling, advertising, and promotion of products that are placed on the market. The FDA and other regulatory agencies impose stringent restrictions on sponsors' communications regarding off-label use. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However companies may share truthful and not misleading information that is not inconsistent with the labeling. 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. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. Violation of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. In addition, the former Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach the required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions have been suspended multiple times. Most recently, the Protecting Medicare and American Farmers from Sequester Cuts Act impacts payments for all Medicare Fee for Services claims as follows: no payment adjustment through March 31, 2022; 1% payment adjustment April 1 - June 30, 2022; and 2% payment adjustment beginning July 1, 2022. The sequester may be delayed by future legislation. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On January 2, 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.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, the former Trump administration's budget for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The former Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers.

On November 30, 2020, HHS issued regulations excluding from the definition of a "discount" eligible for Anti-Kickback Statute safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D or pharmacy benefit managers under contract with them, modifying the existing discount safe harbor in particular contexts; and creating safe harbors for certain point-of-sale reductions in price on prescription pharmaceutical products and for certain PBM service fees. Following a lawsuit brought by the Pharmaceutical Care Management Association, the Biden Administration delayed the rule's effective date to January 1, 2023. Subsequently, the Infrastructure Investment and Jobs Act, signed by President Biden on November 15, 2021, has further delayed implementation to January 2026.

On September 24, 2020, HHS and FDA issued a final rule under Section 804 of the Food, Drug, and Cosmetic Act allowing commercial importation of certain prescription drugs from Canada without the manufacturer's authorization. The validity final rule has been challenged in federal court by the Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines and the Council for Affordable Health Coverage.

On November 20, 2020, CMS announced a new payment model, the Most Favored Nation Model and issued a corresponding interim final rule, intended to lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals than the lowest price that drug manufacturers receive in other similar countries. The interim rule was enjoined on December 29, 2020 and withdrawn by CMS on December 27, 2021.

On November 20, 2020, CMS and the HHS Office of the Inspector General issued two final rules implementing changes to the Physician Self-Referral Law, or Stark Law, and the Anti-Kickback Statute. These new rules codify new value-based exceptions and safe harbors to the Stark Law and the Anti-Kickback Statute, as well as offer additional clarification in the form of updated definitions. We continue to analyze and monitor the potential impact of these new and amended exceptions and safe harbors.

On December 23, 2020, the Health Resources and Services Administration issued a final rule requiring federally qualified health centers in the 340B Drug Pricing Program to pass drug discounts on to certain low-income patients as a condition of receiving federal grant funding.

HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress has indicated that it will continue to seek new legislative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In November 2021, the Departments of Health and Human Services, Labor, the Treasury, and the Office of Personnel Management proposed rules under the Consolidated Appropriations Act of 2021 requiring health plans, health insurance issuers offering group or individual health insurance coverage, and health benefits plans offered to federal employees to submit key drug pricing data with a goal of increasing transparency of drug cost, with the ultimate goal of promoting competition and bringing down overall health care costs.

On August 16, 2022 the Inflation Reduction Act of 2022 was passed, which among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The effect of the Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic 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.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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

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

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

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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 and development 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, and cause 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 us and 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 and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of specified 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.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering and shipping conditions. Third parties with whom we contract are subject to registration, inspections and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Risks Related to Government Regulations Internationally

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and in respect of the U.K. (which is longer a member of the EU), the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplier, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. Breach of this provision is an offence under the Human Medicines Regulations 2012, which is the national implementing legislation of Directive 2001/83/EC in the U.K.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including those in the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers (including information relating to their representatives) in connection with clinical trials. Processing of personal data, including health related information, is increasingly subject to legislation and regulations in numerous jurisdictions around the world, including General Data Protection Regulation, (EU) 2016/679, or GDPR, and each of the California Consumer Privacy Act of 2018, or CCPA, and the Health Insurance Portability and Accountability Act, or HIPAA, in the United States, among many others. Our regulatory obligations in foreign jurisdictions could harm the use or cost of our solution in international locations as data protection and privacy laws and regulations around the world continue to evolve. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

The CCPA, which went into effect on January 1, 2020, provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA (a) allows enforcement by the California Attorney General, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. Additionally, on November 3, 2020, California voters approved the California Privacy Rights Act or CPRA ballot initiative. The CPRA, which will come into effect on January 1, 2023, will significantly modify the CCPA and expand the privacy rights of California residents. We cannot yet predict the impact of the CPRA on our business or operations, but it may require us to incur additional costs and expenses. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The new California law may lead to similar laws in other U.S. states or at a national level, which could increase our potential liability and adversely affect our business.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, may seek to conduct clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The GDPR, became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR has extra-territorial application and applies not only to organizations with a presence in the EU or the UK but also to businesses based outside the EU or the UK that carry out processing that is related to (i) an offer of goods or services to individuals in the EU or the UK, or (ii) the monitoring of their behavior so long as this takes place in the EU or the UK, even if the data is stored outside the EU or the UK. Running clinical trials involving participants in the EU or the UK and processing personal data in the context of that activity will trigger the application of the GDPR. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and restrictions on cross-border data transfers unless a legal mechanism as set out in the GDPR can be relied on, such as transferring such information outside the EEA, including to the United States, (as detailed further below) providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping.

The EU and UK may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase. In addition, the GDPR imposes strict rules on the transfer of personal data out of the EU/UK to third countries deemed to lack adequate privacy protections (including the United States), unless an appropriate safeguard specified by the GDPR is implemented, such as the Standard Contractual Clauses, or SCCs, approved by the European Commission, or a derogation applies. The Court of Justice of the European Union, or CJEU, recently deemed that the SCCs are valid. However, the CJEU ruled that transfers made pursuant to the SCCs and other alternative transfer mechanisms need to be analyzed on a case-by-case basis to ensure EU standards of data protection are met in the jurisdiction where the data importer is based, and there continue to be concerns about whether the SCCs and other mechanisms will face additional challenges. European regulators have issued recent guidance following the CJEU ruling that imposes significant new diligence requirements on transferring data outside the EEA, including under an approved transfer mechanism. This guidance requires an "essential equivalency" assessment of the laws of the destination country. If essentially equivalent protections are not available in the destination country, the exporting entity must then assess if supplemental measures can be put in place that, in combination with the chosen transfer mechanism, would address the deficiency in the laws and ensure that essentially equivalent protection can be given to the data. Complying with this guidance will be expensive and time consuming and may ultimately prevent us from transferring personal data outside the EEA, which would cause significant business disruption. Until the legal uncertainties regarding how to legally continue transfers pursuant to the SCCs and other mechanisms are settled, we will continue to face uncertainty as to whether our efforts to comply with our obligations under the GDPR will be sufficient. This and other future developments regarding the flow of data across borders could increase the complexity of transferring personal data across borders in some markets and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity, which could have an adverse effect on our reputation and business.

In addition, following the UK's exit from the European Union, or Brexit, on January 31, 2020 and the transition period through December 31, 2020 during which the GDPR continued to apply in the UK, on January 1, 2021, the GDPR was brought into UK law as the 'UK GDPR.' On June 28, 2021, the EU Commission adopted two adequacy decisions for the UK, which enabled the free flow of data from the EU to the UK, where the level of data protection is essentially the same as that guaranteed under EU law. Nonetheless, there may be further developments about the regulation of particular issues such as UK-EU data transfers that may require us to take steps to ensure the lawfulness of our data transfers.

The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR also introduces the right for non-profit organizations to bring claims on behalf of data subjects.

Further, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. The United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

In the event we commence clinical trials in the EEA, the GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. 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, as well as materially and adversely affecting our operations and business performance. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or biopharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and healthcare providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to Our Securities

There is a limited public market for our common stock and warrants, the stock price of our common stock and warrants may be volatile or may decline regardless of our operating performance and you may not be able to resell your common stock or warrants at or above price you paid for them.

There is a limited public market for our common stock and warrants. You may not be able to sell your shares or warrants quickly or at the market price if trading in our common stock or warrants is not active. An active or liquid market in common stock and warrants may not develop or, if it does develop, it may not be sustainable. As a result of these and other factors, you may be unable to resell your shares of our common stock or warrants at or above price you paid for them.

Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The price of our common stock and warrants may be volatile, and you could lose all or part of your investment.

The trading price of our common stock and warrants may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the commencement, enrollment or results of any clinical trials of any of our programs;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;

- adverse results or delays in our clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of any product candidate;
- changes in laws or regulations applicable to any product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use any of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock and public warrants by us or our stockholders in the future;
- trading volume of our common stock and public warrants;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including any impact of the ongoing COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, as well as local or global socio-economic and political factors, including the conflict between Russia and Ukraine, may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock and warrants does not exceed the price you paid for them, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

We are a "controlled company" within the meaning of Nasdaq rules and the rules of the SEC. As a result, we qualify for exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.

Poseidon Bio, LLC owns a majority of our outstanding common stock. As a result, we are a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including:

- the requirement that a majority of our board of directors consist of "independent directors" as defined under the rules of Nasdaq;
- the requirement that we have a compensation committee that is composed entirely of directors who meet the Nasdaq independence standards for compensation committee members; and
- the requirement that our director nominations be made, or recommended to our full board of directors, by our independent directors or by a nominations committee that consists entirely of independent directors.

We currently rely on these exemptions. If we continue to utilize such exemptions available to controlled companies, we may not have a majority of independent directors, our nominations committee and compensation committee may not consist entirely of independent directors and such committees may not be subject to annual performance evaluations. Accordingly, under these circumstances, you will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our Common and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and their affiliates and our principal stockholders beneficially hold, in the aggregate, approximately 75% of our outstanding voting stock. These stockholders, acting together, would be able to significantly influence all matters requiring stockholder approval. For example, these stockholders would be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to compliance with its public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting and other expenses that Legacy Ocean did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. EGCs are permitted to implement many of these requirements over a longer period. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Our management team has limited experience managing a public company.

Most of the members of our management team have limited to no experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team has not worked together at prior companies that were publicly traded. Our management team may not successfully or efficiently manage their new roles and responsibilities. Our transition to being a public company has subjected us to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could have a material adverse effect on our business, financial condition and results of operations.

The Company’s Third Amended and Restated Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, as applicable, against their respective directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders, as applicable.

Pursuant to the Company's Third Amended and Restated Certificate of Incorporation ("the "Amended Certificate"), unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware, the Amended Certificate and the Company's bylaws; (iv) any action to interpret, apply, enforce or determine the validity of the Amended Certificate and the Company's bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware forum provision. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United States District Courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the federal forum provision, as our principal office is located in Providence, Rhode Island. In addition, the Amended Certificate that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware forum provision and the federal forum provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. In addition, these forum selection clauses in the Amended Certificate may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our federal forum provision. If the federal forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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 federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. As noted above, the Amended Certificate provides that the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. Due to the concurrent jurisdiction for federal and state courts created by Section 22 of the Securities Act over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, there is uncertainty as to whether a court would enforce the exclusive forum provision. Investors also cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Anti-takeover provisions contained in the Amended Certificate and the Company's bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

The Amended Certificate and the Company's bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;

- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of the Amended Certificate;

- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock; and

The Amended Certificate contains a prohibition on us engaging in a business combination with an interested stockholder for a period of three years following becoming an interested stockholder unless (i) approved by the Board prior to the person becoming an interested stockholder, (ii) the interested stockholder owning at least 85% of the voting stock of the company at the time the transaction commenced or (iii) approved by the Board and at least 66 2/3% of the outstanding stock of the company not owned by the interested stockholder. An interested stockholder includes persons owning 15% or more of the company's voting stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in the Amended Certificate and the Company's bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

The Amended Certificate and the Company's bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, the Amended Certificate, the Company's bylaws and the indemnification agreements that we entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at its request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we are be obligated by our organizational documents to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; and

- the rights conferred in the Amended Certificate and the Company's bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

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

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

Future issuances of debt securities and equity securities may adversely affect us, including the market price of our common stock and warrants and may be dilutive to existing stockholders.

In the future, we may incur debt or issue equity-ranking senior to our common stock. Those securities will generally have priority upon liquidation. Such securities also may be governed by an indenture or other instrument containing covenants restricting our operating flexibility. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges more favorable than those of our common stock. Because our decision to issue debt or equity in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of our common stock and warrants and be dilutive to existing stockholders.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and warrants.

Following the Business Combination, our common stock and warrants (other than warrants issued to Second Street Capital, LLC (the "Second Street Warrants")) were listed on Nasdaq under the symbols "OCEA" and "OCEAW," respectively. If we are not able to comply with the continued listing standard of Nasdaq, we and our stockholders could face significant material adverse consequences including, but not limited to:

- a limited availability of market quotations for our securities;

- reduced liquidity for our securities;

- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock;

- a limited amount of analyst coverage; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Since our common stock and warrants are listed on Nasdaq, they will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. While we are not aware of a state, other than the state of Idaho, having used these powers to prohibit or restrict the sale of securities issued by blank check companies, certain state securities regulators view blank check companies unfavorably and might use these powers, or threaten to use these powers, to hinder the sale of securities of blank check companies in their states. Further, if our securities were no longer listed on Nasdaq, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist its securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by it to restore compliance with listing requirements would allow its securities to become listed again, stabilize the market price or improve the liquidity of its securities, prevent its securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on any of the markets offered by OTC Markets Group Inc., the liquidity and price of these securities may be more limited than if they were quoted or listed on Nasdaq or another national securities exchange. Our securityholders may be unable to sell their securities unless a market can be established or sustained.

An active market for our securities may not develop, which would adversely affect the liquidity and price our securities.

The price of our securities may vary significantly due to factors specific to us as well as to general market or economic conditions. Furthermore, an active trading market for our securities may never develop or, if developed, it may not be sustained. Holders of our securities may be unable to sell their securities unless a market can be established and sustained.

The market price of our securities may decline as a result market factors.

Fluctuations in the price of our securities could contribute to the loss of all or part of your investment. If an active market for our securities develops and continues, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on your investment in our securities and our securities may trade at prices significantly below the price you paid for our securities. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

The market price of our securities may decline as a result for a number of other reasons including:

- if the effect of the Business Combination on our business and prospects is not consistent with the expectations of securities or industry analysts;
- if we do not achieve the perceived benefits of the Business Combination as rapidly or to the extent anticipated by securities or industry analysts;
- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our results of operations;
- success of competitors;
- changes in financial estimates and recommendations by securities analysts concerning us or the biopharmaceutical industry in general;
- operating and share price performance of other companies that investors deem comparable to us;
- our ability to market new and enhanced products and technologies on a timely basis;

- changes in laws and regulations affecting our business;
- our ability to meet compliance requirements;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of our securities available for public sale; or
- any major change in our board of directors or management.

Certain existing stockholders purchased our securities at a price below the current trading price of such securities, and may experience a positive rate of return based on the current trading price.

Certain of our securityholders acquired shares of our common stock or warrants at prices below the current trading price of our common stock, and may experience a positive rate of return based on the current trading price. Such securityholders may be incentivized to sell their securities at prices below the prevailing trading price of such securities because the prices at which they acquired their shares may be lower than prevailing market prices and/or the prices at which public investors purchased our securities in the open market, and therefore such shareholders may generate positive rates of return on their investment that would not be available to public shareholders that acquired their securities at higher prices.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our common stock to decline.

The sale of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that it deems appropriate.

Following the Business Combination, we had a total of 33,774,467 shares of common stock outstanding (excluding any outstanding warrants). Shares held by our public stockholders are freely tradable without registration under the Securities Act, and without restriction, following the Closing, by persons other than our "affiliates" (as defined under Rule 144 of the Securities Act, "Rule 144"), including our directors, executive officers and other affiliates.

In addition, the shares of our common stock reserved for future issuance under the 2022 Stock Option and Incentive Plan (the "Incentive Plan") and 2022 Employee Stock Purchase Plan (the "ESPP") will become eligible for sale in the public market once those shares are issued, subject to any applicable vesting requirements, lockup agreements and other restrictions imposed by law. The Incentive Plan and ESPP will initially reserve up to 6,540,000 shares of our common stock for issuance as awards in accordance with the terms of the Incentive Plan and ESPP. We expect to file one or more registration statements on Form S-8 under the Securities Act to register shares of our common stock or securities convertible into or exchangeable for shares of our common stock issued pursuant to the Incentive Plan or the ESPP. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market. The initial registration statement on Form S-8 is expected to cover shares of our common stock.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of the then-outstanding shares of our common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

We qualify as an "emerging growth company" as well as a "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We qualify as an "emerging growth company" within the meaning of the Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the end of that year's second fiscal quarter, (ii) the last day of the fiscal year in which we have total annual gross revenue of $1.1 million or more during such fiscal year (as indexed for inflation), (iii) the date on which we have issued more than $1.0 million in non-convertible debt in the prior three-year period or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock, as defined by the JOBS Act. Investors may find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of its reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for its securities and the trading prices of its securities may be more volatile.

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 an election to opt out is irrevocable. We intend to take advantage 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, we, 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 our 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.

Additionally, we qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K promulgated by the SEC. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company for so long as the market value of its common stock held by non-affiliates is less than $250.0 million measured on the last business day of its second fiscal quarter, or its annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of its common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of its financial statements with other public companies difficult or impossible.

Following consummation of the Business Combination, we may be required to take write-downs or write-offs, or we may be subject to restructuring, impairment or other charges that could have a significant negative effect on our financial condition, results of operations and the price of our securities, which could cause you to lose some or all of your investment.

We may redeem unexpired public warrants prior to their exercise at a time that is disadvantageous to the holders, thereby making your public warrants worthless.

We have the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of our common stock equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date we give notice of redemption. If and when the public warrants become redeemable by us, we may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding public warrants could force the holders (i) to exercise their public warrants and pay the exercise price therefor at a time when it may be disadvantageous for them to do so, (ii) to sell their public warrants at the then-current market price when you might otherwise wish to hold your public warrants or (iii) to accept the nominal redemption price which, at the time the outstanding public warrants are called for redemption, is likely to be substantially less than the market value of their public warrants. None of the private placement warrants will be redeemable by us so long as they are held by their initial purchasers or their permitted transferees.

If we do not file and maintain a current and effective registration statement relating to the common stock issuable upon exercise of the warrants, holders will only be able to exercise such warrants on a "cashless basis."

If we do not file and maintain a current and effective prospectus relating to our common stock issuable upon exercise of the warrants at the time that holders wish to exercise such warrants, they will only be able to exercise them on a "cashless basis" provided that an exemption from registration is available. As a result, the number of shares of our common stock that holders will receive upon exercise of the warrants will be fewer than it would have been had such holder exercised its Warrant for cash. Further, if an exemption from registration is not available, holders would not be able to exercise on a cashless basis and would only be able to exercise their warrants for cash if a current and effective registration statement relating to our common stock issuable upon exercise of the warrants is available. Under the terms of certain warrant agreements, we have agreed to use its best efforts to meet these conditions and to file and maintain a current and effective registration statement relating to our common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that it will be able to do so. If we are unable to do so, the potential "upside" of the holder's investment in us may be reduced or the warrants may expire worthless.

There is no guarantee that the warrants will ever be in the money, and they may expire worthless and the terms of warrants may be amended.

The exercise price for the warrants (other than the Second Street Warrants) is $11.50 per share of common stock. There is no guarantee that the warrants will ever be in the money prior to their expiration, and as such, the warrants may expire worthless.

The exercise price for our public warrants is higher than in many similar blank check company offerings in the past, and, accordingly, the public warrants are more likely to expire worthless.

The exercise price of our public warrants is higher than is typical with many similar blank check companies in the past. Historically, with regard to units offered by blank check companies, the exercise price of a public warrant was generally a fraction of the purchase price of the units in the initial public offering. The exercise price for our public warrants is $11.50 per share, subject to adjustment as provided therein. As a result, the public warrants are less likely to ever be in the money and more likely to expire worthless.

The warrants will become exercisable for our common stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

Our private placement warrants are exercisable for 5,411,000 shares of common stock at $11.50 per share and our public warrants are exercisable for 5,250,000 shares of common stock at $11.50 per shares. The Second Street Warrants are exercisable for 511,712 shares of common stock at an exercise price of $8.06 per share, 102,342 shares of common stock at an exercise price of $7.47 per share and 75,000 shares of common stock at an exercise price of $10.34. The additional shares of our common stock issued upon exercise of our warrants will result in dilution to the then existing holders of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our common stock.

The Excise Tax included in the Inflation Reduction Act of 2022 may decrease the value of our securities or decrease the amount of funds available for distribution in connection with a liquidation.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IR Act"), which, among other things, imposes a 1% excise tax on certain repurchases (including certain redemptions) of stock by publicly traded domestic (i.e., U.S.) corporations and certain domestic subsidiaries of publicly traded foreign (i.e., non-U.S.) corporations (each, a "covered corporation"). The excise tax will apply to repurchases occurring in 2023 and beyond. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. The U.S. Department of Treasury has authority to provide regulations and other guidance to carry out, and prevent the abuse or avoidance of, the excise tax. On December 27, 2022, the U.S. Department of the Treasury issued a notice that provides interim operating rules for the excise tax, including rules governing the calculation and reporting of the excise tax, on which taxpayers may rely until the forthcoming proposed Treasury regulations addressing the excise tax are published. Although such notice clarifies certain aspects of the excise tax, the interpretation and operation of other aspects of the excise tax remain unclear, and such interim operating rules are subject to change. Because Ocean Biomedical is a Delaware corporation and its securities are trading on Nasdaq, it is expected that Ocean Biomedical is a "covered corporation" for this purpose, and it is expected that Ocean Biomedical will be subject to the excise tax with respect to any redemptions of its shares in connection with the Business Combination that are treated as repurchases for this purpose.

The extent of the excise tax that may be incurred would depend on a number of factors, including (i) whether the redemption is treated as a repurchase of stock for purposes of the excise tax, (ii) the fair market value of the redemption treated as a repurchase of stock in connection with the Business Combination, (iii) the nature and amount of the equity issued in connection with the Business Combination, and (iv) the content of forthcoming regulations and other guidance from the U.S. Department of the Treasury. Generally, issuances of stock by a repurchasing corporation in a year in which such corporation repurchases stock would reduce the amount of excise tax imposed with respect to such repurchase. The excise tax is imposed on the repurchasing corporation itself, not the shareholders from which shares are repurchased, and only limited guidance on the mechanics of any required reporting and payment of the excise tax on which taxpayers may rely has been issued to date. The imposition of the excise tax could reduce the amount of cash available to Ocean Biomedical to fund operations and to make distributions to shareholders.

If the number of securities redeemed exceeds the number of securities issued under the Business Combination Agreement, Backstop Agreement and Common Stock Purchase Agreement, however, the amount of excise tax could be substantial. Consequently, the value of your investment in our securities may decrease as a result of the excise tax.

We may be the target of securities class action and derivative lawsuits which could result in substantial costs.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger or business combination agreements. Additionally, our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. We may be the target of this type of litigation in the future. Even if the lawsuits are without merit, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. We cannot predict whether any such lawsuits will be filed.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our executive offices are located at 55 Claverick St., Room 325, Providence, RI 02903. We do not have any manufacturing facilities or personnel at this time. We currently rely, and expect to continue to rely, on contract manufacturing organizations for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing and commercial manufacturing if our product candidates receive marketing approval. Our research and development efforts have taken place in state-of-the-art facilities at our academic partners, principally at Brown University, which are being used under the sponsored research agreements. We anticipate relying on these facilities going forward through sponsored research arrangements with Brown University and with other university partners. In addition, we expect to access laboratory facilities and resources through various contract research organization partners such as Lonza Group AG, with whom we are currently engaged.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows, except as set forth in the financial statements included in this Annual Report.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

The Company's public shares and public warrants began trading on Nasdaq under the symbols "OCEA" and "OCEAW," respectively. The Company's publicly traded units automatically separated into their component securities upon the closing of the Business Combination, and as a result, no longer trade as a separate security.

Holders

As of November 22, 2024, there were approximately 60 holders of record of our common stock. These numbers of holders of record do not include a substantially greater number of "street name" holders or beneficial holders whose common stock and public warrants are held of record by banks, brokers and other financial institutions.

Dividends

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

Recent Sales of Unregistered Securities

Set forth below is information regarding securities issued by Aesther and Legacy Ocean in 2022 that were not registered under the Securities Act. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

Issuances of Capital Stock

In connection with the Closing of the Business Combination, on February 14, 2023, Aesther issued to Sponsor 1,365,000 shares of the Company's Class A common stock in connection with Sponsor obtaining two (2) three-month extensions beyond the September 16, 2022 deadline to complete an initial business combination. Such shares were reclassified as Ocean Biomedical common stock in connection with the Business Combination pursuant to the Amended Certificate. These securities were issued pursuant to Section 4(a)(2) of the Securities Act.

Issuance of Warrants

On February 22, 2022, Legacy Ocean entered into a Loan Agreement with Second Street Capital, LLC (the "Second Street Loan"), where Legacy Ocean borrowed $0.6 million, which was used to pay a $15,000 loan fee and certain accrued expenses of Legacy Ocean. The Second Street Loan accrues interest at the rate of 15% per annum, with principal and interest due at maturity. Legacy Ocean was required to repay the Second Street Loan on the earlier of (i) 5 business days after Legacy Ocean's next financing or (ii) May 23, 2022. Legacy Ocean issued to Second Street Capital, LLC a warrant to purchase 312,500 shares of Legacy Ocean's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. For a period of 180 days from the closing of Legacy Ocean's next financing, Second Street Capital, LLC has the right to put the warrants to Legacy Ocean in exchange for a payment of $0.3 million. On April 22, 2022, the February 2022 Second Street Loan Agreement was amended whereas the maturity date was extended from May 23, 2022 to November 18, 2022. The Company recognized a loss and recorded the liability of $0.3 million for the put option in its consolidated financial statements for the fiscal year ended December 31, 2022. There was no impact in 2023.

In April 2022, Legacy Ocean entered into a second Loan Agreement with Second Street Capital, LLC (the "Second Street Loan 2"), where Legacy Ocean borrowed $0.2 million, which was used to pay a $15,000 loan fee, $15,000 fee for amending the Second Street Loan to extend the maturity date, and $20,000 next day loan fee. The Second Street Loan 2 accrues interest at the rate of 15% per annum, with principal and interest due at maturity. Legacy Ocean issued to Second Street Capital, LLC a warrant to purchase 62,500 shares of Legacy Ocean's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. There is no put option associated with this loan. Legacy Ocean was required to repay the April 2022 Second Street Loan on the earlier of (i) 5 business days after Legacy Ocean's next financing or (ii) November 18, 2022. Legacy Ocean recognized a loss of $0.4 million for the warrants issued based on the estimated fair value of the awards on the date of grant in Legacy Ocean's consolidated financial statements for the fiscal year ended December 31, 2022.

On September 30, 2022, the Second Street Loan and the Second Street Loan 2 were amended whereas the maturity date was extended from November 18, 2022 to December 30, 2022. In consideration of the extension, Legacy Ocean issued to Second Street Capital, LLC a warrant to purchase 75,000 shares of Legacy Ocean's common stock with an exercise price of $10.20 per share exercisable until September 30, 2026. Legacy Ocean recognized a loss of $435,075 for the warrants issued based on the estimated fair value of the awards on the date of the grant in Legacy Ocean's consolidated financial statements for the period ended September 30, 2022. Legacy Ocean recognized a total expense in the amount of $1.1 million of which $0.3 million was for the put option and $0.8 million was for the warrants issued for the fiscal year ended December 31, 2022.

On November 17, 2022, Legacy Ocean, Aesther and Second Street Capital, LLC entered into a Warrant Exchange Agreement, pursuant to which Legacy Ocean and Aesther agreed as of the Closing of the Business Combination to issue warrants (the "Second Street Warrants") to Second Street Capital, LLC in exchange for warrants previously issued by Legacy Ocean to Second Street Capital, LLC. As of the Closing, the Second Street Warrants consisted of two warrants for the number of shares of common stock equal to the economic value of the warrants previously issued to Second Street Capital, LLC in exchange for the termination of such previously issued warrants. The Second Street Warrants are exercisable for a total of 511,712 shares of the our common stock at an exercise price of $8.06 per share and 102,342 shares of our common stock at an exercise price of $7.47 per share. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

On February 15, 2023, the Second Street Loan and Second Street Loan 2 were further amended whereas the maturity dates were extended from February 15, 2023 to March 31, 2023. The Company is required to repay the principal and accrued interest of the Second Street Loan and Second Street Loan 2 the earlier of (i) 5 business days after the Company's next financing or closing of the Business Combination or (ii) March 31, 2023. In consideration of the extension of the Second Street Loan, the Company paid a $50,000 extension fee and issued to Second Street Capital, LLC a warrant to purchase 50,000 shares of the Company's common stock with an exercise price of $10.34 per share exercisable until February 15, 2028. In consideration of the extension of the Second Street Loan 2, the Company paid a $25,000 extension fee and issued to Second Street Capital, LLC a warrant to purchase 25,000 shares of the Company's common stock with an exercise price of $10.34 per share exercisable until February 15, 2028. The Company recognized a loss on extinguishment of debt of $0.1 million for the shares issued and an expense for the fair value of the warrants issued of $0.1 million in its consolidated financial statements for the fiscal year ended December 31, 2023. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In 2024, the Company entered into a settlement agreement with Second Street Capital and McKra Investments III with regard to $2.7 million principal amount of promissory notes, plus accrued and unpaid interest and fees. The Company will satisfy payment of past due loan fees by the issuance of 225,000 shares of restricted common stock. The Company will also satisfy the amount due for the principal amount of the notes and accrued and unpaid interest through (i) the issuance of $1.7 million worth of restricted common stock (at a price per share equal to the 30 day vwap of a share of Company common stock as of July 22, 2024), and (ii) payment of the remaining balance of $1.7 million in cash at the time of closing of the Company's next financing with net proceeds to the Company of more than $10 million either in a public offering or private transaction, or if such a closing does not occur on or before September 30, 2024, in shares of restricted Common Stock of the Company (at a price per share equal to the 30 day vwap of a share of Company common stock as of September 30, 2024). Since the Company did not close a financing transaction with net proceeds to the Company of more than $10 million prior to September 30, 2024, the Company did not pay the remaining balance of $1.7 million in cash.

Grants and Exercises of Stock Options and Restricted Stock

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED.]

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

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the notes related thereto which follow Item 16 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 "Cautionary Note Regarding Forward-Looking Statements," "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.

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

On February 14, 2023, the registrant consummated the previously announced business combination (the "Business Combination") pursuant to that certain Agreement and Plan of Merger, dated August 31, 2022, as amended on December 5, 2022 by Amendment No. 1 (as amended, the "Business Combination Agreement"), by and among Ocean Biomedical, Inc., formerly known as Aesther Healthcare Acquisition Corp. (the "Company"), AHAC Merger Sub, Inc., a Delaware corporation ("Merger Sub"), Aesther Healthcare Sponsor, LLC (the "Sponsor"), in its capacity as purchaser representative, Ocean Biomedical Holdings, Inc., formerly known as Ocean Biomedical, Inc., a Delaware corporation ("Legacy Ocean"), and Dr. Chirinjeev Kathuria, in his capacity as seller representative. In connection with the closing of the Business Combination (the "Closing"), the Company changed its name from "Aesther Healthcare Acquisition Corp." to Ocean Biomedical, Inc." References to the "Company", "Ocean Biomedical", "we", "us" and "our" refer to the Legacy Ocean prior to the Closing of the Business Combination and Ocean Biomedical, Inc., formerly known as Aesther Healthcare Corp., on a consolidated basis with Legacy Ocean, for periods after the Closing of the Business Combination.

Overview

We are a biopharmaceutical company that seeks to bridge the "bench-to-bedside" gap between medical research discoveries and patient solutions. We do this by leveraging our strong relationships with research universities and medical centers to license their inventions and technologies with the goal of developing them into products that address diseases with significant unmet medical needs. We believe that our differentiated business model positions us to capture inventions created at these institutions that might otherwise fail to be commercialized to benefit patients. Our team of accomplished scientists, business professionals and entrepreneurs bring together the interdisciplinary expertise and resources required to develop and commercialize a diverse portfolio of assets. We are organized around a licensing and subsidiary structure that we believe will enable us to create mutual value both for us and potential licensing partners. We believe this structure, combined with the professional networks of our leadership team members, allows us to opportunistically build a continuous pipeline of promising product innovations through our existing and potential future relationships with research institutions. Our goal is to optimize value creation for each of our product candidates, and we intend to continuously assess the best pathway for each as it progresses through the preclinical and clinical development process—including through internal advancement, partnerships with established companies and spin-outs or initial public offerings, ("IPOs")—in order to benefit patients through the commercialization of these products. Our current active assets are licensed from Brown University and Rhode Island Hospital. Our scientific co-founders and members of our Board of Directors ("Board"), Dr. Jack A. Elias and Dr. Jonathan Kurtis, are both affiliated with Brown University and with Rhode Island Hospital. Our strategy is to accelerate the flow of the academic discoveries and the required clinical development required for these product candidates and advance them commercially. The number of potential opportunities at research universities and medical centers is large, but only a small fraction of these opportunities is currently tapped in the market. The gap remains wide and we believe this presents an attractive opportunity for us to become an industry leader by addressing a need to accelerate the advancement of therapeutics that can address significant unmet medical needs. The core elements that we believe differentiate our business model include:

- Harnessing inventions and technologies from research universities and medical centers. We are experienced at identifying and sourcing breakthrough discoveries at academic and research institutions, including our current partnerships with Brown University and Rhode Island Hospital.

- Developing new drug therapies through an operationally efficient, evidence-based and milestone- driven approach. Once we select an asset for development, we pursue what we believe are appropriate development strategies that we aim to execute efficiently by leveraging contract research and contract manufacturing organizations, or contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), and other drug development experts and consultants.

- Building a diverse portfolio of product candidates. We are evidence-based and program agnostic, meaning that our resources are driven strictly by program progress and milestone achievements. Our approach is to develop multiple diverse programs in parallel which mitigates business risk.

- Providing attractive economic upside to our partners at research universities and medical centers. We have a structure wherein our parent company houses each program in a subsidiary. We believe this structure is optimal to provide attractive economic incentives to the discovering institution and its researchers.

- Employing a multi-disciplinary approach to drug discovery and development across our programs. Our business model is based on bringing together the appropriate disciplines and expertise needed for each of our programs and leveraging learnings across programs and disease areas.

- Exploiting multiple commercialization options to maximize each program's value. Throughout the development of our product candidates, we plan to continually assess that program's potential paths to market, and we will endeavor to identify and maximize commercial value through various options, including internal advancement, partnerships with established companies, and spin-outs or IPOs.

- Leadership team comprised of academic, scientific and business innovators. We have assembled an industry-leading, multi-disciplinary team consisting of physicians, scientists and business leaders with significant experience in progressing product candidates from early-stage research through clinical trials, regulatory approval and ultimately to commercialization. Although our company has not yet developed or commercialized any biopharmaceutical products, key members of our management team have experience doing so in previous endeavors.

We believe our differentiated business model will enable us to commercialize our products, if approved, and will allow us to replicate our licensing partnerships through aligned incentive structures with research universities and medical centers.

Our pipeline consists of both preclinical and clinical-stage programs. We anticipate moving certain preclinical product candidates in our oncology, fibrosis and/or infectious disease programs into the clinic in the next 12 to 24 months.

On December 31, 2020, we executed a Development and Manufacturing Services Agreement with Lonza AG and affiliate Lonza Sales AG ("Lonza"). We engaged Lonza (and Lonza affiliates) for the development and manufacture of certain products and services along with assistance in developing the product OCX-253. Under this agreement, Lonza will perform the following key activities in two stages in support of our IND-enabling program plan: first, to perform a manufacturability assessment of the OCX- 253 monoclonal antibody drug candidates, generate or arrange to be generated synthetic genes and single gene vectors and vector constructions, and conduct gene vector construct testing; and second, to generate and assess growth and productivity for cell lines to be used for synthesizing OCX-253 drug candidate. The agreement provides that we will pay for all raw materials and related fees. Further, the agreement stipulates immediate 100% payment of invoices for any stage of work worth less than GBP 50,000, and deferral of 50% of payment for any stage of work worth more than GBP 50,000 to the release of applicable batches or completion of applicable services.

In December 2020, the sole stockholder of Legacy Ocean contributed 100% of his founders shares in the amount of 17,112,298 shares to Poseidon Bio, LLC ("Poseidon") which became the sole stockholder of Legacy Ocean. In February 2021, Poseidon transferred 342,244 shares of Legacy Ocean's common stock back to Legacy Ocean's founder. In February 2021, Poseidon amended and restated its operating agreement to allow additional members into Poseidon by issuing Class A units and Class B units in which Legacy Ocean's founder is the sole Class A unit holder who holds 100% of the voting power of Poseidon. In addition, certain executives and employees were granted Class B unit profit interests in Poseidon. These profit interests grants in Legacy Ocean's controlling shareholder were deemed to be transactions incurred by the shareholder and within the scope of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, Stock Compensation. As a result, the related transactions by the stockholder were pushed down into our consolidated financial statements. As of March 31, 2023, Legacy Ocean's founder held 100% of the voting power and 69% of the equity interests in Poseidon. The Business Combination will have no impact on the Poseidon Class B units and we do not anticipate that Poseidon will make any additional grants.

In March 2021, we authorized the issuance of shares of common stock in Legacy Ocean to certain persons who were accredited investors (consisting of friends and family of Legacy Ocean's employees) at an aggregate offering price of $1.0 million. As of February 14, 2023, Legacy Ocean had issued 41,828 shares of common stock at an aggregate offering price of $1.0 million.

In February 2022, we entered into a Loan Agreement (the "Second Street Loan") with Second Street Capital, LLC ("Second Street Capital"), pursuant to which we borrowed $0.6 million. The Second Street Loan accrues interest at the rate of 15% per annum, with principal and interest due at maturity. We issued to Second Street Capital a warrant to purchase 312,500 shares of Legacy Ocean common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. For a period of 180 days from the closing of our next financing, Second Street Capital has the right to put the warrants to the Company in exchange for a payment of $0.3 million. We were originally required to repay the Second Street Loan on the earlier of (i) 5 business days after our next financing or (ii) November 18, 2022. We recognized as interest expense in Other income/(loss) $0.3 million for the put option in the first quarter of 2022.

In May 2022, we entered into a second Loan Agreement with Second Street Capital (the "Second Street Loan 2"), pursuant to which the Company borrowed $0.2 million. The Second Street Loan 2 accrues interest at the rate of 15% per annum, with principal and interest due at maturity. We issued to Second Street Capital a warrant to purchase 62,500 shares of Legacy Ocean common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. There is no put option associated with this loan. We were originally required to repay the Second Street Loan 2 on the earlier of (i) 5 business days after our next financing or (ii) November 18, 2022. We recognized as interest expense in Other income/(loss) $0.4 million in the second quarter of 2022 for the warrants issued based on the estimated fair value of the awards on the date of grant.

On September 30, 2022, the Second Street Loan and Second Street Loan 2 were amended whereas the maturity dates were extended from November 18, 2022 to December 30, 2022. We were required to repay the principal and accrued interest of the Second Street Loan and Second Street Loan 2 the earlier of (i) 5 business days after our next financing or closing of the Business Combination or (ii) December 30, 2022. In consideration of the extensions, we issued to Second Street Capital a warrant to purchase 75,000 shares of Legacy Ocean common stock with an exercise price of $10.20 per share exercisable until September 30, 2026. We recognized as interest expense in Other income/(loss) $0.4 million for the warrants issued based on the estimated fair value of the awards on the date of grant.

On December 30, 2022, the Second Street Loan and the Second Street Loan 2 were further amended to extend the maturity dates to February 15, 2023. No additional warrants were issued to Second Street Capital in connection with the extensions. We were required to repay the Second Street Loan and the Second Street Loan 2 on the earlier of (i) 5 business days after our next financing or (ii) February 15, 2023.

We recognized a total expense in the amount of $1.1 million as interest expense in Other income/(loss) for the fiscal year ended December 31, 2022 for the put option and warrants issued to Second Street Capital of which $0.3 million was for the put option and $0.8 million was for the warrants issued for the year ended December 31, 2022. The warrants issued to Second Street Capital were converted into warrants to purchase our common stock, post-closing of the Business Combination, as described below under "Closing of Business Combination."

On January 10, 2023, the Second Street Loan 2 was further amended whereas increasing the loan amount from $0.2 million to $0.4 million. A loan fee of $15,000 and a minimum return assessment fee of $35,000 were charged and paid from the $0.2 million loan advance for net proceeds of $0.2 million. We were originally required to repay the principal and accrued interest of the Second Street Loan 2 the earlier of (i) 5 business days after our next financing or closing of the Business Combination or (ii) February 15, 2023.

Effective February 15, 2023, the Second Street Loan and Second Street Loan 2 were further amended whereas the maturity dates were extended from February 15, 2023 to March 31, 2023. We were required to repay the principal and accrued interest of the Second Street Loan and Second Street Loan 2 the earlier of (i) 5 business days after our next financing or (ii) March 31, 2023. In consideration of the extensions, we issued to Second Street Capital a warrant to purchase 75,000 shares of our common stock with an exercise price of $10.34 per share exercisable until March 31, 2028. An extension fee of $0.1 million was recorded and $0.2 million was recognized as interest expense in Other income/(loss) in our consolidated financial statements for the quarter ended March 31, 2023.

Effective March 29, 2023, we entered into a Loan Agreement with Second Street Capital (the "March Second Street Loan") pursuant to which we could borrow up to $1.0 million to pay certain accrued expenses. Of this amount, we borrowed $0.7 million. The loan bears interest at 15% per annum and is due as described under "Short-Term Loans" below. We issued a warrant to the lender for 200,000 shares of our common stock, exercisable for five years at an exercise price of $10.34 and will pay up to $0.2 million in loan fees at maturity. Since the Company only borrowed $0.7 million, the loan fee due is $0.1 million at maturity. The estimated fair value of the warrant was $0.7 million that is amortized over the term of the loan. The Company recognized $50 thousand as interest expense in Other income/(loss) in its consolidated financial statements for the fiscal year ended December 31, 2023.

Effective March 31, 2023, the Second Street Loan and the Second Street Loan 2 were further amended to extend the maturity dates to May 31, 2023, and we are currently required to repay the loans as described under "Short-Term Loans" below. In addition, an additional warrant was issued to purchase 150,000 shares of our common stock with an exercise price of $11.50 and a loan fee of $0.1 million was charged. We recognized as interest expense in Other income/(loss) $0.5 million for the warrants issued based on the estimated fair value of the awards on the date of grant in our consolidated financial statements for the fiscal year ended December 31, 2023.

Effective March 28, 2023, we entered into a Loan Agreement (the "McKra Loan") with McKra Investments III ("McKra") pursuant to which we borrowed $1.0 million. We issued a warrant to purchase 200,000 shares of our common stock, with an exercise price of $10.34 per share, exercisable until March 27, 2028. We are required to pay a $0.2 million loan and convenience fee due upon repayment of the loan. Repayment of the loan is due as described under "Short-Term Loans" below. The Company has to amortize the fair value calculation over the term of the loan on a straight-line basis by days. The estimated fair value of the warrant was $0.8 million that is amortized over the term of the loan. The Company recognized $0.3 million as interest expense in Other income/(loss) in its consolidated financial statements for the fiscal year ended December 31, 2023, including $0.2 million related to the amortization of debt issuance costs.

Effective May 12, 2023, we entered into an Omnibus Amendment to Loan Agreements with Second Street Capital ("Second Street Loans Amendment"), pursuant to which the Second Street Loan, the Second Street Loan 2, and the March Second Street Loan were each amended to extend the maturity dates of the loans. See "Short-Term Loans" below for information regarding repayment of the loans.

Effective May 12, 2023, we entered into an Amendment to Loan Agreement with McKra ("McKra Loan Amendment"), pursuant to which the McKra Loan was amended to extend the maturity date of the loan. See "Short-Term Loans" below for information regarding repayment of the loan.

Since Legacy Ocean's inception in 2019, we have devoted substantially all of our efforts to organizing, research and development activities, business planning, building our intellectual property positions and providing general and administrative support for these operations. We have not generated any revenue from product sales.

We have incurred significant operating losses since inception. Our ability to generate product revenues sufficient to achieve profitability will depend heavily upon the successful development and eventual commercialization of one or more of our current products or any future products. Our net operating losses were $10.2 million and $16.1 million for the fiscal year ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and December 31, 2022, we had an accumulated deficit of $196.1 million and $81.6 million, respectively. Our current liabilities are $30.0 million and $12.7 million as of December 31, 2023 and December 31, 2022, respectively. The current liabilities consisted of accrued expenses including transaction costs, accounting and legal fees, accrued research and development costs, and short-term loans. We expect that our expense and capital requirements will increase substantially in connection with ongoing activities to commercialize our products in the future.

We expect to continue to generate operating losses for the foreseeable future. Our future viability is dependent on the success of our research and development and our ability to access additional capital to fund our operations. There can be no assurance that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, and the ability to obtain additional capital to fund operations. Our therapeutic products will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require additional capital, adequate personnel and extensive compliance reporting capabilities. There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable.

In January 2019, we formed three wholly-owned subsidiaries of Legacy Ocean. In February 2021, we formed a fourth wholly-owned subsidiary. The subsidiaries were formed to organize our therapeutic programs in order to optimize multiple commercialization options and to maximize each program's value. We anticipate that additional subsidiaries will also be formed in connection with future programs to provide attractive economic upside to our partners at research universities and medical centers. Our license agreements with Brown University and Rhode Island Hospital are licensed or sublicensed directly or indirectly, to the following subsidiaries:

- Ocean ChitofibroRx Inc. (January 15, 2019)—Fibrosis program (one license with Elkurt/ Brown University);
- Ocean ChitoRx Inc (January 15, 2019)—Oncology programs (three licenses with Elkurt/Brown University);
- Ocean Sihoma Inc. (January 15, 2019)—Malaria disease program (one license with Elkurt/Rhode Island Hospital);
- Ocean Promise, Inc. (February 12, 2021)—Reserved for future programs.

Impacts of Market Conditions on Our Business

Disruption of global financial markets and a recession or market correction, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and other global macroeconomic factors such as inflation, could reduce the Company's ability to access capital, which could in the future negatively affect our liquidity and could materially affect our business and the value of its common stock.

Business Combination Agreement with Aesther Healthcare Acquisition Corp.

Closing of Business Combination

On February 14, 2023 (the "Closing Date"), the Company, formerly known as Aesther Healthcare Acquisition Corp. ("Aesther" or "AHAC"), consummated the Business Combination pursuant to the Business Combination Agreement. Pursuant to the Business Combination Agreement, on the Closing Date, Merger Sub merged with and into Legacy Ocean, with Legacy Ocean continuing as the surviving entity and a wholly-owned subsidiary of the Company. In connection with the Closing, the Company changed its name from "Aesther Healthcare Acquisition Corp." to "Ocean Biomedical, Inc." and Legacy Ocean changed its name from "Ocean Biomedical, Inc." to "Ocean Biomedical Holdings, Inc."

On the Closing Date, in connection with the Closing:

- the Company issued to the holders of Legacy Ocean's securities as of immediately prior to the Closing approximately 23,355,432 shares of the Company's Class A common stock (with a per-share value of $10.00) with an aggregate value equal to $233.6 million, as adjusted as required by the Business Combination Agreement to take into account net working capital, closing net debt and Legacy Ocean's transaction expenses, in exchange for all of the issued and outstanding capital stock of Legacy Ocean;
- Aesther Healthcare Sponsor, LLC.'s (the "Sponsor") 2,625,000 shares of the Company's Class B common stock converted on a one-for-one basis into 2,625,000 shares of the Company's Class A common stock pursuant to the Company's Third Amended and Restated Certificate of Incorporation (the "Amended Certificate");
- the Company issued to the Sponsor 1,365,000 additional shares of the Company's Class A common stock in connection with the Sponsor obtaining two (2) three-month extensions beyond the September 16, 2022 deadline to complete an initial business combination (the "Sponsor Extension Shares");

- the Backstop Parties (as defined below) purchased 1,200,000 shares of the Company's Class A common stock prior to the closing that were not redeemed (the "Share Consideration Shares");

- the Backstop Parties (as defined below) purchased 3,535,466 shares of the Company's Class A common stock prior to the closing that were not redeemed and are subject to the forward purchase provisions of the Backstop Agreement (the "Recycled Shares");

- 5,570,965 shares of the Company's Class A Common Stock were redeemed immediately prior to Closing of the Business Combination;

- the Company issued to Second Street Capital, Legacy Ocean's lender, three (3) warrants for the number of shares of the Company's common stock equal to the economic value of the Legacy Ocean warrants previously issued to Second Street in exchange for the termination of the Legacy Ocean warrants. The new warrants are exercisable for a total of 511,712 shares of the Company's common stock at an exercise price of $8.06 per share and 102,342 shares of the Company's common stock at an exercise price of $7.47 per share;

- the Company issued to Polar (as defined below) 1,350,000 newly issued shares of its common stock that are subject to the forward purchase provisions of the Backstop Agreement; and

- all shares of the Company's Class A common stock were reclassified as common stock pursuant to the Amended Certificate.

In addition, pursuant to Business Combination Agreement, the holders of Legacy Ocean's common stock shall be entitled to receive from the Company, in the aggregate, up to an additional 19,000,000 shares of the Company's common stock (the "Earnout Shares") as follows: (a) in the event that the volume-weighted average price (the "VWAP") of the Company's common stock exceeds $15.00 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing Date until the 36-month anniversary of the Closing Date, the holders of Legacy Ocean securities pre-Closing shall be entitled to receive an additional 5,000,000 shares of the Company's common stock, (b) in the event that the VWAP of the Company's common stock exceeds $17.50 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing Date until the 36-month anniversary of the Closing Date, the holders of Legacy Ocean's securities pre-Closing shall be entitled to receive an additional 7,000,000 shares of the Company's common stock and (c) in the event that the VWAP of the Company's common stock exceeds $20.00 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing Date until the 36-month anniversary of the Closing Date, the holders of Legacy Ocean's securities pre-Closing shall be entitled to receive an additional 7,000,000 shares of the Company's common stock. In addition, for each issuance of Earnout Shares, the Company will also issue to Sponsor an additional 1,000,000 shares of the Company's common stock.

Upon consummation of the Business Combination, there was outstanding an aggregate of 5,250,000 Public Warrants and 5,411,000 Private Placement Warrants. Each of our outstanding whole warrants is exercisable commencing 30 days following the Closing for one share of common stock.

The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Under this method of accounting, AHAC, who is the legal acquirer, is treated as the "acquired" company for financial reporting purposes and Legacy Ocean is treated as the accounting acquirer.

The Business Combination is accounted for as the equivalent of a capital transaction in which Legacy Ocean has issued stock for the net assets of AHAC. The net assets of AHAC are stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Closing of the Business Combination are Legacy Ocean and operations post-Closing of the Business Combination are the Company, on a consolidated basis with Legacy Ocean.

Backstop Agreement

On February 12, 2023, AHAC, Legacy Ocean and Vellar Opportunity Fund SPV LLC – Series 3 ("Vellar") entered into an amended and restated OTC Equity Prepaid Forward Transaction (the "Backstop Agreement"), which amended and restated in their entirety earlier OTC Equity Prepaid Forward Transactions entered into between the parties on August 31, 2022 and February 10, 2023. On February 13, 2023, AHAC, Vellar and Legacy Ocean entered into separate assignment and novation agreements (the "Assignment Agreements") with Meteora Special Opportunity Fund I, LP, Meteora Select Trading Opportunities Master, LP and Meteora Capital Partners, LP (collectively "Meteora"), and Polar Multi-Strategy Master Fund ("Polar" and, together with Vellar and Meteora, the "Backstop Parties"), pursuant to which Vellar assigned to each of Meteora and Polar its rights and obligations in respect of one-third of the shares of Class A common stock subject to the Backstop Agreement. Following the Assignment Agreements, the rights and obligations of each Backstop Party under the Backstop Agreement were and are separate and distinct from the those of the other Backstop Parties, with each Backstop Party acting independently of the others, without reference to or knowledge of any other Backstop Party's actions or inactions.

Pursuant to the Backstop Agreement, the Backstop Parties intended, but were not obligated, to purchase up to 8,000,000 shares of the AHAC Class A common stock. The Backstop Parties made these purchases after the expiration of the redemption deadline for holders to redeem shares in connection with the Business Combination and in brokered transactions in the open market, typically from AHAC stockholders that had elected to redeem their shares. In connection with these purchases, the Backstop Parties revoked any redemption elections. The Backstop Parties purchased 3,535,466 shares (the "Recycled Shares") pursuant to the Backstop Agreement at a price approximately equal to the redemption price for shares of AHAC Class A common stock of $10.56 per share.

The Backstop Agreement provided that we pay to the Backstop Parties out of funds held in the trust account, not later than one local business day following the Closing of the Business Combination, a cash amount equal to the product of the number of shares acquired and the redemption price of approximately $10.56 (the "Prepayment"). On February 16, 2023, we made the Prepayment of $50.4 million and commissions and fee payments of $1.2 million for a total amount of $51.6 million.

We also provided the Backstop Parties with an additional $12.7 million, to compensate them for their purchase of 1,200,000 additional shares of Class A common stock in the open market (the "Share Consideration Shares"). Under the Backstop Agreement, the Share Consideration Shares are not subject to the terms applicable to the Recycled Shares, including with regard to repayment and repurchase as described below.

The Backstop Agreement grants the Backstop Parties the right to purchase from us additional shares (the "Additional Shares") up to an amount equal to the difference between the number of Recycled Shares and the maximum number of shares of 8,000,000. On February 14, 2023, pursuant to Polar's exercise of its right to purchase Additional Shares, AHAC, Legacy Ocean and Polar entered into a subscription agreement pursuant to which Polar purchased 1,350,000 newly issued shares of our common stock at a per share purchase price of approximately $10.56 and an aggregate purchase price of $14.3 million (the "Polar Subscription"). Under the Backstop Agreement, the Additional Shares are subject to the same terms as the Recycled Shares, including with regard to repayment and repurchase as described below.

From time to time, each Backstop Party, in its discretion, may declare an early termination of the Backstop Agreement with regard to all or a portion of the Recycled Shares and Additional Shares (such shares "Terminated Shares") and remit to us, no later than the later of (i) the third local business day following the date the shares become Terminated Shares and (ii) the last day of each calendar quarter after the date the shares become terminated shares, an amount equal to the number of Terminated Shares multiplied by a price (the "Reset Price") that adjusts on the first scheduled trading day of each month to be the lowest of (a) the then-current Reset Price, (b) the per share redemption price of $10.56 and (c) the VWAP for the last ten trading days of the prior month, but in no case less than $10.34.

Under the Backstop Agreement, we have agreed to purchase the Recycled Shares and Additional Shares (together, the "Backstop Shares") from the Backstop Parties on a forward basis upon the maturity of the Backstop Agreement at a per share purchase price equal to the redemption price, which has been funded by the Prepayment. The Backstop Agreement matures on the earlier to occur of (a) February 14, 2026 (three years after the closing of the Business Combination Agreement), (b) the date specified by a Backstop Party in a written notice delivered at a Backstop Party's discretion if either (i) the volume weighted average price ("VWAP") of the shares during 30 out of 45 consecutive trading days is less than $4.00 per share, (ii) we fail to register the Backstop Shares as required by the Backstop Agreement, or (iii) the shares cease to be listed on a national securities exchange, and (c) the date specified by us in a written notice delivered at our discretion if (i) the VWAP of the shares is at or above $20.00 per share for any 30 trading days during a 45 consecutive trading day-period, (ii) the Backstop Shares are freely tradable by the Backstop Parties without restriction and (iii) the aggregate trading volume in respect of such shares during the same 30-day period is equal to at least three times the number of Backstop Shares (less any Terminated Shares).

On May 23, 2023 the Company received an Equity Prepaid Forward Transaction - Valuation Date Notice ("Notice") from Vellar stating that due to the Company's alleged failure to timely register the shares held by Vellar, Vellar had the right to terminate the Backstop Agreement as to their portion of the shares and Vellar claimed that it is entitled to receive Maturity Consideration (as defined in the Backstop Agreement) equal to $6.7 million, which at the Company's discretion may be paid in cash or by offset to the shares currently held by Vellar. Management takes issue with multiple aspects of the Notice including, but not limited to, Vellar's right to terminate their portion of the Backstop Agreement and their asserted Maturity Consideration calculation. As such, the Company is consulting with advisors and other parties and is considering the potential resources and remedies it may elect to pursue and intends to assert its rights should this matter not be resolved. After a review of all applicable documents related to the Backstop Agreement, the Company believes its position with respect to the terms of the Backstop Agreement and intent of the parties is supported by the Backstop Agreement and facts and circumstances under which it was entered into. Further, given the early stage of this matter and the uncertainty inherent in litigation and investigations, the Company does not currently believe it is (i) probable to incur losses or (ii) possible to develop estimates of reasonably possible losses (or a range of possible losses) for this matter.

On October 2, 2023, the Company entered into a Side Letter Agreement (the "Side Letter") with Polar. The Side Letter amended certain terms of the Polar Agreement, as discussed in Note 3, Business Combination and Backstop Agreement. The Side Letter amended the definitions of "Seller VWAP Trigger Event" and "Reset Price" as used in the Backstop Agreement as it relates to Polar and the Polar Agreement. Per the amended definitions, the (i) "Seller VWAP Trigger Event" is an event that occurs if the VWAP price is below $2.50 per share for any 20 trading days during a 30 consecutive trading day-period thereafter and (ii) the "Reset Price" is defined as $8.00. The Side Letter did not amend any terms of the Backstop Agreement as it relates to the other Backstop Parties.

The "Seller VWAP Trigger Event" for Polar occurred in October 2023 and the other Backstop Parties in November 2023. The Company received written notice from Polar on November 6, 2023 acknowledging its right to designate any date as the Maturity Date from the date of the notice to, and including, the third anniversary of the Business Combination. As of the date of this filing, one of the Backstop Parties, Polar has not designated a Maturity Date. Refer to Note 3, *Business Combination and Backstop Agreement*, for further detail around the purported Maturity Date for Vellar.

Sponsor Promissory Notes

On December 13, 2022, AHAC entered into a Loan and Transfer Agreement between AHAC, the Sponsor, and NPIC Limited (the "NPIC Lender"), pursuant to which the Lender loaned $1.1 million to the Sponsor and the Sponsor loaned $1.1 million to AHAC (the "NPIC Sponsor Extension Loan"). Amounts loaned from the NPIC Lender to the Sponsor accrue interest at 8% per annum and amounts loaned from the Sponsor to AHAC do not accrue interest until the Closing of the Business Combination, after which time, we have agreed to pay the interest due to the NPIC Lender. The total amounts advanced by NPIC Lender to the Sponsor in connection with the $1.1 million loan (the "NPIC Funded Amounts") were required to be repaid, together with all accrued and unpaid interest thereon, within five days of the closing of the initial Business Combination, at the option of the NPIC Lender, in either (a) cash; or (b) shares of Class A common stock held by the Sponsor which are deemed to have a value of $10 per share for such repayment right. As additional consideration for the NPIC Lender making the loan available to Sponsor, Sponsor agreed to transfer 10 Shares of Class B common stock to NPIC Lender for each $10 multiple of the NPIC Funded Amounts, which included the registration rights previously provided by AHAC to the Sponsor, and, pursuant to the terms of the Business Combination Agreement, the parties agreed that we would issue 1.05 shares of our common stock per $1.00 of the NPIC Funded Amounts at Closing of the Business Combination Agreement to Sponsor, as described below. Sponsor transferred a total of 1,050,000 shares to the NPIC Lender post-Closing of the Business Combination Agreement.

On March 22, 2023 we entered into a Loan Modification Agreement, dated March 22, 2023 (the "Modification Agreement"), with the Sponsor and NPIC Lender, and a Side Letter Agreement with the Sponsor (the "Side Letter"), which modifies the NPIC Sponsor Extension Loan.

The Modification Agreement modified the NPIC Sponsor Extension Loan to provide that, among other things, (i) the maturity date of the loan from NPIC to Sponsor (the "NPIC Sponsor Loan") is extended to May 22, 2023 (the "Maturity Date"); (ii) the extension will take effect concurrently with, and not until, the Sponsor transfers 1,050,000 shares of the Company's common stock (the "Initial SPAC Shares") to the NPIC Lender; (iii) effective as of the date of the Modification Agreement, the NPIC Sponsor Loan shall accrue fifteen percent (15%) interest per annum, compounded monthly; (iv) the maturity date of the $1.1 million loan by Sponsor to us (the "SPAC Loan") is extended to May 19, 2023; (v) the proceeds of any capital raise of at least $15.0 million by the Company shall be first used by the Company to promptly repay the SPAC Loan and then Sponsor shall promptly repay the NPIC Sponsor Loan and all accrued interest; (vi) in exchange for the extension of the Maturity Date, we shall issue 50,000 shares of common stock to Lender on the date of the Modification Agreement and shall issue an additional 50,000 shares of common stock thereafter on each 30-day anniversary of the Maturity Date to the Lender until the Sponsor Loan is repaid in full; (vii) in the event Sponsor defaults on its obligations to repay the NPIC Sponsor Loan by the Maturity Date, the Sponsor shall transfer to the NPIC Lender 250,000 shares of our common stock owned by the Sponsor and shall transfer an additional 250,000 such shares each month thereafter until the default is cured; (viii) we are obligated to file a registration statement with the SEC registering the shares to be issued to Lender within 30 days of the transfer, including the Initial SPAC shares; and (ix) in the event that we default on its obligations to the Lender set forth in (v), (vi) and (viii), we shall issue to NPIC Lender 250,000 shares of common stock and shall transfer an additional 250,000 shares of common stock each month thereafter until the default is cured. The Side Letter provides that, in the event we fail to repay the SPAC Loan by May 19, 2023, we shall issue to Sponsor 250,000 shares of common stock and shall issue an additional 250,000 such shares to Sponsor each month thereafter until the default is cured.

The Sponsor Extension Loan was paid down at Closing of the Business Combination to $0.5 million. The outstanding balance of the Sponsor Extension Loan was paid in full from the proceeds of the initial draw under the Ayrton Convertible Note Financing.

During the fiscal year ended December 31, 2023, NPIC Lender was issued 200,000 shares of our common stock as consideration of the Modification Agreement. The fair value was our closing stock price on the date granted. We recognized a loss of $1.2 million as loss on extinguishment of debt. In addition, we recorded interest expense in the amount of $50 thousand on the outstanding balance in our consolidated financial statements for the fiscal year ended December 31, 2023.

Deferred Underwriting Commissions

At Closing, the underwriters for AHAC's initial public offering ("IPO") agreed to defer payment of $3.2 million of deferred underwriting discounts otherwise due to them until November 14, 2023, pursuant to the terms of a promissory note (the "Underwriter Promissory Note"). The deferred amounts bear interest at 9% per annum and 24% per annum following an event of default under the promissory note. The Company has a right to pay up to fifty percent (50%) of the principal and interest due on this promissory note using the common stock of the Company at a price per share of $10.56. The remaining fifty percent (50%) of the principal and interest due on this promissory note must be paid in cash. As of December 31, 2023 the Company had not repaid the Underwriter Promissory Note and the outstanding balance of $3.2 million is recorded as a short-term loan in the consolidated financial statements. The Company recorded $0.3 million of interest expense on the outstanding balance in the Company's consolidated financial statements for the fiscal year ended December 31, 2023.

Common Stock Purchase Agreement

On September 7, 2022, AHAC entered into the Common Stock Purchase Agreement (the "Common Stock Purchase Agreement") and the White Lion Registration Rights Agreement ("White Lion RRA") with White Lion. Pursuant to the Common Stock Purchase Agreement, we have the right, but not the obligation to require White Lion to purchase, from time to time, up to $75.0 million in aggregate gross purchase price of Equity Line Shares, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement.

We are obligated under the Common Stock Purchase Agreement and the White Lion RRA to file a registration statement with the SEC to register under the Securities Act the common stock subject to the Common Stock Purchase Agreement, for the resale by White Lion of shares of the Company's common stock that the Company may issue to White Lion under the Common Stock Purchase Agreement.

Subject to the satisfaction of certain customary conditions, our right to sell the Equity Line Shares to White Lion will commence on the effective date of the registration statement and extend for a period of two years. During such term, subject to the terms and conditions of the Common Stock Purchase Agreement, we may notify White Lion when it exercises its right to sell Equity Line Shares (the effective date of such notice, a "Notice Date"). The number of Equity Line Shares sold pursuant to any such notice may not exceed (i) $2.0 million, divided by the closing price of the Company's common stock on Nasdaq preceding the Notice Date and (ii) a number of shares of common stock equal to the average daily trading volume multiplied by 67%.

At any given time of any sale by us to White Lion, we may not sell, and White Lion may not purchase, Equity Line Shares of the Company's common stock that would result in White Lion owning more than the 9.99% Beneficial Ownership Cap upon such issuance.

The purchase price to be paid by White Lion for any such shares will equal 93% of the lowest daily volume-weighted average price of the Company's common stock during a period of two consecutive trading days following the applicable Notice Date. However, if during such two-trading day period the trading price of the Company's common stock falls below a price (the "Threshold Price") equal to 90% of the opening trading price of the common stock on Nasdaq on the Notice Date, then the number of shares to be purchased by White Lion pursuant to such notice will be reduced proportionately based on the portion of the two-trading day period that has elapsed, and the purchase price will equal 95% of the Threshold Price.

In consideration for the commitments of White Lion to purchase the Equity Line Shares under the Common Stock Purchase Agreement, the Common Stock Purchase Agreement required us to issue to White Lion shares of Common Stock having a value of $0.8 million based upon the closing sale price two trading days prior to the filing of an initial registration statement. Effective as of April 18, 2023, the Company and White Lion entered into a Consent Agreement pursuant to which the Company agreed to issue to White Lion, and White Lion agreed to accept from the Company, 75,000 Initial Commitment Shares in lieu of the shares to be issued to White Lion based on the closing sale price. The 75,000 Initial Commitment Shares had a fair value of $0.5 million upon issuance. The $0.5 million in commitment costs was recorded in other income/(expense) in the Company's consolidated statements of operations for the fiscal year ended December 31, 2023.

Effective October 4, 2023, the Company and White Lion entered into the first amendment of the Common Stock Purchase Agreement (the "Amendment"). On November 2, 2023, White Lion purchased 41,677 shares of the Company's common stock under the Common Stock Purchase Agreement for which the Company received approximately $64 thousand. This facility is now deemed terminated.

License Agreements

Elkurt/Brown License Agreements

On July 31, 2020, we entered into four separate Exclusive License Agreements (the "Initial Brown License Agreements") with Elkurt, Inc.("Elkurt"), a licensee of Brown University. On March 21, 2021, we and Elkurt amended each of the Initial Brown License Agreements. Elkurt is a company formed by our scientific co-founders and members of our Board, Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., PhD, Chair of the Department of Pathology and Laboratory Medicine at Brown University. Under the Initial Brown License Agreements, Elkurt grants us exclusive, royalty-bearing licenses to patent rights and nonexclusive, royalty-bearing licenses to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in certain fields. On August 31, 2021, the Initial Brown License Agreements were amended to extend the date after which Elkurt can terminate the license agreements if we have not raised at least $10 million in equity financing by April 1, 2022. On March 25, 2022, the Initial Brown License Agreements were amended to extend those termination dates to May 1, 2022. On July 1, 2022, we amended the Initial Brown License Agreements to extend the termination dates to November 1, 2022 and acknowledge the accounts payable due and terms of payment.

On July 2, 2022, we amended the Initial Brown License Agreements to extend the termination dates of the commercialization plan of the license agreements to an additional two years. On August 25, 2022, we amended the four Initial Brown License Agreements to extend the termination dates to November 1, 2023 and to extend the termination dates of the commercialization plan of the license agreements from an additional two years to three years. For each of the Initial Brown License Agreements, as amended, we are required to pay Elkurt a maintenance fee of $67,000 increased by interest at the rate of 1% per month from October 15, 2021 until paid. In addition, beginning on January 1, 2022 and each year thereafter until January 1, 2027, we are required to pay an annual license maintenance fee of $3,000. Beginning on January 1, 2028, and every year thereafter the annual license maintenance fee shall become $4,000 per year. Upon successful commercialization, we are required to pay Elkurt between 0.5% to 1.5% of net sales based on the terms under the Initial Brown License Agreements. In addition, we must pay Elkurt, under each of the Initial Brown License Agreements, 25% of all non-royalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that we enter into sublicenses for the subject intellectual property. If net sales or non-royalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or non-royalty sublicense income) shall be reduced by 50%. For the fiscal years ended December 31, 2023 and 2022, the Company recorded annual license maintenance fees of $12 thousand in each year. For the fiscal year ended December 31, 2023, the Company recorded license fees of $0.3 million. On June 13, 2024, we amended the Initial Brown License Agreements such that $0.2 million of past due license fees were paid on July 17, 2024, and $0.2 million of past due license fees and $0.1 million in past due patent expenses were to be paid by October 1, 2024, which remain unpaid and are subject to negotiation between the parties.

We will also pay Elkurt developmental and commercialization milestone payments for each of the Initial Brown License Agreements ranging from $50,000 for the filing of an IND, or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. We are also responsible for reimbursement of patent costs. We recorded reimbursement of patent costs as general and administrative costs in the statements of operations as incurred. For the fiscal years ended December 31, 2023 and 2022, the Company incurred reimbursed patent costs expenses to Brown University in the amount of $0.1 million and $0.2 million, respectively. As of December 31, 2023, the Company reflected a balance due of $0.1 million in accrued expenses – related parties on its consolidated balance sheet.

The contract term for each of the Initial Brown License Agreements, as amended, continues until the later of the date on which the last valid claim expires or ten years.

On September 13, 2022, we entered into an additional Exclusive License Agreement (the “Brown Anti-PfGARP Small Molecules License Agreement”), with Elkurt. Under the Brown Anti-PfGARP Small Molecules License Agreement, Elkurt grants us an exclusive, royalty-bearing license to patent rights and a nonexclusive, royalty-bearing license to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in the field of malaria research.

For the Brown Anti-PfGARP Small Molecules License Agreement, we are required to pay Elkurt an initial license fee of $70,000, payable in two installments of $35,000 each on April 1, 2023 and June 30, 2023. Beginning September 13, 2023, we are obligated to pay Elkurt an annual license maintenance fee equal to (a) $3,000 until September 13, 2027, and (b) thereafter, an annual license maintenance fee of $4,000. Upon successful commercialization, we are required to pay Elkurt 1.25% of net sales based on the terms under the Brown Anti- PfGARP Small Molecules License Agreement. In addition, we must pay Elkurt 25% of all non-royalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that we enter into sublicenses for the subject intellectual property. If net sales or non-royalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or non-royalty sublicense income) shall be reduced by 50%. We also are required to pay Elkurt $0.1 million in the event that we or one of sublicensees sublicenses this technology to a major pharmaceutical company or if the license agreement or any sublicense agreement for this technology is acquired by a major pharmaceutical company. A major pharmaceutical company is one that is publicly traded, with market capitalization of at least $5 billion and has been engaged in drug discovery, development, production and marketing for no less than 5 years.

We will also pay Elkurt developmental and commercialization milestone payments pursuant to the Brown Anti-PfGARP Small Molecules License Agreement ranging from $50,000 for the filing of an IND, or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. We are also responsible for reimbursement of patent costs.

The contract term for the Brown Anti-PfGARP Small Molecules License Agreement continues until the later of the date on which the last valid claim expires or ten years. Either party may terminate the Brown Anti-PfGARP Small Molecules License Agreement in certain situations, including Elkurt being able to terminate the Brown Anti-PfGARP Small Molecules License Agreement at any time and for any reason after November 1, 2023 if we have not raised at least $10 million in equity financing by then.

Elkurt/Rhode Island Agreement

On January 25, 2021, we entered into an Exclusive License Agreement (the "Rhode Island License Agreement") with Elkurt, a licensee of Rhode Island Hospital. On April 1, 2021, September 10, 2021, March 25, 2022, July 1, 2022 and August 26, 2022, we and Elkurt amended the Rhode Island License Agreement. Under the Rhode Island License Agreement, as amended, Elkurt grants us an exclusive, royalty-bearing license to patent rights and a nonexclusive, royalty-bearing license to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in a certain field.

For the Rhode Island License Agreement, we are required to pay Elkurt $0.1 million, due within 45 days of an equity financing of at least $10 million or May 1, 2022, whichever comes first, and beginning on January 1, 2022, an additional $3,000 annual maintenance fee thereafter, until January 1, 2028, at which point the annual maintenance fee will become $4,000 per year. We are also required to pay Elkurt 1.5% of net sales under the Rhode Island License Agreement. In addition, we must pay Elkurt 25% of all non-royalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that we enter into sublicenses for the subject intellectual property. If net sales or non-royalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or non-royalty sublicense income) shall be reduced by 50%. We will also pay Elkurt developmental and commercialization milestone payments under the Rhode Island License Agreement, ranging from $50,000 for the filing of an IND, or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. For the fiscal years ended December 31, 2023 and 2022, the Company has incurred reimbursed patent costs expenses to Rhode Island Hospital in the amount of $0.1 million and $0.3 million, respectively. As of December 31, 2023, the Company reflected a balance due of $0.2 million in accrued expenses – related parties on its consolidated balance sheet. With respect to a July 19, 2024 amendment, we paid Rhode Island Hospital $0.1 million.

The contract term for the Rhode Island License Agreement began February 1, 2020 and will continue until the later of the date on which the last valid claim expires or fifteen years. Either party may terminate the Rhode Island License Agreement in certain situations, including Elkurt being able to terminate the license agreement at any time and for any reason by May 1, 2022, if we have not raised at least $10 million in equity financing by then. Currently, the Rhode Island License Agreement is still in effect and the license agreement has been sublicensed to our subsidiary, Ocean Sihoma, Inc. On July 1, 2022, we amended the Elkurt/Rhode Island License Agreement to extend the termination date to November 1, 2022, to extend the termination dates of the commercialization plan of the Rhode Island License Agreement to an additional one year, and acknowledge the accounts payable due and terms of payment. On August 26, 2022, we amended the Rhode Island License Agreement to extend the termination date to November 1, 2023 and to extend the termination dates of the commercialization plan of the Rhode Island License Agreement from an additional one year to three years.

Ayrton Convertible Note Financing

On May 15, 2023, we entered into a Securities Purchase Agreement (the "SPA") with an accredited investor (the "Investor") for the sale of up to three Senior Secured Convertible Notes (each, a "Note" and collectively, the "Notes"), which Notes are convertible into shares of our Common Stock, in an aggregate principal amount of up to $27 million, in a private placement (the "Offering" or the "Ayrton Convertible Note Financing"). These are the same Notes as described in footnote 7 to the audited financial statements included herewith. We consummated the closing for the sale of (i) the initial Note in the principal amount of $7.56 million and (ii) a warrant to initially acquire up to 552,141 additional shares of our Common Stock with an initial exercise price of $11.50 per share of Common Stock, subject to adjustment, exercisable immediately and expiring five years from the date of issuance (the "Ayrton Warrant"), which is subject to customary closing conditions, on May 25, 2023. The Notes will be sold at an original issue discount of eight percent (8%). Future issuances of Notes ("Additional Closings") are subject to satisfaction of certain conditions. The SPA contains certain representations and warranties, covenants and indemnities customary for similar transactions. At the closing of the first Additional Closing, $8.64 million of Notes will be issued (the "First Additional Closing Date") and $10.8 million of Notes will be issued at the closing of the second Additional Closing. So long as any Notes remain outstanding, we are prohibited from effecting or entering into an agreement to effect any subsequent placement involving a Variable Rate Transaction, other than pursuant to the White Lion Common Stock Purchase Agreement. "Variable Rate Transaction" means a transaction in which we (i) issue or sell any convertible securities either (A) at a price that is based upon with the trading prices of our Common Stock, or (B) with a price that is subject to being reset at some future date or upon the occurrence of specified events related to the business of the Company or the market for our Common Stock, other than pursuant to a customary "weighted average" anti-dilution provision or (ii) enters into any agreement whereby we may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights).

We are required to obtain stockholder approval authorizing the issuance of our common stock under the Notes and the Ayrton Warrant in compliance with the rules and regulations of the Nasdaq Capital Market ("Nasdaq") (without regard to any limitations on conversion or exercise set forth in the Notes or the Ayrton Warrant, respectively), including, shares of our Common Stock to be issued in connection with any Additional Closing. Unless we obtain the approval of our stockholders as required by Nasdaq, we will be prohibited from issuing any shares of Common Stock upon conversion of the Notes or otherwise pursuant to the terms of the Notes or the Ayrton Warrant, if the issuance of such shares of Common Stock would exceed 19.99% of our outstanding shares of Common Stock as of the date of the SPA or otherwise exceed the aggregate number of shares of Common Stock which we may issue without breaching our obligations under the rules and regulations of Nasdaq.

The interest rate applicable to each Note is, as of any date of determination, the lesser of (I) eight percent (8%) per annum and (II) the greater of (x) five percent (5%) per annum and (y) the sum of (A) the "secured overnight financing rate," which from time to time is published in the "Money Rates" column of The Wall Street Journal (Eastern Edition, New York Metro), in effect as of such date of determination and (B) two percent (2%) per annum; provided, further, that each of the forgoing rates shall be subject to adjustment from time to time in accordance with the SPA. Each Note will mature on the first anniversary of its issuance (the "Maturity Date"). Additionally, each Note is required to be senior to all of our other indebtedness, other than certain permitted indebtedness. The Notes will be secured by all of our existing and future assets (including those of our significant subsidiaries). Upon the occurrence of certain events, the Notes will be payable in monthly installments. A noteholder may, at its election, defer the payment of all or any portion of the installment amount due on any installment date to another installment payment date.

All or any portion of the principal amount of each Note, plus accrued and unpaid interest, any late charges thereon and any other unpaid amounts (the "Conversion Amount"), is convertible at any time, in whole or in part, at the noteholder's option, into shares of our common stock at an initial fixed conversion price of $10.34 per share, subject to certain adjustments. At any time during certain events of default under the Note, a noteholder may alternatively (the "Alternate Conversion") elect to convert all or any portion of the Conversion Amount into shares of our Common Stock at an Alternate Conversion Price set forth in the SPA. A noteholder will not have the right to convert any portion of a Note, to the extent that, after giving effect to such conversion, the noteholder (together with certain of its affiliates and other related parties) would beneficially own in excess of 9.99% of the shares of our Common Stock outstanding immediately after giving effect to such conversion.

Upon a change of control of the Company (the "Change of Control"), noteholders may require us to redeem all, or any portion, of the Notes at a price equal to the greater of: (i) the product of (w) 115% multiplied by (y) the Conversion Amount being redeemed, (ii) the product of (x) 115% multiplied by (y) the product of (A) the Conversion Amount being redeemed multiplied by (B) the quotient determined by dividing (I) the greatest closing sale price of the shares of our Common Stock during the period beginning on the date immediately preceding the earlier to occur of (1) the consummation of the applicable Change of Control and (2) the public announcement of such Change of Control and ending on the date the holder delivers the Change of Control redemption notice by (II) the Alternate Conversion Price then in effect and (iii) the product of (y) 115% multiplied by (z) the product of (A) the Conversion Amount being redeemed multiplied by (B) the quotient of (I) the aggregate cash consideration and the aggregate cash value of any non-cash consideration per share of our Common Stock to be paid to our stockholders upon consummation of such Change of Control divided by (II) the Conversion Price then in effect.

The Notes provide for certain events of default, including, among other things, any breach of the covenants described below and any failure of Dr. Chirinjeev Kathuria to be the chairman of our Board of Directors. In connection with an event of default, the noteholders may require us to redeem all or any portion of the Notes, at a price equal to the greater of (i) the product of (A) the Conversion Amount to be redeemed multiplied by (B) 115% and (ii) the product of (X) the Conversion Rate (using the Alternate Conversion Price then in effect) with respect to the Conversion Amount in effect at such time as the holder delivers an event of default redemption notice multiplied by (Y) the product of (1) 115% multiplied by (2) the greatest closing sale price of our Common Stock on any trading day during the period commencing on the date immediately preceding such event of default and ending on the date we make the entire payment required to be made.

We are subject to certain customary affirmative and negative covenants regarding the rank of the Notes, the incurrence of indebtedness, the existence of liens, the repayment of indebtedness and the making of investments, the payment of cash in respect of dividends, distributions or redemptions, the transfer of assets, the maturity of other indebtedness, and transactions with affiliates, among other customary matters. We also will be subject to financial covenants requiring that (i) the amount of our available cash equal or exceed $3.0 million at the time of each Additional Closing; (ii) the ratio of (a) the outstanding principal amount of the Notes, accrued and unpaid interest thereon and accrued and unpaid late charges to (b) our average market capitalization over the prior ten trading days, not exceed 35%; and (iii) at any time any Notes remain outstanding, with respect to any given calendar month (each, a "Current Calendar Month") (x) the available cash on the last calendar day in such Current Calendar Month shall be greater than or equal to the available cash on the last calendar day of the month prior to such Current Calendar Month less $1.5 million.

On May 25, 2023, we entered into Amendment No. 1 to Securities Purchase Agreement (the "SPA Amendment"). The SPA Amendment changed two provisions in the SPA and amended and restated the Disclosure Schedules attached to the SPA.

The SPA Amendment added the definition of "all the Registrable Securities" to Section 1(b)(ii)(3) of the SPA. "All the Registrable Securities" means "100% of the sum of (i) the maximum number of Conversion Shares issuable upon conversion of the Notes (assuming for purposes hereof that the Notes are convertible at the Floor Price (as defined in the Notes) as of such time of determination, (y) interest on the Notes shall accrue through the first anniversary of the Initial Closing Date and will be converted in shares of Common Stock at a conversion price equal to the Floor Price as of such time of determination and (z) any such conversion shall not take into account any limitations on the conversion of the Notes set forth in the Notes), and (ii) the maximum number of Warrant Shares initially issuable upon exercise of the Warrants (assuming the issuance of each of the Additional Notes issuable hereunder and without taking into account any limitations on the exercise of the Warrants set forth therein)."

The SPA Amendment also amended and restated Section 7(b)(xxii) of the SPA as follows: "No Equity Conditions Failure (as defined in the Initial Notes) then exists (assuming for such purposes, as applicable, that such applicable Additional Closing shall have occurred immediately prior to such time of determination)."

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

To date, research and development expenses consist primarily of costs incurred for our research activities, including the development of our product candidates. We expense research and development costs as incurred, which we expect will include:

- expenses incurred under our licenses and services agreements; and
- employee related expenses, including salaries and benefits for personnel engaged in research and development functions.

Research and development expenses for the fiscal years ended December 31, 2023 and 2022, included:

- stock-based compensation expense related to the grant by Poseidon, our controlling shareholder, of profit interests in Poseidon to our executives and employees in 2022, and
- expenses incurred for outside services with our CMO relating to the development of certain of our preclinical assets.

We recognize external development costs based on an evaluation of the progress to completion of specific milestones using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our direct external research and development expenses consist (or are expected to consist) primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under license agreements. We have not allocated and do not expect to allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are or will be deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are key to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years, which will include:

- expenses incurred under our licenses and services agreements to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with CROs, that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and CMOs, that are primarily engaged to provide preclinical and clinical product for our research and development candidates;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- employee-related expenses, including salaries and benefits, and stock-based compensation expense for employees engaged in research and development functions; and
- costs related to compliance with regulatory requirements.

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

- scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- ability to successfully in-license attractive product candidates from our partners;
- establishing an appropriate safety and efficacy profile with Investigational New Drug, or IND, enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of approvals from applicable regulatory authorities including the FDA and other non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to produce product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety protocol of our product candidates following any approval; and
- significant and potential changing government regulations.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates, such as if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct other clinical trials or testing beyond those that we currently expect or if significant delays in enrollment in any of our planned clinical trials occurred. Such delays or changes may require us to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, travel and stock-based compensation expense for personnel in executive, business development, finance, legal, human resources, information technology, pre-commercial and support personnel functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for accounting and audit services, legal, patent, consulting, investor and public relations.

General and administrative expenses for the fiscal years ended December 31, 2023 and 2022 included stock-based compensation expense related to the grant by Poseidon, our controlling shareholder, of profits interests in Poseidon to our executives and employees in 2022, the grant of a warrant to purchase common stock to a consultant in 2023, and stock option grants to all of our non-employee directors as of February 15, 2023, accounting, legal and public relations fees, and deferred offering costs from the Business Combination.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates and prepare for potential commercialization activities. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, tax, compliance with Nasdaq and SEC requirements, and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. If and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations as it relates to the sales and marketing of that product candidate.

Income Taxes

Income taxes are recorded in accordance with FASB ASC 740, Income Taxes, or FASB ASC 740, which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss, or NOL, carryforwards and research and development tax credit carryforwards. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have recorded a full valuation allowance to reduce our net deferred income tax assets to zero. In the event we were to determine that we would be able to realize some or all of our deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made. As a consequence, we have recorded no income tax expense nor benefit for all years presented.

Comparison of the fiscal years ended December 31, 2023 and 2022

	For the Fiscal Year Ended December 31,		
(in thousands)	2023	2022	$ Change
Revenue	$ —	$ —	$ —
Operating Expenses:			
Research and development	709	8,409	(7,700)
General and administrative	9,505	7,712	1,793
Total operating expenses	10,214	16,121	(5,907)
Operating loss	(10,214)	(16,121)	5,907
Other income/(loss)	(104,252)	(1,238)	(103,014)
Net loss	$ (114,466)	$ (17,359)	$ (97,107)

Operating Expenses

Research and development

Research and development expenses for the fiscal year ended December 31, 2023 decreased by approximately $7.7 million compared to the fiscal year ended December 31, 2022 driven by (i) a decrease of stock-based compensation expense of approximately $8.2 million related to the grant by Poseidon, our controlling shareholder, of profits interests in Poseidon to our executives and employees in 2021, 60% of the profits interests granted were immediately vested and the remaining 40% of the profits interests were amortized over 18 months that were 100% amortized as of August 31, 2022 and (ii) an increase in costs of approximately $0.5 million for license fees and non-employee compensation.

General and administrative

General and administrative expenses for the fiscal year ended December 31, 2023 increased by approximately $1.8 million, compared to the fiscal year ended December 31, 2022, primarily driven by (i) an increase in accounting fees of approximately $1.3 million; (ii) an increase in legal fees of approximately $1.6 million; (iii) an increase in insurance expense of approximately $0.7 million; (iv) an increase in compensation expense of approximately $1.0 million; and (v) an increase in outside services of approximately $0.6 million, partially offset by a decrease of stock-based compensation expense of approximately $2.9 million and other expenses of approximately $0.4 million.

Other Income/(Loss)

Other income/(Loss) for the fiscal year ended December 31, 2023 increased by approximately $103.0 million compared to the fiscal year ended December 31, 2022 primarily driven by the costs incurred with respect to the Business Combination and the debt financing, including: (i) the loss on the Backstop Forward Purchase Agreement asset of approximately $62.6 million; (ii) stock issuance loss of approximately $12.7 million relating to the fair value of the 1,200,000 Share Consideration Shares issued to the Backstop Parties in February 2023; (iii) loss on the extinguishment of the debt of approximately $15.1 million resulting from the fair value of the 1,365,000 Sponsor Extension Shares issued to the Sponsor under the terms of the Sponsor Extension Loan and NPIC Extension Loan; (iv) expense for deferred transaction costs of approximately $7.6 million recognized in the period; (v) fair value of non-cash stock issuances of approximately $0.7 million; (vii) fair value of warrants issued of approximately $2.3 million and (vii) interest expense of approximately $1.6 million.

Other income/(expense) consisted of the following (in thousands):

	Fiscal Years Ended December 31,	
	2023	2022
Other income/(loss)		
Change in fair value of 2023 Convertible Note, SPA Warrant and the Ayrton Note Purchase Option	1,171	-
Loss in connection with the Share Consideration shares	(12,676)	-
Loss in connection with Backstop Put Option Liability and Fixed Maturity Consideration	(62,646)	-
Fair value of warrant issuances	(2,301)	-
Fair value of non-cash stock issuances	(740)	-
Transaction costs	(8,732)	-
Loss on extinguishment of debt	(15,080)	-
Interest expense, including warrant issuances and amortization of debt issuance costs	(1,762)	(1,244)
Net loss attributable to equity interest in Virion	(708)	-
Change in fair value of Virion Contribution Liability	(777)	-
Other	(1)	6
Total Other income/(loss)	(104,252)	(1,238)

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations from the proceeds from the issuance of common stock and debt, proceeds from the Backstop Agreement and through self-funding by our founder and have limited current cash on hand to fund our operations. Based on our current operational plans and assumptions, we expect that the net proceeds from the Ayrton Convertible Note Financing and future debt and equity financings which total net proceeds we estimate need to be at least $45.0 million, as well as further deferrals of certain of our accrued expenses and contingency payments due upon the closing of future financings, are required to fund operations through the fourth quarter of 2025. The Company borrowed an additional $1.7 million in March 2023, the proceeds of which were used to pay certain accrued expenses. We consummated the closing for the sale of (i) the initial Note in the principal amount of $7.6 million and (ii) a warrant to initially acquire up to 552,141 additional shares of our Common Stock with an initial exercise price of $11.50 per share of Common Stock, subject to adjustment, exercisable immediately and expiring five years from the date of issuance (the "Ayrton Warrant"), which is subject to customary closing conditions, on May 25, 2023.We have up to an additional $7.7 million under the amended Ayrton financing from July 2024. We intend to obtain further equity financing as soon as our financials are fully current. The Company is currently out of compliance with Nasdaq standards due to its failure to file this report and the 10-Q reports for the first and second quarters of 2024.

Each Public Warrant and each Private Placement Warrant entitle the holder thereof to purchase one share of our Common Stock at a price of $11.50 per share. The Second Street Warrants are exercisable for 511,712 shares of Common Stock at an exercise price of $8.06 per share, 102,342 shares of our common stock at an exercise price of $7.47 per share, 275,000 shares of our common stock at an exercise price of $10.34 per share, and 150,000 shares of our common stock at an exercise price of $11.50 per share. The McKra Warrant (as defined below) is exercisable for 200,000 shares of our common stock at an exercise price of $10.34 per share. The Special Forces Warrant (as defined below) is exercisable for 150,000 shares of our common stock at an exercise price of $11.50 per share. The warrant issued to the Investor pursuant to the Ayrton Convertible Note Financing is initially exercise able for 552,141 shares of our common stock at an initial exercise price of $11.50 per share, subject to adjustment. On June 15, 2023, the closing price for our common stock was $5.17. If the price of our common stock remains below the exercise price of the Warrants, warrant holders will be unlikely to exercise their Warrants for cash, resulting in little or no cash proceeds to us from such exercises. We expect to use any proceeds from the exercise of the Warrants for general corporate and working capital purposes, which would increase our liquidity. As described above, in order to fund planned operations while meeting obligations as they come due, we will need to secure additional debt or equity financing if substantial cash proceeds from the exercise of the Warrants are not received. Furthermore, to the extent that warrants are exercised on a "cashless basis," the amount of cash we would receive from the exercise of the warrants will decrease.

Going Concern Considerations

The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

We had no cash inflows from operating activities for the fiscal year ended December 31, 2023. As of December 31, 2023 we had minimal cash and a working capital deficiency of $27.9 million. Our current operating plan indicates we will incur losses from operations and generate negative cash flows from operating activities, given anticipated expenditures related to research and development activities and we lack revenue generating ability at this point in our lifecycle. These events and conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued.

We will need to raise additional funds in order to advance our research and development programs, operate our business, and meet our future obligations as they come due, as described above under "Liquidity and Capital Resources." We will seek additional funding through private equity financings, debt financings, collaborations, strategic alliances, or marketing, distribution, or licensing arrangements. There is no assurance that we will be successful in obtaining additional financing on terms acceptable to us, if at all, and we may not be able to enter into collaborations or other arrangements. If we are unable to obtain funding, we could be forced to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects and our ability to continue operations.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we will incur additional ongoing costs associated with operating as a public company, including significant legal, accounting, compliance, investor relations and other expenses that we did not incur as a private company. We intend to raise additional capital through one or more means, including public offerings pursuant to Form S-1, among others. The timing and amount of our operating expenditures will depend on our ability to:

- advance preclinical development of our early-stage programs;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- obtain regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize our product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our research and clinical development, manufacturing and commercialization efforts and our operations as a public company; and obtain, maintain, expand and protect our intellectual property portfolio.

We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Because of the numerous risks and uncertainties associated with research, development and commercialization of biologic product candidates, we are unable to estimate the exact amount of our working capital.

Contingent Compensation and Other Contingent Payments

Under the management employment agreements, we have salaries and bonuses that are contingently payable upon financing, collectively called contingent compensation, that are contingently payable based only upon our first cumulative capital raise of at least $50 million. As of December 31, 2023, we have contingent compensation and bonuses in the amount of $12.4 million to certain members of senior management.

We also have $1.0 million of contingent vendor payments, which are also contingently payable based only upon our first cumulative capital raise of at least $50 million.

These amounts will not be paid if the contingencies do not occur. Since the payment of obligations under these agreements are contingent upon these future events, which are not considered probable as such future events are deemed outside of our control, we have not included these amounts in our consolidated financial statements. During the fiscal year ended December 31, 2023, $0.9 million of contingent compensation was paid and recorded in general and administrative expenses on the Company's consolidated statement of operations.

Other Contractual Obligations

We have entered and anticipate we will continue to enter into contracts in the normal course of business with external organizations such as CMOs, CROs and other third parties for the manufacture of our product candidates and to support clinical trials and preclinical research studies and testing. We expect that these contracts will be generally cancelable by us, and we anticipate that payments due upon cancellation will consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. We accrued CMO services in the amount of $0.6 and $0.5 million for the fiscal years ended December 31, 2023 and 2022, respectively, under the Development and Manufacturing Services Agreement with Lonza in developing the product OCX-253.

Short-Term Loans

As of December 31, 2023, we had the following outstanding short-term loans (in thousands):

Loan	Principal Amount Outstanding	Annual Interest Rate	Outside Maturity Date
March Second Street Loan	$ 700	15%	(4)
McKra Loan	$ 1,000	15%	(5)
Second Street Loan	$ 600	15%	(4)
Second Street Loan 2	$ 400	15%	(4)
Underwriter Promissory Note	$ 3,150	9%	
2023 Convertible Note	$ 5,618	7.4%	
Poseidon Demand Note	$ 650	5%	
Total Short-term loans	$ 12,118		

(4) Pursuant to the Second Street Loans Amendment, (i) the Company shall pay to Second Street Capital an amount of $0.3 million upon the execution of the Second Street Loans Amendment (ii) within five (5) business days of the Company's receipt of funds in connection with the first Additional Closing (as defined in the SPA) under the SPA, the Company shall pay Second Street Capital an amount of $0.5 million; (iii) the Company shall repay advances made under the loan agreements plus any accrued unpaid interest to Second Street Capital in the event of a capital raise of the Company of a minimum amount of $25.0 million; (iv) in exchange for the Second Street Loans Amendment, the Company shall issue 25,000 shares of Common Stock of the Company (the "Second Street Extension Shares") to Second Street Capital within five (5) business days of the execution of the Second Street Loans Amendment; and (v) the Company shall file a registration statement for the issuance of the Second Street Extension Shares no later than thirty (30) days following such issuance of Second Street Extension Shares.

(5) Pursuant to the McKra Loan Amendment, (i) the Company shall pay to McKra an amount of $0.2 million upon the execution of the McKra Loan Amendment; (ii) within five (5) business days of the Company's receipt of funds in connection with the first Additional Closing (as defined in the SPA) under the SPA, the Company shall pay McKra an amount of $0.5 million; (iii) within five (5) business days of the Company's receipt of funds in connection with the second Additional Closing (as defined in the SPA) under the SPA, the Company shall pay McKra an amount of $0.5 million plus any accrued unpaid interest; (iv) the Company shall repay advances made under the McKra Loan Agreement plus any accrued unpaid interest to McKra in the event of a capital raise of a minimum amount of $25.0 million; (v) in exchange for the McKra Loan Amendment, the Company shall issue 25,000 shares of Common Stock of the Company (the "McKra Extension Shares") to McKra within five (5) business days of the execution of the McKra Loan Amendment; and (vi) the Company shall file a registration statement for the issuance of the McKra Extension Shares no later than thirty (30) days following such issuance of McKra Extension Shares.

The terms of the loans listed in the above table are described above.

Cash Flows

To date, we have not generated any revenue. Cash flows to date have resulted from financing activities, including payments made on behalf of the Company by related parties and net proceeds from issuance of shares of common stock consisting of friends and family of our employees and short-term borrowings. As of December 31, 2023, our restricted cash balance of approximately $1.0 million is held in an escrow account .. We do not have any cash equivalents. Cash used in operating activities was used to pay legal and accounting fees. Accounts payable and accrued expenses of $17.1 million and $11.9 million as of December 31, 2023 and 2022, respectively, were recorded.

Quantitative and Qualitative Disclosures about Market Risk

To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities. We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation for Profit Interests in Poseidon and Stock Option Grants

We account for all stock-based payments to employees and non-employees, including profits interest grants in Poseidon, based on their respective grant date fair values. We estimate the fair value of profits interest grants using the Black-Scholes option pricing model, which is affected principally by the estimated fair value of shares of our common stock and requires management to make a number of other assumptions, including the expected life of the profits interest, the volatility of the underlying shares, the risk-free interest rate and expected dividends. Expected volatility is based on the historical share volatility of a set of comparable publicly traded companies over a period of time equal to the expected term of the profits interests. Due to the lack of historical exercise history, the expected term of the profit interests is determined using the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. The fair value of common stock underlying our profit interests was estimated by our Board of Directors considering, among other things, contemporaneous valuations of our common stock prepared by unrelated third-party valuation firms. The profit interests are valued based on the fair value of Poseidon units on the date of grant. We expense stock-based compensation related to these profit interests over the requisite service period using the straight-line method such that recognized compensation expense is at least equal to the vested portion of the awards. All stock-based compensation costs are recorded in research and development expense or general and administrative expense in the consolidated statements of operations based upon the respective employee's roles within our company. Forfeitures are recorded as they occur.

Stock Options to Non-Employee Directors

Under the Non-employee Director Compensation Policy, upon initial election or appointment to the Board, each new nonemployee director will be granted under the Incentive Plan a one-time grant of a non-statutory stock option to purchase 75,000 shares of its common stock on the date of such director's election or appointment to the Board, issuable under the incentive plan. These will vest in substantially equal monthly installments over three years, subject to the director's continued service as a member of the Board through each applicable vesting date.

On February 15, 2023, 75,000 options were granted to each of the non-employee directors at a strike price of $10.00 per share.
The estimated fair value of a non-statutory stock option to purchase common stock on the grant date was $3.73 per share and was determined using the Black-Scholes Merton model. The stock-based compensation expense recorded for the fiscal year ended December 31, 2023 was $0.6 million and was recorded within general and administrative expense in the Company's condensed consolidated statements of operations, as discussed below.

Due to the lack of historical exercise history, the expected term of the stock options is determined using the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. The fair value of common stock underlying our stock options was estimated by our Board of Directors considering, among other things, contemporaneous valuations of our common stock prepared by unrelated third-party valuation firms. We expense stock-based compensation related to these stock options over the requisite service period using the straight-line method such that recognized compensation expense is at least equal to the vested portion of the awards. The non-employee director stock option compensation costs are recorded in general and administrative expense in the consolidated statements of operations. Forfeitures are recorded as they occur.

Accounting for Warrants

We account for warrants issued based on their respective grant dates fair values. Prior to September 2022, the value of the warrants issued to Second Street (together, with warrants subsequently issued to Second Street Capital, the "Second Street Warrants") was estimated considering, among other things, contemporaneous valuations for our common stock prepared by unrelated third-party valuation firms and prices set forth in our previous filings with the SEC for a proposed IPO of our common stock that was not pursued by us ("Legacy Ocean IPO filings"). We used the mid-range price per share based upon our Legacy Ocean IPO filings. Starting in September 2022, following the execution of the Business Combination Agreement with AHAC, the value of the Second Street Warrants was based on the closing price of AHAC's Class A common stock as reported on the Nasdaq Global Select Market on the grant date. Following the Closing of the Business Combination, the value of warrants issued by us was based on the closing price of our common stock as reported on the Nasdaq Capital Market on the Grant date. We estimate the fair value, based upon these values, using the Black-Scholes option pricing model and Level 3 inputs, which is affected principally by the life of the warrant, the volatility of the underlying shares, the risk-free interest rate, and expected dividends. Expected volatility is based on the historical share volatility of a set of comparable publicly traded companies over a period of time equal to the expected term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the warrant for time periods approximately equal to the expected term of the warrant. Expected dividend yield is zero based on the fact that we have never paid cash dividends and do not expect to pay any case dividends in the foreseeable future. We expense the amount as interest in Other expenses.

Valuation of Backstop Put Option Liability and Fixed Maturity Consideration

The Company utilized a Monte-Carlo simulation to value the Backstop Put Option Liability and Fixed Maturity Consideration. The key inputs and assumptions used in the Monte-Carlo Simulation, including volatility, expected term, expected future stock price, and various simulated paths, were utilized to estimate the fair value of the associated derivative liabilities. The values of the Backstop Put Option Liability and Fixed Maturity Consideration were calculated as the average present value over 50,000 simulated paths. The Company measures the fair values at each reporting period, with changes in fair values recorded within other income/(expense) in its consolidated statements of operations.

	Estimated volatility	Expected future stock price	Risk-free rate
Backstop Put Option Liability and Fixed Maturity Consideration	100%	$1.95 - $13.93	4.4%

Valuation of the 2023 Convertible Note and SPA Warrant

The Company utilized a Monte-Carlo simulation to value the 2023 Convertible Note and SPA Warrant. The Monte-Carlo simulation is calculated as the average present value over all simulated paths. The key inputs and assumptions used in the Monte-Carlo Simulation, including volatility, estimated market yield, risk-free rate, the probability of various scenarios, including subsequent placement and change in control, and various simulated paths, were utilized to estimate the fair value of the associated liabilities. The Company measures the fair values at each reporting period, with changes in fair values recorded within other income/(expense) in the Company's consolidated statements of operations.

The following table summarizes some of the significant inputs and assumptions used in the Monte-Carlo simulation:

	Estimated volatility	Range of probabilities	Risk-free rate
2023 Convertible Note	50%	5% - 80%	5.3%
SPA Warrant	100%	5% - 80%	3.9%

Valuation of the Ayrton Note Purchase Option

The Company utilized the Black-Scholes Merton model to value the Ayrton Note Purchase Option. The key inputs and assumptions used in the Black-Scholes Merton model, including volatility and risk-free rate, were utilized to estimate the fair value of the associated liability. The Company measures the fair value at each reporting period, with changes in fair value recorded within other income/(expense) in the Company's consolidated statements of operations. As of December 31, 2023, it was determined that the fair value of the Ayrton Note Purchase Option was zero.

The following table summarizes some of the significant inputs and assumptions used in the Black-Scholes Merton model:

	Estimated volatility	Risk-free rate
Ayrton Note Purchase Option	13%	4.4%

Segments

We operate and manage the business as one reportable and operating segment, which is the business of discovering and developing therapeutic products in oncology, fibrosis, infectious diseases and inflammation. Our chief executive officer, who is the chief operating decision maker, or CODM, reviews financial information on an aggregate basis for allocating and evaluating financial performance.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued Accounting Standard Update ("ASU") No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20*) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The Company early adopted ASU 2020-06 as of January 1, 2023, using a modified retrospective approach, noting the Company's prior instruments would not be impacted by this adoption. The Company utilized the updated derivative guidance when accounting for the 2023 Convertible Note (as defined in Note 7, *Senior Secured Convertible Notes*).

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for public business entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of adopting ASU 2023-07 on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* to enhance the transparency and decision usefulness of income tax disclosures. This standard is effective for the Company for fiscal years beginning after December 15, 2024 and can be applied on a prospective or retrospective basis. The Company is currently evaluating the effect that the adoption of this ASU may have on its Consolidated Financial Statements.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not "opt out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a "smaller reporting company" meaning that the market value of our stock held by non- affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is expected to be less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time that we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Internal Control over Financial Reporting

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In connection with the preparation and audits of our financial statements as of December 31, 2023, we have identified a material weakness as defined under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting, as follows:

- Management does not have adequate staffing in its accounting department and has not yet designed and implemented the appropriate processes and internal controls to support accurate and timely financial reporting.

We have begun taking measures, and plan to continue to take measures, to remediate the material weakness. These measures include hiring or engaging additional accounting personnel with familiarity with reporting under U.S. GAAP, including hiring of Jolie Kahn as our Chief Financial Officer and implementing and adopting additional controls and formal policies, processes and documentation procedures relating to financial reporting. We plan to undertake recruitment efforts to identify additional accounting personnel, including possible use of third-party service providers. Remediation costs consist primarily of additional personnel expenses. We may identify additional material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce accurate financial statements on a timely basis.

However, the implementation of these measures may not be sufficient to remediate the control deficiencies that may lead to a material weakness in our internal control over financial reporting or to prevent or avoid potential future material weaknesses. Moreover, our current controls and any new controls that we develop may become inadequate in the future because of changes in conditions in our business. Furthermore, we may not have identified all material weaknesses and weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result.

We also could become subject to investigations by Nasdaq, the SEC, or other regulatory authorities. Any failure to develop or maintain effective controls or any difficulties encountered in its implementation or improvement could negatively impact our operating results or cause us to fail to meet its reporting obligations and may result in a restatement of our financial statements for prior periods, which could cause the price of our common stock and warrants to decline.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about directors, executive officers and corporate governance is presented under the same captions in our definitive Proxy Statement for the Annual Meeting of Shareowners to be held in the fourth quarter of fiscal 2024 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information about executive compensation is presented under the same captions in our definitive Proxy Statement for the Annual Meeting of Shareowners to be held in the fourth quarter of fiscal 2024 and is incorporated herein by reference.

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

Information about security ownership of certain beneficial owners and management and related stockholder matters is presented under the same captions in our definitive Proxy Statement for the Annual Meeting of Shareowners to be held in the fourth quarter of fiscal 2024 and is incorporated herein by reference.

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

Pre-Business Combination Related Party Transactions of Aesther

Certain Relationships and Related Transactions

The following is a summary of transactions since our formation on June 17, 2021, to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2023, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Founder Shares

On June 30, 2021, our Sponsor purchased 2,875,000 founder shares for an aggregate purchase price of $25,000, or approximately $0.009 per share. The number of founder shares issued was determined based on the expectation that such founder shares would represent 20% of the outstanding shares upon completion of our IPO (excluding the placement warrants and underlying securities, and the representative's shares).

Up to 375,000 founder shares held by our Sponsor are subject to forfeiture by our Sponsor depending on the extent to which the underwriters' over-allotment option is exercised. The founder shares (including the Class A common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder. The Sponsor agreed to cancel up to 375,000 of such shares depending on the extent to which the underwriters' over-allotment option in connection with our IPO was exercised. The underwriters' exercised a portion (500,000 units) of the underwriters' option to purchase up to an additional 1,500,000 units to cover over-allotments, and such over-allotment option subsequently expired. As such, the Sponsor cancelled 250,000 of the Class B common stock originally issued to the Sponsor on November 3, 2021.

Sponsor Lock-Up Agreement

The Sponsor and its members have agreed, subject to certain exceptions, not to transfer their 2,625,000 shares of common stock or securities convertible into or exchangeable for shares of common stock ending on the earlier of (i) one year from the Closing, (ii) if the reported last sale price of the common stock equals or exceeds $12.00 per share (as adjusted for stock splits, stock dividends, right issuances, reorganizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Closing, or (iii) the date on which the Company completes a liquidation, merger, capital stock exchange, reorganization or other similar transaction that results in all of our stockholders having the right to exchange their shares of common stock for cash, securities or other property.

Private Placement Warrants

Our Sponsor purchased an aggregate of 5,411,000 placement warrants at a price of $1.00 per warrant for an aggregate purchase price of $5.4 million in connection with the IPO and the exercise by the underwriters of a portion of the over-allotment option. There will be no redemption rights or liquidating distributions from the trust account with respect to the founder shares or placement warrants, which would have expire worthless if we did not consummate a business combination within 12 months from the closing of the IPO or during any extension period. The private placement warrants are identical to the warrants sold in the IPO except that the private placement warrants, so long as they are held by our Sponsor, the underwriters or their permitted transferees, (i) may not (including the shares of Class A common stock issuable upon exercise of these warrants), subject to certain limited exceptions, be transferred, assigned or sold by the holders until 30 days after the completion of our initial business combination, and (ii) will be entitled to registration rights. The private placement warrants (including the shares of Class A common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder.

Office Space and Related Support Services

Commencing on the date of the IPO and ending upon consummation of the Business Combination, we agreed to pay our Sponsor $10,000 per month for office space and administrative and support services pursuant to an administrative support agreement entered into with our Sponsor. A total of $155,000 had been paid as of December 31, 2023.

Sponsor IPO Loan

Prior to the closing of the IPO, our Sponsor agreed to loan us up to $0.3 million to be used for a portion of the expenses of the IPO. These loans were non-interest bearing, unsecured and were due at the earlier of June 30, 2022 or the closing of the IPO. Prior to the closing of the IPO, the Company had borrowed $0.2 million from the Sponsor, which amount was repaid from proceeds from the IPO. The loan was repaid upon the closing of the IPO out of the offering proceeds that were allocated to the payment of offering expenses (other than underwriting commissions).

Indemnification Agreements

We had previously entered into agreements with Aesther's officers and directors to provide contractual indemnification in addition to the indemnification provided for in Aesther's amended and restated certificate of incorporation. Aesther's bylaws also permitted us to secure insurance on behalf of any officer, director or employee for any liability arising out of his or her actions, regardless of whether Delaware law would permit such indemnification.

Sponsor Extension Loans

On September 15, 2022, we entered into a Loan and Transfer Agreement (the "First Extension Loan Agreement") with the Sponsor and certain individuals (the "First Extension Lenders"), pursuant to which the First Extension Lenders loaned $1.1 million to the Sponsor (the "First Sponsor Loan") and the Sponsor loaned $1.1 million to us (the "First SPAC Loan"). Amounts loaned from the First Extension Lenders to the Sponsor accrue interest at 8% per annum and amounts loaned from the Sponsor to us do not accrue interest. The Sponsor Extension Loan was paid down at Closing of the Business Combination to $0.5 million. The outstanding balance of the Sponsor Extension Loan was paid in full from the proceeds of the initial draw under the Ayrton Convertible Note Financing.

On December 13, 2022, we entered into a Loan and Transfer Agreement (the "Second Extension Loan Agreement") with the Sponsor and NPIC Limited (the "Second Extension Lender" and, together with the First Extension Lenders, the "Lenders"), pursuant to which the Second Extension Lender loaned $1.1 million to the Sponsor (the "Second Sponsor Loan" and, together with the First Sponsor Loan, the "Sponsor Loans") and the Sponsor loaned $1.1 million to us (the "Second SPAC Loan" and together with the First SPAC Loan, the "SPAC Loans"). Amounts loaned from the Second Extension Lender to the Sponsor accrue interest at 8% per annum and amounts loaned from the Sponsor to us do not accrue interest.

The total amounts advanced by Lenders to the Sponsor in connection with the Sponsor Loans (the "Funded Amounts") were required to be repaid, together with all accrued and unpaid interest thereon, within five days of the Closing, at the option of the Lenders, in either (a) cash; or (b) shares of Class A common stock held by the Sponsor which are deemed to have a value of $10 per share for such repayment right. As additional consideration for the Lenders making the Sponsor Loans available to Sponsor, Sponsor agreed to transfer between 1 and 2.5 Shares of Class B common stock to Lenders for each $10 multiple of the Funded Amounts, which included the registration rights previously provided by the Company to the Sponsor. While the SPAC Loans do not have a stated interest rate and do not accrue interest, the SPAC Loans require the issuance of 1,365,000 shares of Class A common stock, with a fair value of $13.65 million, which well exceeds the interest at 8% per annum on the underlying Sponsor Loans paid by the Sponsor.

On March 22, 2023, we entered into a Loan Modification Agreement (the "Modification Agreement") with the Sponsor and the Second Extension Lender, which modifies the terms of the Second Extension Loan Agreement, and a Side Letter Agreement with the Sponsor (the "Side Letter"), which further modifies the Second Extension Loan Agreement. The Modification Agreement modified the Second Extension Loan Agreement to provide that, among other things, (i) the maturity date of the $1.1 million Second Sponsor Loan is extended to May 22, 2023 (the "Maturity Date"); (ii) the extension will take effect concurrently with, and not until, the Sponsor transfers 1,050,000 shares of the Company's common stock (the "Initial SPAC Shares") to the Second Extension Lender; (iii) effective as of the date of the Modification Agreement, the Second Sponsor Loan shall accrue fifteen percent (15%) interest per annum, compounded monthly; (iv) the maturity date of the $1.1 million Second SPAC Loan is extended to May 19, 2023; (v) the proceeds of any Capital Raise of at least $15.0 million by the Company shall be first used by the Company to promptly repay the Second SPAC Loan and then Sponsor shall promptly repay the Second Sponsor Loan and all accrued interest; (vi) in exchange for the extension of the Maturity Date, the Company shall issue 50,000 shares of common stock to Second Extension Lender on the date of the Modification Agreement and shall issue an additional 50,000 shares of common stock thereafter on each 30-day anniversary of the Maturity Date to the Second Extension Lender until the Second Sponsor Loan is repaid in full; (vii) in the event Sponsor defaults on its obligations to repay the Second Sponsor Loan by the Maturity Date, the Sponsor shall transfer to the Second Extension Lender 250,000 shares of Company common stock owned by the Sponsor and shall transfer an additional 250,000 such shares each month thereafter until the default is cured; (viii) the Company is obligated to file a registration statement with the SEC registering the shares to be issued to Second Extension Lender within 30 days of the transfer, including the Initial SPAC Shares; and (ix) in the event that the Company defaults on its obligations to the Second Extension Lender set forth in (v), (vi) and (viii), the Company shall issue to Second Extension Lender 250,000 shares of common stock and shall transfer an additional 250,000 shares of common stock each month thereafter until the default is cured. The Side Letter provides that, in the event the Company fails to repay the Second SPAC Loan by May 19, 2023, the Company shall issue to Sponsor 250,000 shares of common stock and shall issue an additional 250,000 such shares to Sponsor each month thereafter until the default is cured. All capitalized terms used in the foregoing descriptions of the Modification Agreement or Side Letter, and not otherwise defined herein, have the meanings ascribed to such terms in the Modification Agreement or Side Letter.

On December 14, 2022, we entered into a Loan and Transfer Agreement with the Sponsor and Michael L. Peterson ("Mr. Peterson"), pursuant to which Mr. Peterson loaned $50,000 to the Sponsor (the "Third Sponsor Loan") and the Sponsor loaned $50,000 to us (the "Third SPAC Loan"). Amounts loaned from Mr. Peterson to the Sponsor accrue interest at 8% per annum and amounts loaned from the Sponsor to us do not accrue interest. We were only required to repay the Third SPAC Loan upon completion of the Business Combination. The total amounts advanced by Mr. Peterson to the Sponsor in connection with the $50,000 loan (the "Funded Amounts") were required to be repaid, together with all accrued and unpaid interest thereon, within five days of the Closing of the Business Combination, at the option of Mr. Peterson, in either (a) cash; or (b) shares of Class A common stock held by the Sponsor which were deemed to have a value of $10 per share for such repayment right. As additional consideration for Mr. Peterson making the loan available to Sponsor, Sponsor agreed to transfer 1 share of Class B common stock to Mr. Peterson for each $10 multiple of the Funded Amounts, which included the registration rights previously provided by the Company to the Sponsor. Furthermore, the letter agreement with the Company's initial stockholders contains a provision pursuant to which the Sponsor agreed to waive its right to be repaid for such loans out of the funds held in the Trust Account in the event that the Company did not complete a Business Combination. The Third Sponsor Loan and the Third SPAC Loan have been paid in full.

Registration Rights Agreement

In connection with our IPO, we entered into a Registration Rights Agreement with our Sponsor and its members (collectively, the "Holders"). The Holders are entitled to make up to three demands, excluding short form registration demands, that the Company register the Registerable Securities (as defined in the Registration Rights Agreement). In addition, the Holders have certain "piggy-back" registration rights with respect to registration statements filed subsequent to the Company's completion of the Business Combination and rights to require the Company to register for resale such securities pursuant to Rule 415 under the Securities Act. The Company will bear the expenses incurred in connection with the filing of any such registration statements.

Pre-Business Combination Related Party Transactions of Legacy Ocean

Certain Relationships and Related Transactions

Transactions with Poseidon Bio, LLC

In December 2020, Chirinjeev Kathuria, the then sole shareholder of Legacy Ocean, contributed 100% of his shares to a then-wholly-owned entity, Poseidon Bio, LLC ("Poseidon"). In February 2021, Poseidon transferred 342,244 shares back to Chirinjeev Kathuria and Legacy Ocean's employees and the remaining members of its management team became members of Poseidon. Prior to the Closing, Poseidon's sole asset was 17,112,298 shares of Legacy Ocean's common stock, which were exchanged for Company common stock pursuant to the Business Combination, and voting and investment authority over those shares is controlled by Poseidon's five-member board of managers, which consists of Chirinjeev Kathuria, Elizabeth Ng, Daniel Behr, Dr. Jack Elias and Jonathan Kurtis.

License Agreements with Elkurt, Inc.

On July 31, 2020, Legacy Ocean entered into four separate Exclusive License Agreements (the "Initial Brown License Agreements"), with Elkurt, Inc. ("Elkurt"), a licensee of Brown University. Legacy Ocean amended each of the Initial Brown License Agreements on March 21, 2021, August 31, 2021, March 25, 2022, July 1, 2022, July 2, 2022, August 25, 2022, November 1, 2023 and June 13, 2024. On September 13, 2022, Legacy Ocean entered into another Exclusive License Agreement (the "Brown Anti-PfGARP Small Molecules License Agreement") with Elkurt. Elkurt is a company formed by Legacy Ocean's scientific co-founders and members of our board of directors Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., PhD, Chair of the Department of Pathology and Laboratory Medicine at Brown University. Under the Initial Brown License Agreements and the Anti-PfGARP Small Molecules License Agreement, Elkurt grants to Legacy Ocean exclusive, royalty-bearing licenses to patent rights and nonexclusive, royalty-bearing licenses to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in certain fields.

On January 25, 2021, Legacy Ocean entered into an Exclusive License Agreement (the "Rhode Island License Agreement") with Elkurt, a licensee of Rhode Island Hospital. Legacy Ocean amended the Rhode Island License Agreement on April 1, 2021, September 10, 2021, March 25, 2022, July 1, 2022, August 26, 2022 and July 18, 2024. Under the Rhode Island License Agreement, Elkurt, grants to Legacy Ocean an exclusive, royalty-bearing license to patent rights and a nonexclusive, royalty-bearing license to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in a certain field.

For more information regarding the Initial Brown License Agreements and the Rhode Island License Agreement please see Item 1 of the Annual Report on Form 10-K.

Equity Sales

In March and April 2021, Legacy Ocean issued 41,828 shares of common stock to certain persons who were accredited investors (consisting of friends and family of Legacy Ocean's employees), at an aggregate offering price of $1.0 million. These shares were exchanged for our common stock in connection with the Business Combination. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(2) promulgated thereunder.

For more information please see Legacy Ocean's financial statements and the notes thereto in Amendment No. 2 to our Current Report on Form 8-K, initially filed on February 15, 2023, which is incorporated herein by reference.

Consulting Agreement with Jonathan Kurtis

On February 22, 2021, Legacy Ocean entered into a Consulting Agreement with Jonathan Kurtis, a member of its board of directors, that was amended effective August 2, 2021 and further amended effective December 31, 2021. The Consulting Agreement provides for Mr. Kurtis to provide consulting services as requested by Legacy Ocean in exchange for an annual payment of $0.2 million which is payable only upon Legacy Ocean's first cumulative capital raise equal to at least $50 million, subject to his continued service relationship with Legacy Ocean through such payment date. In addition, in connection with this consulting arrangement, Poseidon granted Mr. Kurtis 969,000 profits interests. The profits interests are subject to the terms and conditions of Poseidon's Amended and Restated Operating Agreement and a profits interest agreement. Upon his termination of services for Legacy Ocean, other than by Legacy Ocean for "cause", Poseidon has the right to purchase any vested profit interests at fair market value as determined by its board. If the termination is by Legacy Ocean for "cause," vested profits interests are forfeited. The profits interests are fully vested.

Advisor Agreement with Dr. Jack Elias

On February 22, 2021, Legacy Ocean entered into an Advisor Agreement with Dr. Jack Elias, a member of Legacy Ocean's board of directors. The Advisor Agreement provides for Dr. Elias to work with and advise Legacy Ocean from time to time on matters relating to Legacy Ocean's actual or potential business, technology and products in exchange for an annual payment of $0.3 million, beginning on the start date of January 1, 2020, which is payable only upon Legacy Ocean's first cumulative capital raise equal to at least $50 million, subject to his continued service relationship with Legacy Ocean through such payment date. In addition, in connection with this advising arrangement, Poseidon granted Dr. Elias 1,326,000 profits interests. The profits interests are subject to the terms and conditions of Poseidon's Amended and Restated Operating Agreement and a profits interest agreement. Upon his termination of services for Legacy Ocean, other than by Legacy Ocean for "cause", Poseidon has the right to purchase any vested profit interests at fair market value as determined by its board. If the termination is by Legacy Ocean for "cause", vested profits interests are forfeited. The profits interests are fully vested.

Consulting Agreement with Chief Accounting Officer

The Company's Chief Accounting Officer previously provided consulting services to Legacy Ocean with RJS Consulting, LLC, his wholly owned limited liability company, through June 15, 2021, before becoming the Company's Chief Accounting Officer. As of December 31, 2023 and 2022, Legacy Ocean owed RJS Consulting, LLC $0.1 million.

Executive Officer Compensation

See the section entitled "Executive Compensation" in our Proxy Statement for our 2024 Annual Meeting of Shareholders on Schedule 14A for information regarding compensation of our executive officers.

Related Party Transactions of the Company

Indemnification Agreements

In connection with the Business Combination, we entered into new agreements to indemnify our directors and officers. These agreements require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of the Company or that person's status as a member of our Board or as an officer of the Company to the maximum extent allowed under Delaware law.

Non-Competition Agreement

Simultaneously with the Closing, Chirinjeev Kathuria entered into non-competition agreement pursuant to which he agreed not to compete with the Company, Legacy Ocean and all subsidiaries of the companies, subject to certain requirements and customary conditions.

Related Party Transaction Policy

Effective as of February 14, 2023, the Board adopted a written related party transactions policy setting forth the policies and procedures for the identification, review, consideration and approval or ratification of related person transactions. More information on our related party transaction policy can be found under the caption "Policy For Approval of Related Party Transactions" in Item 10 of this Annual Report on Form 10-K.

Director Independence

Nasdaq's rules generally require that a majority of a listed company's board of directors be comprised of independent directors. In addition, such rules require that all members of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act.

In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Poseidon Bio, LLC owns a majority of our outstanding common stock. As a result, we are a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including:

(i) the requirement that a majority of our board of directors consist of "independent directors" as defined under the rules of Nasdaq;

(ii) the requirement that we have a compensation committee that is composed entirely of directors who meet the Nasdaq independence standards for compensation committee members; and

(iii) the requirement that our director nominations be made, or recommended to our full board of directors, by our independent directors or by a nominations committee that consists entirely of independent directors.

We currently rely on these exemptions. If we continue to utilize such exemptions available to controlled companies, we may not have a majority of independent directors, our nominations committee and compensation committee may not consist entirely of independent directors and such committees may not be subject to annual performance evaluations. Accordingly, under these circumstances, you may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

Our independent directors, as such term is defined by the applicable rules and regulations of Nasdaq, are Dr. Michelle Berrey, William Owens, Michael Peterson and Amy Griffith. Martin Angle passed away in September 2023.

Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that all members of the Board, except Dr. Chirinjeev Kathuria, Elizabeth Ng, Dr. Jake Kurtis, Dr. Jack Elias, and Suren Ajjarapu are independent directors, including for purposes of the rules of Nasdaq and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Dr. Chirinjeev Kathuria and Elizabeth Ng are not independent directors under the applicable rules because they are employed as our Chairman and former Chief Executive Officer, respectively. Suren Ajjarapu is not an independent director under the applicable rules due to his prior role as Chairman and Chief Executive Officer of Aesther. Dr. Jonathan Kurtis and Dr. Jack Elias are not independent directors under the applicable rules because of their consulting arrangements and their ownership of Elkhart, Inc.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information about principal accountant fees and services is presented under the same captions in our definitive Proxy Statement for the Annual Meeting of Shareowners to be held in the fourth quarter of fiscal 2024 and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements

(2) Financial Statements Schedule

All financial statement schedules are omitted because they are not applicable or the amounts are immaterial and not required, or the required information is presented in the financial statements and notes beginning on page F-1 in this Report.

(3) Exhibits [to be updated]

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of August 31, 2022 by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), AHAC Merger Sub Inc., Aesther Healthcare Sponsor, LLC, Dr. Chirinjeev Kathuria and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) (incorporated by reference from Exhibit 2.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 8, 2022).
2.2	Amendment to Agreement and Plan of Merger, dated as of December 5, 2022, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), AHAC Merger Sub Inc., Aesther Healthcare Sponsor, LLC, Dr. Chirinjeev Kathuria and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) (incorporated by reference from Exhibit 2.2 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
3.1	Third Amended and Restated Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference from Exhibit 3.2 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
4.1	Warrant Agreement, dated September 14, 2021, by and between Continental Stock Transfer & Trust Company and Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and Form of Warrant Certificate (incorporated by reference from Exhibit 4.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 17, 2021).
10.1	Lock-Up Agreement, dated as of February 14, 2023, by and between the Registrant and Dr. Chirinjeev Kathuria (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.2	Lock-Up Agreement, dated as of February 14, 2023, by and between the Registrant and Poseidon Bio, LLC (incorporated by reference from Exhibit 10.2 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.3	Non-Competition and Non-Solicitation Agreement, dated as of February 14, 2023, by and between the Registrant and Dr. Chirinjeev Kathuria (incorporated by reference from Exhibit 10.3 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.4#†	2022 Stock Option and Incentive Plan and Form of Non-Qualified Stock Option Agreement for Non-Employee Directors (incorporated by reference from Exhibit 10.4 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.5#	2022 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.5 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.6#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference from Exhibit 10.3 to the Form S-1/A filed by Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) (File No. 333-256950) on April 11, 2022).
10.7#†	Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Elizabeth Ng, dated February 22, 2021 (incorporated by reference from Exhibit 10.7 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.8#	Amendment to February 22, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Elizabeth Ng dated August 2, 2021 (incorporated by reference from Exhibit 10.8 to the Form 8-K filed by Ocean Biomedical, Inc. (File No.

001-40793) on February 15, 2023).

10.9#†	Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Chirinjeev Kathuria, dated February 22, 2021 (incorporated by reference from Exhibit 10.9 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.10#	Amendment to February 22, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Chirinjeev Kathuria dated August 2, 2021 (incorporated by reference from Exhibit 10.10 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.11#†	Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Daniel Behr, dated February 22, 2021 (incorporated by reference from Exhibit 10.11 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.12#	Amendment to February 22, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Daniel Behr dated August 2, 2021 (incorporated by reference from Exhibit 10.12 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.13#†	Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Gurinder Kalra, dated February 22, 2021 (incorporated by reference from Exhibit 10.13 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.14#	Amendment to February 22, 2021 Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Gurinder Kalra dated August 2, 2021 (incorporated by reference from Exhibit 10.14 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.15#	Second Amendment to February 22, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Gurinder Kalra dated April 22, 2022 (incorporated by reference from Exhibit 10.15 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.16#†	Offer Letter between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Inderjote Kathuria, dated February 22, 2021 (incorporated by reference from Exhibit 10.16 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.17#	Amendment to February 22, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Inderjote Kathuria dated August 2, 2021 (incorporated by reference from Exhibit 10.17 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.18#†	Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Robert Sweeney dated June 14, 2021 (incorporated by reference from Exhibit 10.18 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.19#	Amendment to June 14, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Robert Sweeney dated August 2, 2021 (incorporated by reference from Exhibit 10.19 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.20#	Second Amendment to June 14, 2021 Offer of Employment between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Robert Sweeney dated April 22, 2022 (incorporated by reference from Exhibit 10.20 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).

10.21	Consulting Agreement between Jonathan Kurtis and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.), dated February 22, 2021 (incorporated by reference from Exhibit 10.21 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.22	Amendment to Consulting Agreement between Jonathan Kurtis and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 2, 2021 (incorporated by reference from Exhibit 10.22 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.23	Amendment No. 2 to Consulting Agreement between Jonathan Kurtis and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) effective as of December 31, 2021 (incorporated by reference from Exhibit 10.23 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.24	Form of Director and Officer Indemnification Agreement, by and between the Registrant and each of its directors, the Chief Executive Officer and the Chief Financial Officer (incorporated by reference from Exhibit 10.24 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.25†	Exclusive License Agreement BROWN ID 2465, 2576, 2587 (FRG) Antibody between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 31, 2020 (incorporated by reference from Exhibit 10.25 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.26	First Amendment to Exclusive License Agreement (BROWN ID 2465, 2576, 2587) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 21, 2021 (incorporated by reference from Exhibit 10.26 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.27	Second Amendment to Exclusive License Agreement (BROWN ID 2465, 2576, 2587) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 31, 2021 (incorporated by reference from Exhibit 10.27 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.28	Third Amendment to Exclusive License Agreement (BROWN ID 2465, 2576, 2587) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 25, 2022 (incorporated by reference from Exhibit 10.28 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.29†	Fourth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 1, 2022 (incorporated by reference from Exhibit 10.29 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.30	Fifth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 2, 2022 (incorporated by reference from Exhibit 10.30 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.31†	Sixth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 25, 2022 (incorporated by reference from Exhibit 10.31 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).

10.32†	Exclusive License Agreement BROWN ID 3039 – Bi Specific Antibody Anti-CTLA4 between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 31, 2020 (incorporated by reference from Exhibit 10.32 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.33	First Amendment to Exclusive License Agreement (BROWN ID 3039) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 21, 2021 (incorporated by reference from Exhibit 10.33 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.34	Second Amendment to Exclusive License Agreement (BROWN ID 3039) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 31, 2021 (incorporated by reference from Exhibit 10.34 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.35	Third Amendment to Exclusive License Agreement (BROWN ID 3039) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 25, 2022 (incorporated by reference from Exhibit 10.35 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.36†	Fourth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 1, 2022 (incorporated by reference from Exhibit 10.36 to the Form 8-K filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.37	Fifth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 2, 2022 (incorporated by reference from Exhibit 10.37 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.38†	Sixth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 25, 2022 (incorporated by reference from Exhibit 10.38 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.39†	Exclusive License Agreement BROWN ID 2613 Bispecific (FRG)xAnti-PD-1 (FRGxPD-1) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 31, 2020 (incorporated by reference from Exhibit 10.39 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.40	First Amendment to Exclusive License Agreement (BROWN ID 2613) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 21, 2021 (incorporated by reference from Exhibit 10.40 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.41	Second Amendment to Exclusive License Agreement (BROWN ID 2613) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 31, 2021 (incorporated by reference from Exhibit 10.41 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.42	Third Amendment to Exclusive License Agreement (BROWN ID 2613) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 25, 2022 (incorporated by reference from Exhibit 10.42 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).

10.43†	Fourth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 1, 2022 (incorporated by reference from Exhibit 10.43 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.44	Fifth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 2, 2022 (incorporated by reference from Exhibit 10.44 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.45†	Sixth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 25, 2022 (incorporated by reference from Exhibit 10.45 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.46†	Exclusive License Agreement BROWN ID 2502 – (Chit1) Small Molecule Antifibrotic between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 31, 2020 (incorporated by reference from Exhibit 10.46 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.47	First Amendment to Exclusive License Agreement (BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 21, 2021 (incorporated by reference from Exhibit 10.47 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.48	Second Amendment to Exclusive License Agreement (BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 31, 2021 (incorporated by reference from Exhibit 10.48 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.49	Third Amendment to Exclusive License Agreement (BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 25, 2022 (incorporated by reference from Exhibit 10.49 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.50†	Fourth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 1, 2022 (incorporated by reference from Exhibit 10.50 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.51	Fifth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 2, 2022 (incorporated by reference from Exhibit 10.51 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.52†	Sixth Amendment to Exclusive License Agreements (BROWN ID 2465, 2576, 2587, BROWN ID 3039, BROWN ID 2613, BROWN ID 2502) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 25, 2022 (incorporated by reference from Exhibit 10.52 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.53†	Exclusive License Agreement Brown ID 3085J – Compositions and Treatments for Malaria, dated September 13, 2022, between Elkurt, Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) (incorporated by reference from Exhibit 10.53 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).

10.54†	Exclusive License Agreement RIH #154 "PfsLSP-1 a Vaccine for Falciparum Malaria" RIH #305 "Antibodies to Pfgarp Kill Plasmodium Falciparum Malaria Parasites and Protect Against Infection and Severe Disease" between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated January 25, 2021 (incorporated by reference from Exhibit 10.54 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.55	First Amendment to Exclusive License Agreement RIH #154 "PfsLSP-1 a Vaccine for Falciparum Malaria" RIH #305 "Antibodies to Pfgarp Kill Plasmodium Falciparum Malaria Parasites and Protect Against Infection and Severe Disease" between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated April 1, 2021 (incorporated by reference from Exhibit 10.55 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.56	Second Amendment to Exclusive License Agreement RIH #154 "PfsLSP-1 a Vaccine for Falciparum Malaria" RIH #305 "Antibodies to Pfgarp Kill Plasmodium Falciparum Malaria Parasites and Protect Against Infection and Severe Disease" between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated September 10, 2021 (incorporated by reference from Exhibit 10.56 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.57	Third Amendment to Exclusive License Agreement (RIH #154) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated March 25, 2022 (incorporated by reference from Exhibit 10.57 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.58	Fourth Amendment to Exclusive License Agreement RIH #154 "PfsLSP-1 a Vaccine for Falciparum Malaria" RIH #305 "Antibodies to Pfgarp Kill Plasmodium Falciparum Malaria Parasites and Protect Against Infection and Severe Disease" between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated July 1, 2022 (incorporated by reference from Exhibit 10.58 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.59	Fifth Amendment to Exclusive License Agreement (RIH #154) between Elkurt Inc. and Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) dated August 26, 2022 (incorporated by reference from Exhibit 10.59 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.60	Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated February 22, 2022 (incorporated by reference from Exhibit 10.60 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.61	First Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated April 22, 2022 (incorporated by reference from Exhibit 10.61 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.62	Second Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated September 30, 2022 (incorporated by reference from Exhibit 10.62 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.63	Third Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated December 30, 2022 (incorporated by reference from Exhibit 10.63 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.64*	Fourth Amendment to Loan Agreement between the Registrant and Second Street Capital, LLC effective as of February 15, 2023.

10.65	Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated April 22, 2022 (incorporated by reference from Exhibit 10.64 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.66	First Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated September 30, 2022 (incorporated by reference from Exhibit 10.65 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.67	Second Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated December 30, 2022 (incorporated by reference from Exhibit 10.66 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.68	Third Amendment to Loan Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Second Street Capital, LLC dated January 10, 2023 (incorporated by reference from Exhibit 10.67 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.69*	Fourth Amendment to Loan Agreement between the Registrant and Second Street Capital, LLC effective as of February 15, 2023.
10.70†	Warrant Exchange Agreement between Second Street Capital, LLC, Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) dated November 17, 2022 (incorporated by reference from Exhibit 10.68 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.71	Warrant No. 2022-1 to Subscribe to Common Shares issued by the Registrant to Second Street Capital, LLC (incorporated by reference from Exhibit 10.69 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.72	Warrant No. 2022-2 to Subscribe to Common Shares issued by the Registrant to Second Street Capital, LLC (incorporated by reference from Exhibit 10.70 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.73	Warrant No. 3 to Subscribe to Common Shares issued by the Registrant to Second Street Capital, LLC (incorporated by reference from Exhibit 10.71 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.74*	Warrant No. 2023-1 to Subscribe to Common Shares issued by the Registrant to Second Street Capital, LLC.
10.75*	Warrant No. 2023-2 to Subscribe to Common Shares issued by the Registrant to Second Street Capital, LLC.
10.76+†	Development and Manufacturing Services Agreement between Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.), Lonza Sales AG and Lonza AG dated December 15, 2020 (incorporated by reference from Exhibit 10.72 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
10.77	Promissory Note, dated June 30, 2021, issued to Aesther Healthcare Sponsor, LLC by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (incorporated by reference from Exhibit 10.2 to the Form S-1/A filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 333-258012) on September 2, 2021).

10.78	Securities Subscription Agreement, dated June 30, 2021, between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and Aesther Healthcare Sponsor, LLC (incorporated by reference from Exhibit 10.5 to the Form S-1/A filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 333-258012) on September 2, 2021).
10.79	Letter Agreement, dated September 14, 2021, between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), its officers and directors and Aesther Healthcare Sponsor, LLC (incorporated by reference from Exhibit 10.3 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 17, 2021).
10.80	First Amendment to Insider Letter, dated September 2, 2022, between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), its officers and directors, Aesther Healthcare Sponsor, LLC and EF Hutton, division of Benchmark Investments, LLC (incorporated by reference from Exhibit 10.4 to the Form 10-Q filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on October 17, 2022).
10.81	Investment Management Trust Agreement, dated September 14, 2021, by and between Continental Stock Transfer & Trust Company and Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 17, 2021).
10.82	Registration Rights Agreement, dated September 14, 2021, by and among Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and the Sponsor (incorporated by reference from Exhibit 10.2 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 17, 2021).
10.83	Private Placement Warrants Purchase Agreement, dated September 14, 2021, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and the Sponsor (incorporated by reference from Exhibit 10.4 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 17, 2021).
10.84	OTC Equity Prepaid Forward Transaction Letter Agreement, dated August 31, 2022, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc) and Vellar Opportunity Fund SPV LLC – Series 3 (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 7, 2022).
10.85	Common Stock Purchase Agreement, dated as of September 7, 2022, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and White Lion Capital LLC (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 9, 2022).
10.86	Registration Rights Agreement, dated as of September 7, 2022, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) and White Lion Capital LLC (incorporated by reference from Exhibit 10.2 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on September 9, 2022).
10.87	Amended and Restated OTC Equity Prepaid Forward Transaction Letter Agreement, dated February 10, 2023, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Vellar Opportunity Fund SPV LLC – Series 3 (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on February 10, 2023).
10.88	Amended and Restated OTC Equity Prepaid Forward Transaction Letter Agreement, dated February 12, 2023, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Vellar Opportunity Fund SPV LLC – Series 3 (incorporated by reference from Exhibit 10.1 to the Form 8-K filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 001-40793) on February 13, 2023).

10.89*	Assignment and Novation Agreement, dated February 13, 2023, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.), Vellar Opportunity Fund SPV LLC – Series 3, Meteora Special Opportunity Fund I, LP, Meteora Capital Partners, LP and Meteora Select Trading Opportunities Master, LP.
10.90*	Assignment and Novation Agreement, dated February 13, 2023, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.), Vellar Opportunity Fund SPV LLC – Series 3 and Polar Multi-Strategy Master Fund.
10.91*	Subscription Agreement, dated February 14, 2023, by and between Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Ocean Biomedical, Inc. (n/k/a Ocean Biomedical Holdings, Inc.) and Polar Multi-Strategy Master Fund.
10.92*	Promissory Note, dated February 14, 2023, issued to EF Hutton, division of Benchmark Investments, LLC by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.).
10.93*	Loan and Transfer Agreement, by and among Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.), Aesther Healthcare Sponsor, LLC and NPIC Limited dated December 13, 2022, as modified by that certain Loan Modification Agreement by and among Ocean Biomedical, Inc. (f/k/a Aesther Healthcare Acquisition Corp.), Aesther Healthcare Sponsor, LLC and NPIC Limited dated March 22, 2023 and Side Letter Agreement by and among Ocean Biomedical, Inc. (f/k/a Aesther Healthcare Acquisition Corp.) and Aesther Healthcare Sponsor, LLC.
10.94*	Loan Agreement, dated August __, 2024, by and among Ocean Biomedical, Inc. (f/k/a Aesther Healthcare Acquisition Corp.) and McKra Investments III.
14.1	Code of Ethical Business Conduct (incorporated by reference from Exhibit 14.1 to the Form S-1/A filed by Aesther Healthcare Acquisition Corp. (n/k/a Ocean Biomedical, Inc.) (File No. 333-258012) on September 2, 2021).
19.1*	Insider Trading Compliance Policy.
21.1	List of Subsidiaries (incorporated by reference from Exhibit 21.1 to the Form 8-K/A filed by Ocean Biomedical, Inc. (File No. 001-40793) on February 15, 2023).
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
32.1**	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act.
32.2**	Certification of Principal Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act.
101.INS	Inline 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 Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon request; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act, as amended, for any schedule or exhibit so furnished.

Represents management compensation plan, contract or arrangement.

+ As permitted by Regulation S-K, Item 601(b)(10)(iv) of the Securities Exchange Act of 1934, as amended, certain confidential portions of this exhibit have been redacted from the publicly filed document. The Registrant agrees to furnish supplementally an unredacted copy of the exhibit to the Securities and Exchange Commission upon its request.

ITEM 16. FORM 10-K SUMMARY.

Not applicable.

OCEAN BIOMEDICAL, INC.
(FKA AESTHER HEALTHCARE ACQUISITION CORP.)
INDEX TO FINANCIAL
STATEMENTS

Legacy Ocean's Consolidated Financial Statements for the Years Ended December 31, 2023 and 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Ocean Biomedical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Ocean Biomedical, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's working capital deficiency and anticipated losses from operations and its need to obtain additional capital raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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/ Deloitte & Touche LLP

Chicago, Illinois
November 25, 2024

We have served as the Company's auditor since 2020.

OCEAN BIOMEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share information)

	December 31,	
	2023	**2022**
ASSETS		
CURRENT ASSETS:		
Cash	$ 4	$ 34
Restricted cash	1,000	-
Prepaid expenses	1,105	-
Deferred offering costs	-	1,808
Total current assets	2,109	1,842
Investment in Virion	3,392	-
TOTAL ASSETS	$ 5,501	$ 1,842
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 16,185	$ 11,440
Accrued expenses-related party	946	445
Short term loans, net of issuance costs	12,118	776
SPA Warrant	764	-
Total current liabilities	30,012	12,661
NON-CURRENT LIABILITIES		
Fixed maturity consideration	4,123	-
Backstop put option liability	58,523	-
Virion contribution liability	3,605	-
Total liabilities	96,264	12,661
STOCKHOLDERS' DEFICIT:		
Common stock, $0.0001 par value; 300,000,000 and 180,564,262 shares authorized as of December 31, 2023 and December 31, 2022, respectively, 34,649,046 and 23,355,432 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	-	-
Additional paid-in capital	105,292	70,770
Accumulated deficit	(196,055)	(81,589)
Total stockholders' deficit	(90,763)	(10,819)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 5,501	$ 1,842

See accompanying notes to the consolidated financial statements

OCEAN BIOMEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)

	Fiscal years ended December 31,	
	2023	**2022**
OPERATING EXPENSES:		
Research and development	$ 709	$ 8,409
General and administrative	9,505	7,712
Total operating expenses	10,214	16,121
OPERATING LOSS	(10,214)	(16,121)
OTHER INCOME (EXPENSE)		
Change in fair value of 2023 Convertible Note, SPA Warrant and the Ayrton Note Purchase Option	1,171	-
Loss in connection with the Share Consideration shares	(12,676)	-
Loss in connection with Backstop Put Option Liability and Fixed Maturity Consideration	(62,646)	-
Fair value of warrant issuances	(2,301)	-
Fair value of non-cash stock issuances	(740)	-
Transaction costs	(8,732)	-
Loss on extinguishment of debt	(15,080)	-
Interest expense, including amortization of debt issuance costs	(1,762)	(1,243)
Net loss attributable to equity interest in Virion	(708)	
Change in fair value of Virion Contribution Liability	(777)	
Other	(1)	5
Total other income (expense)	(104,252)	(1,238)
NET LOSS	$ (114,466)	$ (17,359)
Weighted average shares outstanding, basic and diluted	26,292,438	23,355,432
Net loss per share, basic and diluted	$ (4.35)	$ (0.74)

See accompanying notes to the consolidated financial statements

OCEAN BIOMEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands)

	Common		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balances at December 31, 2021	17,496,370	$ -	$ 57,567	$ (64,230)	$ (6,663)
Retroactive application of recapitalization	5,859,062	-	-	-	-
Adjusted beginning balance	23,355,432	-	57,567	(64,230)	(6,663)
Stock-based compensation	-	-	12,378	-	12,378
Issuance of warrants	-	-	825	-	825
Net loss	-	-	-	(17,359)	(17,359)
Balances at December 31, 2022	23,355,432	-	70,770	(81,589)	(10,819)
Net loss				(114,466)	(114,466)
Pre-merger liabilities assumed	-	-	(942)	-	(942)
Effect of Business Combination, including Backstop Agreement, net of redeemed public shares	7,654,035	-	52,070	-	52,070
Backstop Agreement Prepayment	-	-	(51,606)	-	(51,606)
Proceeds from Backstop Agreement	-	-	1,444	-	1,444
Issuance of common stock pursuant to the Subscription Agreement	1,350,000	-	14,260	-	14,260
Issuance of common stock for extension of loan shares to related party	1,365,000	-	13,595	-	13,595
Issuance of common stock related to short-term loans	289,650	-	1,648	-	1,648
Shares issued in consideration pursuant to the Marketing Services Agreement	13,257	-	83	-	83
Shares issued in consideration pursuant to the Common Stock Purchase Agreement	116,667	-	558	-	558
Stock-based compensation	-	-	1,205	-	1,205
Shares issued in consideration pursuant to consulting agreement	350,000	-	676	-	676
Shares issued in consideration pursuant to Virion Contribution Agreement	750,000	-	1,272	-	1,272
Offering costs	-	-	(2,049)	-	(2,049)
Issuance of warrants	-	-	2,301	-	2,301
Shares Issued for conversion of a portion of the outstanding principal due under the 2023 Convertible Note	5,005	-	7	-	7
Balances at December 31, 2023	35,249,046	$ -	$ 105,292	$ (196,055)	$ (90,763)

See accompanying notes to the consolidated financial statements

OCEAN BIOMEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Fiscal years ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (114,466)	$ (17,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	762	929
Non-cash debt issuance costs	627	-
Non-cash stock issuances	667	-
Stock-based compensation	1,205	12,378
Loss on issuance of warrants	2,301	250
Loss on extinguishment of debt	15,080	-
Loss in connection with Share Consideration shares	12,676	-
Loss in connection with Backstop Put Option Liability and Fixed Maturity Consideration	62,646	-
Net loss attributable to equity interest in Virion	708	-
Change in fair value of Virion Contribution Liability	777	-
Change in fair value of 2023 Convertible Note, SPA Warrant and the Ayrton Note Purchase Option	(1,171)	-
Non-cash transaction costs in excess of Business Combination proceeds	7,578	-
Changes in assets and liabilities:		
Prepaid expenses	(519)	
Accounts payable and accrued expenses	1,233	2,809
Accrued expenses - related parties	467	-
Net cash used in operating activities	(9,429)	(993)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment to Backstop Parties for Backstop Agreement	(51,606)	-
Payment to Backstop Parties for Share Consideration	(12,676)	-
Issuance of common stock pursuant to the Backstop Agreement and Subscription Agreement	14,260	-
Proceeds from Backstop Agreement	1,444	-
Proceeds from reverse recapitalization	52,070	-
Proceeds from 2023 Convertible Note	650	-
Proceeds from short-term loans, net of issuance costs	8,258	735
Proceeds from Common Stock Purchase Agreement	64	-
Repayments of short-term loans	(2,100)	-
Expenses paid by related-party shareholder	35	232
Net cash provided by financing activities	10,399	967
Total change in cash and restricted cash	970	(26)
Cash and restricted cash at beginning of period	34	60
Cash and restricted cash at end of period	$ 1,004	$ 34
Supplemental disclosure of non-cash financing activities:		
Offering costs not yet paid	$ 2,049	$ 1,808
Non-cash stock issuances	$ 16,413	$ -
Non-cash investment in Virion	$ (1,272)	$ -
SPA warrant liability upon issuance	$ 1,932	$ -
Warrants issued related to short term loans	$ -	$ 1,074
Short term loans issuance costs not yet paid	$ -	$ 25

See accompanying notes to the consolidated financial statements

1. Organization, Description of Business, and Going Concern

Description of Business

Ocean Biomedical, Inc. is a biopharmaceutical company that is focused on discovering and developing therapeutic products in oncology, fibrosis, and infectious diseases.

Business Combination Agreement

On February 14, 2023, Aesther Healthcare Acquisition Corp. ("AHAC") completed the acquisition of Ocean Biomedical Holdings, Inc. ("Legacy Ocean") pursuant to the definitive agreement dated August 31, 2022, and as amended on December 5, 2022 (the "Business Combination Agreement"), by and among, AHAC, AHAC Merger Sub Inc., a wholly-owned subsidiary of AHAC, Aesther Healthcare Sponsor, LLC, Legacy Ocean, and Dr. Chirinjeev Kathuria (the "Closing"). Upon Closing, AHAC Merger Sub Inc. merged with and into Legacy Ocean, with Legacy Ocean surviving the merger as a wholly-owned subsidiary of AHAC. AHAC changed its name from "Aesther Healthcare Acquisition Corp." to "Ocean Biomedical, Inc." and is referred to herein as "the Company." Unless context otherwise requires, reference to "AHAC" refers to the Company prior to Closing.

Under the Business Combination Agreement, the Company acquired all outstanding capital stock of Legacy Ocean for approximately $240.0 million, in aggregate consideration before transaction and other fees, which Legacy Ocean stockholders received in the form of shares of common stock of the Company (the consummation of the business combination and other transactions contemplated by the Business Combination Agreement, collectively, the "Business Combination").

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Under this method of accounting, AHAC, who is the legal acquirer, is treated as the "acquired" company for financial reporting purposes and Legacy Ocean is treated as the accounting acquirer. The net assets of AHAC are stated at historical cost, with no goodwill or other intangible assets recorded. All historical financial information presented in the consolidated financial statements represents Legacy Ocean and its wholly-owned subsidiaries as Legacy Ocean is the predecessor to the Company. The wholly-owned subsidiaries include: (i) Ocean ChitofibroRx Inc., (ii) Ocean ChitoRx Inc., (iii) Ocean Sihoma Inc., and (iv) Ocean Promise, Inc. The Business Combination is accounted for as the equivalent of a capital transaction in which the Company has issued stock for the net assets of AHAC. The net assets of AHAC are stated at historical cost, with no goodwill or other intangible assets recorded.

The Company's common stock and warrants commenced trading on the Nasdaq Stock Market LLC under the symbols "OCEA" and "OCEAW," respectively, on February 15, 2023. Refer to Note 3, *Business Combination and Backstop Agreement*, for additional details.

The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, risks related to the successful development and commercialization of product candidates, fluctuations in operating results and financial risks, the ability to successfully raise additional funds when needed, protection of proprietary rights and patent risks, patent litigation, compliance with government regulations, dependence on key personnel and prospective collaborative partners, and competition from competing products in the marketplace.

Going Concern

The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company had no cash inflows from operating activities for the year ended December 31, 2023. As of December 31, 2023, the Company had cash of $4 thousand, restricted cash of $1.0 million and a working capital deficiency of $27.9 million. The Company's current operating plan indicates it will incur losses from operations and generate negative cash flows from operating activities, given anticipated expenditures related to research and development activities and its lack of revenue generating activity at this point in the Company's lifecycle. These events and conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued.

In response to these conditions, management's plans include that the Company will need to raise additional funds in order to advance its research and development programs, operate its business, and meet its current and future obligations as they come due. Based on the Company's current operational plans and assumptions, the Company expects to use the net proceeds from the Backstop Agreement (as defined in Note 3, *Business Combination and Backstop Agreement)* and future debt and equity financings, including possibly under the SPA entered into in May 2023 (as defined in Note 7, *Senior Secured Convertible Notes*), the 2024 Notes (as defined in Note 15, *Subsequent Events*), as well as further deferrals of certain of its accrued expenses and contingency payments due upon the closing of future financings to fund operations

However, the Company's ability to utilize certain of its in-place financing arrangements, such as the Backstop Agreement, or execute on new sources of liquidity are dependent on various factors outside of the Company's control, including market conditions and the performance of the Company's common stock.

There is no assurance that the Company will be successful in obtaining such additional financing on terms acceptable to the Company, if at all, and the Company may not be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, which could adversely affect its business prospects and its ability to continue operations. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Impacts of Market Conditions on Our Business

Disruption of global financial markets and a recession or market correction, including the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, the effects of Hamas' attack of Israel and the ensuing war, and other global macroeconomic factors such as inflation and rising interest rates, could reduce the Company's ability to access capital, which could in the future negatively affect the Company's liquidity and could materially affect the Company's business and the value of its common stock.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with U.S. GAAP and stated in U.S. dollars. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification and Accounting Standards Updates of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of all intercompany accounts and transactions. The subsidiaries were formed to organize the Company's therapeutic programs in order to optimize multiple commercialization options and to maximize each program's value.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting periods. Actual results could differ from those estimates. On an ongoing basis, the Company evaluates its estimates, as applicable, including those related to the fair values of the Company's common stock and related stock-based compensation and the valuation of (i) the Backstop Put Option Liability and Fixed Maturity Consideration (both as defined below) and (ii) the 2023 Convertible Note, SPA Warrant, and Ayrton Note Purchase Option (each as defined in Note 7, *Senior Secured Convertible Notes*). The Company bases its estimates using Company forecasts and future plans, current economic conditions, and information from third-party professionals that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources and adjusts those estimates and assumptions when facts and circumstances dictate.

The Company's results can also be affected by economic, political, legislative, regulatory or legal actions. Economic conditions, such as recessionary trends, inflation, interest, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can have a significant effect on operations. The Company could also be affected by civil, criminal, regulatory or administrative actions, claims, or proceedings.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents are stated at fair value and may include money market funds, U.S. Treasury and U.S. government-sponsored agency securities, corporate debt, commercial paper, and certificates of deposit. The Company had minimal cash or cash equivalents as of December 31, 2023 and 2022.

Restricted Cash

The Company's restricted cash is comprised of cash that is restricted as to withdrawal or use. Restricted cash as of December 31, 2023 was $1.0 million, consisting of the portion of proceeds received from the 2023 Convertible Note, as defined in Note 7, *Senior Secured Convertible Notes*, that is being held in an escrow account. As of December 31, 2022, the Company's cash balance was less than $0.1 million.

Concentrations of Credit Risk and Off-balance Sheet Risk

The Company has held minimal cash and cash equivalents since its inception and certain of its expenses have been paid for by the proceeds from the issuance of common stock and debt, and by the Company's Founder and Executive Chairman.

The Company has no significant off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission. The Company's future results of operations involve several other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's product candidates, uncertainty of market acceptance of the Company's product candidates, competition from other products, securing and protecting intellectual property, strategic relationships and dependence on key employees and research partners. The Company's product candidates require Food and Drug Administration ("FDA") and other non-U.S. regulatory agencies approval prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, if approval was delayed, if approval was unable to be maintained, it could have a materially adverse impact on the Company.

Revenue

The Company has not generated any revenue from any sources since its inception, including from product sales. The Company does not expect to generate any revenue from the sale of products in the foreseeable future. If the Company's development efforts for its product candidates are successful and result in regulatory approval, or license agreements with third parties, the Company may generate revenue in the future from product sales. However, there can be no assurance as to when revenue will be generated, if at all.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including the development of product candidates. Research and development costs are expensed as incurred. For the fiscal years ended December 31, 2023 and 2022, research and development expenses consist of expenses recognized for stock-based compensation and incurred for initial license fees, annual maintenance license fees, and services agreements. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting, and other third-party fees associated with equity financings such as the Business Combination as deferred offering costs until such financings are consummated. After consummation of the equity financings, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering. As of December 31, 2022, the Company had recorded $1.8 million of deferred offering costs. During the fiscal year ended December 31, 2023, the Company recognized offering costs of $2.0 million as a reduction to the Business Combination proceeds within additional paid-in capital and $7.6 million as a component of other income/(expense) in its consolidated statements of operations, as the amount of offering costs were in excess of the proceeds generated as a result of the Business Combination. As of December 31, 2023, there were no deferred offering costs.

Income Taxes and Tax Credits

Income taxes are recorded in accordance with FASB ASC 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss ("NOL") carryforwards and research and development tax credit ("R&D Credit") carryforwards. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all of its deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made. The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2023 and 2022, the Company had no liability for income tax associated with uncertain tax positions. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There was no income tax interest or penalties incurred for the fiscal years ended December 31, 2023 and 2022.

Net Loss Per Share

Net loss per share is computed by dividing net loss attributed to common stockholders by the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase, and, if dilutive, the weighted-average number of potential shares of common stock. For the purposes of the diluted net loss per share calculation, common stock warrants, common stock options outstanding, and contingently issuable Earnout Shares (as defined in Note 3, *Business Combination and Backstop Agreement*) are considered to be potentially dilutive securities for all periods presented, and as a result, diluted net loss per share is the same as basic net loss per share for those periods.

Fair Value Measurements

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

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's Backstop Put Option Liability and Fixed Maturity Consideration (both as defined below), 2023 Convertible Note, SPA Warrant, and Ayrton Note Purchase Option, (each as defined and discussed in Note 7, *Senior Secured Convertible Notes*), are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 4, *Fair Value Measurements*). The carrying values of cash, restricted cash, accounts payable, accrued expenses, and short-term loans approximate their fair values due to the short-term nature of these liabilities.

Backstop Put Option Liability and Fixed Maturity Consideration

Backstop Agreement

In connection with the execution of the Business Combination, AHAC and Legacy Ocean entered into an OTC Equity Prepaid Forward Transaction (as amended, the "Backstop Agreement") with the Backstop Parties (as defined in Note 3, Business Combination and Backstop Agreement). The Backstop Agreement grants the Backstop Parties the right to purchase up to a maximum of 8,000,000 of the Company's common stock on the open market for $10.56 per share (the "Redemption Price"). The Company agreed to purchase the unsold portion of the Backstop Shares from the Backstop Parties on a forward basis upon the "Maturity Date" (as amended, the third anniversary of the closing of the Business Combination, subject to certain acceleration provisions). The purchase price payable by the Company includes a prepayment in the amount of the redemption price per share (the "Prepayment") from the proceeds released from the trust account related to those shares. Among the acceleration provisions is the Backstop Parties' right to accelerate the Maturity Date if the Company's stock price trades below a stipulated price per share for any 30 trading days during a 45 day consecutive trading-day period (in October 2023, this acceleration provision was amended with one Backstop Party providing it the right to accelerate the Maturity Date if the Company's stock price trades below a stipulated price per share for any 20 trading days during a 30 day consecutive trading-day period). On any date following the closing of the Business Combination, the Backstop Parties also have the option to early terminate the arrangement in whole or in part by providing an optional early termination date notice to the Company (the "Optional Early Termination"). For those shares that are early terminated (the "Terminated Shares"), the Backstop Parties will owe the Company an amount equal to the product of (x) the number of Terminated Shares and (y) the Redemption Price, which may be reduced in the case of certain dilutive events (the "Reset Price").

Upon the Maturity Date, the Company is obligated to pay the Backstop Parties an amount equal to the product of (i) the maximum number of shares of 8,000,000 less the number of Terminated Shares by (ii) $2.50 (the "Maturity Consideration"). The Company can pay the Maturity Consideration in cash or shares of the Company's common stock if certain conditions are met.

The Backstop Parties have purchased a fixed total of 4,885,466 of the Company's common stock, referred to herein as the "Backstop Shares." The Backstop Parties' Optional Early Termination economically results in the Backstop Agreement operating in substance to grant the Backstop Parties' a put option with the right to sell all or a portion of the 4,885,466 Backstop Shares. Over the three-year maturity period, the Company is entitled to either a return of the Prepayment, the underlying shares, or a combination thereof, at the sole discretion of the Backstop Parties.

For further information regarding the Backstop Agreement, refer to Note 3, Business Combination and Backstop Agreement.

Backstop Put Option Liability and Fixed Maturity Consideration

The Backstop Agreement consists of two financial instruments that are accounted for as follows:

(i) The in-substance written put option which is recorded in the Company's consolidated financial statements as the "Backstop Put Option Liability" and treated as a derivative liability recorded at fair value with changes in fair value recognized in net loss. The Company measures the fair value of the Backstop Put Option Liability on a recurring basis, with any fair value adjustment recorded within other income/(expense) in the consolidated statements of operations. Refer to Note 4, Fair Value Measurements, for further detail.

(ii) The "Fixed Maturity Consideration" representing the 8,000,000 in maximum shares less the 4,885,466 Backstop Shares multiplied by $2.50. The Company has elected to measure the Fixed Maturity Consideration using the Fair Value Option ("FVO") under ASC 825, Financial Instruments. The Company measures the fair value of the Fixed Maturity Consideration on a recurring basis, with any fair value adjustment recorded within other income/(expense) in the consolidated statements of operations. Refer to Note 4, Fair Value Measurements, for further detail.

The Prepayment is accounted for as a reduction to equity to reflect the substance of the overall arrangement as a net purchase of the Backstop Shares and sales of shares to the Backstop Parties.

2023 Convertible Note, SPA Warrant, and Ayrton Note Purchase Option

As discussed within Note 7, Senior Secured Convertible Notes, in May 2023, the Company entered into a securities purchase agreement with an accredited investor for the sale of up to three Senior Secured Convertible Notes (each, a "Note" and collectively, the "Notes"), which Notes are convertible into shares of the Company's common stock, in an aggregate principal amount of up to $27.0 million, in a private placement. On May 25, 2023, the Company consummated the closing for the sale of (i) the initial Note in the principal amount of $7.6 million (referred to in this Report as the "2023 Convertible Note") and (ii) a warrant to initially acquire up to 552,141 additional shares of the Company's common stock with an initial exercise price of $11.50 per share of common stock, subject to adjustment, exercisable immediately and expiring five years from the date of issuance (the "SPA Warrant").

The Company has elected to account for the Notes at fair value under the fair value option, under which the Notes are initially measured at fair value and subsequently remeasured during each reporting period. Changes in fair value will be reflected within other income/(expense) in the consolidated financial statements, except for the portions, if any, related to the instrument specific credit risk which would be recorded in other comprehensive income.

Further, the Company concluded that the investor's right to acquire additional Notes is separately exercisable from the 2023 Convertible Note and the SPA Warrant. If and when the additional Notes are issued, the Company will evaluate whether to account for such additional Notes at (a) fair value under the fair value option or (b) an amortized cost. Refer to Note 7, Senior Secured Convertible Notes, for further detail on the terms of the Notes and potential future issuances.

In addition, the Company determined that the SPA Warrant was (i) freestanding from the 2023 Convertible Note and (ii) classified as a derivative liability. Accordingly, upon issuance the SPA Warrant was measured at fair value with an offset to cash proceeds from the 2023 Convertible Note, with the remainder recorded to other income/(expense) on the consolidated statements of operations. The Company reassess the classification of the SPA Warrant at each reporting period and record any changes to fair value as necessary. To date, there have been no changes in classification.

In addition to the liabilities recorded for the 2023 Convertible Note and the SPA Warrant, the Company also recorded a liability for the purchase option within the SPA in favor of the investor (the "Ayrton Note Purchase Option"), which gives the investor, at its option through 2025, the right to purchase from the Company additional Notes (up to the sum of the aggregate principal amount) at one or more additional closings. The initial fair value of the instrument was recorded to other income/(expense) on the consolidated statements of operations and are remeasured at each reporting period.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company has had no unrealized gains or losses for the fiscal years ended December 31, 2023 and 2022.

Emerging Growth Company and Smaller Reporting Company Status

The Company qualifies as an "emerging growth company" within the meaning of the Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startup Act ("JOBS Act") of 2012. The JOBS Act permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected not to "opt out" of this provision and, as a result, the Company will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

The Company is also a "smaller reporting company" and may continue to be a smaller reporting company if either (i) the market value of the stock held by non-affiliates is less than $250 million or (ii) the Company's annual revenue was less than $100 million during the most recently completed fiscal year and the market value of the Company's stock held by non-affiliates is less than $700 million. If the Company is a smaller reporting company at the time that it ceases to be an emerging growth company, the Company may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, the Company may choose to present only the two most recent fiscal years of audited financial statements in its Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Standards

In August 2020, the FASB issued Accounting Standard Update ("ASU") No. 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20*) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The Company early adopted ASU 2020-06 as of January 1, 2023, using a modified retrospective approach, noting the Company's prior instruments would not be impacted by this adoption. The Company utilized the updated derivative guidance when accounting for the 2023 Convertible Note (as defined in Note 7, *Senior Secured Convertible Notes*).

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for public business entities with fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact of adopting ASU 2023-07 on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* to enhance the transparency and decision usefulness of income tax disclosures. This standard is effective for the Company for fiscal years beginning after December 15, 2024 and can be applied on a prospective or retrospective basis. The Company is currently evaluating the effect that the adoption of this ASU may have on its Consolidated Financial Statements.

3. Business Combination and Backstop Agreement

Business Combination

On February 14, 2023, the Company consummated its Business Combination pursuant to the terms of the Business Combination Agreement.

Upon consummation of the Business Combination and other transactions (or immediately prior to, where indicated), the following occurred:

- AHAC changed its name from "Aesther Healthcare Acquisition Corp." to "Ocean Biomedical, Inc." and is referred to herein as "the Company." Unless the context otherwise requires, references to "AHAC" herein refer to the Company prior to Closing.
- AHAC issued approximately 23,355,432 shares, with an aggregate value equal to $233.6 million, of AHAC's Class A common stock to the holders of Legacy Ocean's securities immediately prior to the Closing, in exchange for all of the issued and outstanding capital stock of Legacy Ocean. The aggregate value was adjusted as required by the Business Combination Agreement to take into account net working capital, closing net debt and Legacy Ocean transaction expenses.
- The 2,625,000 shares of AHAC Class B common stock held by Aesther Healthcare Sponsor, LLC (the "Sponsor") were converted on a one-for-one basis into shares of AHAC's Class A common stock immediately prior to the Closing.
- The Backstop Parties (as defined below within *Backstop Agreement*) purchased 3,535,466 shares of AHAC's Class A common stock prior to the Closing that are subject to the Backstop Agreement (these shares, referred to as the "Recycled Shares," and the "Backstop Agreement" are both further discussed and defined below).
- AHAC issued an additional 1,365,000 shares of Class A common stock to the Sponsor prior to the Closing in consideration for obtaining extensions beyond the September 2022 deadline to complete an initial business combination.
- The Backstop Parties purchased 1,200,000 shares of AHAC's Class A common stock in the open market for an aggregate purchase price of $12.7 million prior to the Closing (the "Share Consideration Shares").
- The Company issued to Second Street Capital, LLC ("Second Street Capital"), Legacy Ocean's lender, three warrants (the "Converted Ocean Warrants") exercisable to acquire that number of shares of the Company's common stock equal to the economic value of the Legacy Ocean warrants previously issued to Second Street Capital in exchange for the termination of the Legacy Ocean warrants. The Converted Ocean Warrants are exercisable for a total of 511,712 shares of the Company's common stock at an exercise price of $8.06 per share and 102,342 shares of the Company's common stock at an exercise price of $7.47 per share.
- The Company issued to Polar (as defined below within *Backstop Agreement*) 1,350,000 newly issued shares of its common stock that are subject to the forward purchase provisions of the Backstop Agreement.
- Each share of AHAC's Class A common stock was automatically reclassified into one share of the Company's common stock, including the remaining shares of AHAC Class A common stock that were not redeemed.

The following table reconciles the elements of the Business Combination to the consolidated statements of stockholders' deficit and cash flows for the fiscal year ended December 31, 2023:

(in thousands)	
Cash from AHAC trust, net of redemptions	$ 52,070
Offering costs from Business Combination	(2,049)
Net impact on total stockholders' deficit	50,021
Non-cash offering costs	2,049
Net impact on cash provided by financing activities	$ 52,070

The Company identified certain errors in its previously issued quarterly financial statements that have been corrected in the consolidated financial statements as of and for the twelve months ended December 31, 2023. The errors primarily relate to improper presentation of liabilities assumed from AHAC upon closing of the Business Combination. Such amounts previously recognized as expenses have been properly presented within Additional paid-in capital. Management considered the quantitative and qualitative factors associated with these matters and concluded that the amounts were not material to the previously issued interim financial statements.

Earnout Shares

In addition, pursuant to Business Combination Agreement, Legacy Ocean's stockholders prior to the Closing (the "Legacy Ocean Stockholders") are entitled to receive from the Company, in the aggregate, up to an additional 19,000,000 shares of the Company's common stock (the "Earnout Shares") as follows: (a) in the event that the volume-weighted average price (the "VWAP") of the Company's common stock exceeds $15.00 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing date until the 36-month anniversary of the Closing, the Legacy Ocean Stockholders shall be entitled to receive an additional 5,000,000 shares of the Company's common stock, (b) in the event that the VWAP of the Company's common stock exceeds $17.50 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing date until the 36-month anniversary of the Closing, the Legacy Ocean Stockholders shall be entitled to receive an additional 7,000,000 shares of the Company's common stock and (c) in the event that the VWAP of the Company's common stock exceeds $20.00 per share for twenty (20) out of any thirty (30) consecutive trading days beginning on the Closing date until the 36-month anniversary of the Closing, the Legacy Ocean Stockholders shall be entitled to receive an additional 7,000,000 shares of the Company's common stock. In addition, for each issuance of Earnout Shares, the Company will also issue to Sponsor an additional 1,000,000 shares of the Company's common stock.

The Company has concluded that the Earnout Shares represent a freestanding equity-linked financial instrument as the arrangement (i) can be indexed to the Company's stock and (ii) meets all of the criteria for equity classification within ASC 815-40. The Company performed the two-step analysis described within ASC 815-40-15 to determine indexation and noted that while the arrangement does contain contingencies, these contingencies are based on the market for the Company's stock and do not preclude indexation.

Upon Closing, the fair value of the Earnout Shares was accounted for as a deemed dividend as of the Closing date. Since the entries to recognize the fair value of the Earnout Shares offset within additional paid-in capital, there is no inherent impact to the consolidated financial statements. Since the Earnout Shares are contingent on the Company's stock price, there will be no impact to outstanding shares and will not represent participating securities until the time at which the contingencies have been met.

Backstop Agreement

As discussed in Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, on August 31, 2022, AHAC and Legacy Ocean entered into the Backstop Agreement with Vellar in connection with the execution of the Business Combination Agreement. Pursuant to the terms of the Backstop Agreement and its subsequent amendments, Vellar agreed to purchase up to 8,000,000 shares of AHAC's Class A common stock in the open market in exchange for up to $80.0 million, including from other stockholders that elected to redeem in connection with the Closing and subsequently revoked their prior elections to redeem their shares, following the expiration of AHAC's redemption offer.

On February 13, 2023, AHAC, Vellar and Legacy Ocean entered into an assignment and novation agreement with Meteora Special Opportunity Fund I, LP, Meteora Select Trading Opportunities Master, LP and Meteora Capital Partners, LP (collectively "Meteora") (the "Meteora Agreement"), pursuant to which Vellar assigned its obligation to purchase 2,666,667 shares of the Company's common stock under the Backstop Agreement to Meteora. In addition, on February 13, 2023, AHAC, Vellar and Legacy Ocean entered into an assignment and novation agreement with Polar Multi-Strategy Master Fund ("Polar" and, collectively with Vellar and Meteora, the "Backstop Parties") (the "Polar Agreement"), as amended on October 2, 2023, pursuant to which Vellar assigned its obligations to 2,667,667 shares of common stock of the Company to be purchased under the Backstop Agreement to Polar.

Further, the Backstop Agreement grants the Backstop Parties the right to purchase additional shares from the Company (the "Additional Shares" and, together with the Recycled Shares (defined below), the "Backstop Shares") up to an amount equal to the difference between the number of Recycled Shares and the maximum number of shares of 8,000,000.

As further discussed in Note 2, *Basis of Presentation and Summary of Significant Accounting Policies*, the Company agreed to purchase the unsold portion of the Backstop Shares from the Backstop Parties on a forward basis upon the Maturity Date. The purchase price payable by the Company includes a Prepayment from the proceeds released from the trust account related to those shares. Upon the Maturity Date, the Company is obligated to pay the Backstop Parties an amount equal to the product of (i) the maximum number of shares of 8,000,000 less the number of Terminated Shares by (ii) $2.50, defined as the Maturity Consideration in the Backstop Agreement. The Company can pay the Maturity Consideration in cash or shares of the Company's common stock if certain conditions are met.

On February 14, 2023, (i) pursuant to the Backstop Agreement, the Backstop Parties purchased 3,535,466 shares of AHAC's Class A common stock for $10.56 per share (the "Recycled Shares") and (ii) pursuant to Polar's exercise of its right to purchase Additional Shares, AHAC, Legacy Ocean and Polar entered into a subscription agreement pursuant to which Polar purchased 1,350,000 newly issued shares of the Company's common stock at a per share purchase price of approximately $10.56 (the "Polar Subscription"). Under the Backstop Agreement, the Additional Shares are subject to the same terms as the Recycled Shares, including with regard to repayment and repurchase.

Subsequent to Closing, the Prepayment amount was equal to $51.6 million, consisting of $37.3 million for the Recycled Shares and $14.3 million for the Polar Subscription shares. As the $14.3 million was a netted transaction between the Company and Polar, only $37.3 million was paid out of the funds the Company received from AHAC's trust account. This net impact from the payment outflow to Backstop Parties for the Backstop Agreement of $51.6 million and the proceeds inflow from the issuance of common stock pursuant to the Backstop Agreement and Polar Subscription of $14.3 million are reported in the Company's consolidated statement of cash flows.

The Backstop Agreement consists of two financial instruments that are accounted for as follows:

(i) The in-substance written put option which is recorded in the Company's consolidated financial statements as the "Backstop Put Option Liability" and treated as a derivative liability recorded at fair value with changes in fair value recognized in net loss. The Company measures the fair value of the Backstop Put Option Liability on a recurring basis, with any fair value adjustment recorded within other income/(expense) in the consolidated statements of operations. Refer to Note 4, *Fair Value Measurements*, for further detail.

(ii) The "Fixed Maturity Consideration" representing the 8,000,000 in maximum shares less the 4,885,466 Backstop Shares multiplied by $2.50. The Company has elected to measure the Fixed Maturity Consideration using the Fair Value Option ("FVO") under ASC 825, Financial Instruments. The Company measures the fair value of the Fixed Maturity Consideration on a recurring basis, with any fair value adjustment recorded within other income/(expense) in the consolidated statements of operations. Refer to Note 4, Fair Value Measurements, for further detail.

The Prepayment is accounted for as a reduction to equity to reflect the substance of the overall arrangement as a net purchase of the Backstop Shares and sales of shares to the Backstop Parties.

At any time prior to the Maturity Date, and in accordance with the terms of the Backstop Agreement, the Backstop Parties may elect an Optional Early Termination to sell some or all of the Backstop Shares. If the Backstop Parties sell any shares prior to the Maturity Date, the pro-rata portion of the Prepayment amount is due back to the Company. As of December 31, 2023, the Backstop Parties have sold 143,261 Backstop Shares, for which the Company has received net proceeds of $1.4 million, after paying related fees to the Backstop Parties. Depending on the manner in which the Backstop Agreement is settled, the Company may never have access to the full Prepayment.

On May 23, 2023 the Company received an Equity Prepaid Forward Transaction - Valuation Date Notice ("Notice") from Vellar stating that due to the Company's alleged failure to timely register the shares held by Vellar, Vellar had the right to terminate the Backstop Agreement as to their portion of the shares and Vellar claimed that it is entitled to receive Maturity Consideration (as defined in the Backstop Agreement) equal to $6.7 million, which at the Company's discretion may be paid in cash or by offset to the shares currently held by Vellar. Management takes issue with multiple aspects of the Notice including, but not limited to, Vellar's right to terminate their portion of the Backstop Agreement and their asserted Maturity Consideration calculation. As such, the Company is consulting with advisors and other parties and is considering the potential resources and remedies it may elect to pursue and intends to assert its rights should this matter not be resolved. After a review of all applicable documents related to the Backstop Agreement, the Company believes its position with respect to the terms of the Backstop Agreement and intent of the parties is supported by the Backstop Agreement and facts and circumstances under which it was entered into. Further, given the early stage of this matter and the uncertainty inherent in litigation and investigations, the Company does not currently believe it is (i) probable to incur losses or (ii) possible to develop estimates of reasonably possible losses (or a range of possible losses) for this matter.

On October 2, 2023, the Company entered into a Side Letter Agreement (the "Side Letter") with Polar. The Side Letter amended certain terms of the Polar Agreement. The Side Letter amended the definitions of "Seller VWAP Trigger Event" and "Reset Price" as used in the Backstop Agreement as it relates to Polar and the Polar Agreement. Per the amended definitions, the (i) "Seller VWAP Trigger Event" is an event that occurs if the VWAP price is below $2.50 per share for any 20 trading days during a 30 consecutive trading day-period thereafter and (ii) the "Reset Price" is defined as $8.00. The Side Letter did not amend any terms of the Backstop Agreement as it relates to the other Backstop Parties.

The "Seller VWAP Trigger Event" for Polar occurred in October 2023 and the other Backstop Parties in November 2023. The Company received written notice from Polar on November 6, 2023 acknowledging its right to designate any date as the Maturity Date from the date of the notice to, and including, the third anniversary of the Business Combination. As of the date of this filing, one of the Backstop Parties, Polar had not designated a Maturity Date. Refer to above in this footnote for further detail around the purported Maturity Date for Vellar.

Common Stock Purchase Agreement

The Company is subject to the terms and conditions of (i) a common stock purchase agreement, dated September 7, 2022, and as amended on October 4, 2023 (the "Common Stock Purchase Agreement") and (ii) a registration rights agreement, dated September 7, 2022 (the "White Lion Registration Rights Agreement"), that AHAC entered into with White Lion Capital LLC ("White Lion"). Pursuant to the Common Stock Purchase Agreement, the Company has the right from time to time at its option to sell to White Lion up to $75.0 million in aggregate gross purchase price of newly issued shares of the Company's common stock (the "Equity Line Shares"), subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement. These limitations stipulate, among other things, that the Company may not sell, and White Lion may not purchase, shares of the Company common stock that would result in White Lion owning more than 9.99% of the outstanding common stock of the Company. The Common Stock Purchase Agreement expires after two years.

In accordance with ASC 815, *Derivatives and Hedging,* the Company has determined that the right to sell additional shares represents a freestanding put option, and as such, the financial instrument was classified as a derivative asset with a nominal fair value.

In consideration for the commitments of White Lion to purchase Equity Line Shares, the Common Stock Purchase Agreement included 75,000 initial commitment shares to White Lion, which had a fair value of $0.5 million upon issuance. The $0.5 million in commitment costs was recorded in other income/(expense) in the Company's consolidated statements of operations for the fiscal year ended December 31, 2023.

Effective October 4, 2023, the Company and White Lion entered into the first amendment of the Common Stock Purchase Agreement (the "Amendment"). The Amendment is intended to afford the Company greater flexibility and provide the Company an additional alternative to issue a fixed price "Purchase Notice" under the Common Stock Purchase Agreement at $7.00 per share if the market price for the Common Stock exceeds $9.00 per share. In addition, on November 2, 2023, White Lion purchased 41,677 shares of the Company's common stock under the Common Stock Purchase Agreement for which the Company received approximately $64 thousand. This facility is now deemed terminated and will not be utilized although it has not been formally terminated.

Sponsor Promissory Notes

Upon consummation of the Business Combination, the Company assumed two of AHAC's loans, totaling $2.1 million, one of which accrued interest at 8% per annum and the other accrued interest at 15% per annum. Both loans were due within five days of Closing. $0.5 million was paid down at Closing, with the remaining paid down in May 2023 via the proceeds received from the initial Note under the Ayrton Convertible Note Financing. Refer to Note 7, *Senior Secured Convertible Notes*, for further detail on the Notes.

In connection with the assumption of AHAC's loans and pursuant to the terms of the Business Combination Agreement described above, the Company issued 1,365,000 shares of its common stock to the Sponsor as consideration for providing the loans to the Company (the "Sponsor Extension Shares"). In addition, pursuant to the terms of an amendment entered into prior to the paydown of the loans, the Company issued a total of 200,000 shares of its common stock in exchange for extensions of the maturity date.

The Company recognized a loss on extinguishment of debt of $1.2 million in its consolidated statements of operations for the fiscal year ended December 31, 2023 for the 200,000 shares issued in exchange for extensions of the maturity date, based on the grant date fair value of the shares issued. In addition, the Company recognized a loss on extinguishment of debt of $13.6 million in its consolidated statements of operations for the fiscal year ended December 31, 2023 for the issuance of the Sponsor Extension Shares, based on the grant date fair value. Further, the Company recorded interest expense of $50 thousand in its consolidated statements of operations for the fiscal year ended December 31, 2023.

Deferred Underwriting Commissions

At Closing, the underwriters for AHAC's initial public offering ("IPO") agreed to defer payment of $3.2 million of deferred underwriting discounts otherwise due to them until November 14, 2023, pursuant to the terms of a promissory note (the "Underwriter Promissory Note"). The deferred amounts bear interest at 9% per annum and 24% per annum following an event of default under the promissory note. The Company has a right to pay up to fifty percent (50%) of the principal and interest due on this promissory note using the common stock of the Company at a price per share of $10.56. The remaining fifty percent (50%) of the principal and interest due on this promissory note must be paid in cash. As of December 31, 2023 the Company had not repaid the Underwriter Promissory Note and the outstanding balance of $3.2 million is recorded as a short-term loan in the consolidated financial statements. The Company recorded $0.3 million of interest expense on the outstanding balance in the Company's consolidated financial statements for the fiscal year ended December 31, 2023.

4. Fair Value Measurements

Financial liabilities measured at fair value during the year on a recurring basis consisted of the following as of December 31, 2023:

	Fair Value Hierarchy			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Financial liabilities:				
Backstop Put Option Liability	$ -	$ -	$ (58,523)	$ (58,523)
Fixed Maturity Consideration	-	-	(4,123)	(4,123)
2023 Convertible Note [1]	-	-	(5,618)	(5,618)
SPA Warrant	-	-	(764)	(764)
Ayrton Note Purchase Option	-	-	-	-
Total financial liabilities	$ -	$ -	$ (69,028)	$ (69,028)

(1) Refer to Note 6, *Short-Term Loan Agreements*, for a reconciliation of the fair value of the 2023 Convertible Note to the total short-term loans, net of issuance costs in the Company's consolidated balance sheets.

During the fiscal year ended December 31, 2023 there were no transfers between Level 1, Level 2 and Level 3. During the fiscal year ended December 31, 2022 there were no liabilities measured at fair value.

Valuation of Backstop Put Option Liability and Fixed Maturity Consideration

The Company utilized a Monte-Carlo simulation to value the Backstop Put Option Liability and Fixed Maturity Consideration. The key inputs and assumptions used in the Monte-Carlo Simulation, including volatility, expected term, expected future stock price, and various simulated paths, were utilized to estimate the fair value of the associated derivative liabilities. The values of the Backstop Put Option Liability and Fixed Maturity Consideration were calculated as the average present value over 50,000 simulated paths. The Company measures the fair values at each reporting period, with changes in fair values recorded within other income/(expense) in its consolidated statements of operations.

	Estimated volatility	Expected future stock price	Risk-free rate
Backstop Put Option Liability and Fixed Maturity Consideration	100%	$1.95 - $13.93	4.4%

Valuation of the 2023 Convertible Note and SPA Warrant

The Company utilized a Monte-Carlo simulation to value the 2023 Convertible Note and SPA Warrant. The Monte-Carlo simulation is calculated as the average present value over all simulated paths. The key inputs and assumptions used in the Monte-Carlo Simulation, including volatility, estimated market yield, risk-free rate, the probability of various scenarios, including subsequent placement and change in control, and various simulated paths, were utilized to estimate the fair value of the associated liabilities. The Company measures the fair values at each reporting period, with changes in fair values recorded within other income/(expense) in the Company's consolidated statements of operations.

The following table summarizes some of the significant inputs and assumptions used in the Monte-Carlo simulation:

	Estimated volatility	Range of probabilities	Risk-free rate
2023 Convertible Note	50%	5% - 80%	5.3%
SPA Warrant	100%	5% - 80%	3.9%

Valuation of the Ayrton Note Purchase Option

The Company utilized the Black-Scholes Merton model to value the Ayrton Note Purchase Option. The key inputs and assumptions used in the Black-Scholes Merton model, including volatility and risk-free rate, were utilized to estimate the fair value of the associated liability. The Company measures the fair value at each reporting period, with changes in fair value recorded within other income/(expense) in the Company's consolidated statements of operations. As of December 31, 2023, it was determined that the fair value of the Ayrton Note Purchase Option was zero.

The following table summarizes some of the significant inputs and assumptions used in the Black-Scholes Merton model:

	Estimated volatility	Risk-free rate
Ayrton Note Purchase Option	13%	4.4%

The following table provides a roll forward of the aggregate fair values of the Company's Backstop Put Option Liability, Fixed Maturity Consideration, the 2023 Convertible Note, SPA Warrant, and Ayrton Note Purchase Option for which fair values are determined using Level 3 inputs:

Level 3 Rollforward *(in thousands)*	Backstop Put Option Liability	Fixed Maturity Consideration	2023 Convertible Note	SPA Warrant	Ayrton Note Purchase Option
Balances as of January 1, 2023	$ -	$ -	$ -	$ -	$ -
Initial fair value measurement	(12,414)	(3,166)	(5,628)	(1,932)	(269)
Changes in fair value	(46,109)	(957)	10	1,168	269
Balance as of December 31, 2023	$ (58,523)	$ (4,123)	$ (5,618)	$ (764)	-

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

(in thousands)	For the fiscal years ended 2023	2022
Accounting and legal fees	$ 12,099	$ 10,250
Vendor fees	2,517	646
Research and development	636	544
Other	933	-
Total accounts payable and accrued expenses	$ 16,185	$ 11,440

6. Short-term Loan Agreements

As of December 31, 2023 and December 31, 2022, the Company had the following short-term loan balances:

(in thousands)	For the fiscal years ended
Short-term loans:	2023	2022
Second Street Loan	$ 600	$ 600
Second Street Loan 2	400	200
March Second Street Loan	700	-
McKra Loan	1,000	-
Underwriter Promissory Note	3,150	-
2023 Convertible Note	5,618	-
Poseidon Demand Note	650	-
Less: issuance costs remaining to be amortized	-	(24)
Short-term loans, net of issuance costs	$ 12,118	$ 776

Second Street Capital Loans

Second Street Loan

In February 2022, the Company entered into a Loan Agreement with Second Street Capital (the "Second Street Loan"), pursuant to which the Company borrowed $0.6 million. The Second Street Loan accrues interest at the rate of 15% per annum, with principal and interest due at maturity. The Company issued to Second Street Capital a warrant to purchase 312,500 shares of the Company's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. For a period of 180 days from the closing of the Company's next financing, Second Street Capital has the right to put the warrants to the Company in exchange for a payment of $0.3 million. The Company was originally required to repay the Second Street Loan on the earlier of (i) 5 business days after the Company's next financing or (ii) November 18, 2022. The Company recognized an expense of $0.3 million for the put option. The accounting treatment for the warrants is discussed within Note 10, *Warrants*.

Second Street Loan 2

In April 2022, the Company entered into a second Loan Agreement with Second Street Capital (the "Second Street Loan 2"), pursuant to which the Company borrowed $0.2 million, which was later amended in January 2023 to borrow an additional $0.2 million. The Second Street Loan 2 accrues interest at the rate of 15% per annum, with principal and interest due at maturity. The Company issued to Second Street Capital a warrant to purchase 62,500 shares of the Company's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. There is no put option associated with this loan. The Company was originally required to repay the Second Street Loan 2 on the earlier of (i) 5 business days after the Company's next financing or (ii) November 18, 2022. The Company recognized an expense of $0.4 million for the warrants issued based on the estimated fair value of the awards on the date of grant. The accounting treatment for the warrants is discussed within Note 10, *Warrants*.

March Second Street Loan

In March 2023, the Company entered into a new loan agreement with Second Street Capital (the "March Second Street Loan" and together with the Second Street Loan and Second Street Loan 2, the "Second Street Loans") pursuant to which the Company could borrow up to $1.0 million to pay certain accrued expenses. Of this amount, the Company borrowed $0.7 million. The loan bears interest at 15% per annum. The Company issued a warrant to Second Street Capital for 200,000 shares of the Company's common stock, exercisable for five years at an exercise price of $10.34 and will pay up to $0.2 million in loan fees at maturity. Since the Company only borrowed $0.7 million, the loan fee of $0.1 million is due at maturity. The accounting treatment for the warrants is discussed within Note 10, *Warrants*.

Second Street Capital Loan Amendments

In connection with amendments to the Second Street Loans, an additional 225,000 and 75,000 warrants to purchase the Company's common stock were issued to Second Street Capital in 2023 and 2022, respectively. The terms of the warrants and respective accounting treatments are summarized in Note 10, *Warrants*.

The most recent amendment, effective as of May 2023, included the following terms, with no conditions present as of December 31, 2023:

(i) Upon execution of the amendment, the Company paid the remainder of outstanding fees due.
(ii) Within 5 business days of the receipt of the first Additional Closing (as defined within the Securities Purchase Agreement, discussed in Note 7, *Senior Secured Convertible Notes*), the Company is required to pay $0.5 million towards its outstanding loans.
(iii) Within 5 business days of the second Additional Closing (as defined within the Securities Purchase Agreement), the Company is required to pay $1.2 million towards its outstanding loans plus any accrued unpaid interest.
(iv) In the event the Company raises additional equity through financing arrangements of at least $25.0 million, the Company is required to use the proceeds to repay the remainder of its outstanding loans plus any accrued unpaid interest.
(v) In exchange for the amendment, the Company issued 25,000 shares of its common stock to Second Street Capital. The fair value of the shares issued are recorded in the Company's consolidated statements of operations as a loss on debt extinguishment.

Second Street Loans – Interest Expense

During the fiscal years ended December 31, 2023 and 2022, the Company recognized $0.7 million and $0.2 million of interest expense on the Second Street Loans, respectively, including $0.4 million and $0.1 million, respectively, related to the amortization of debt issuance costs.

McKra Loan

In March 2023, the Company entered into a Loan Agreement with McKra Investments III ("McKra") pursuant to which the Company borrowed $1.0 million, which bears interest at 15% per annum (the "McKra Loan"). The Company is required to pay a $0.2 million loan and convenience fee due upon repayment of the loan. The Company issued a warrant to purchase 200,000 shares of the Company's common stock, with an exercise price of $10.34 per share, exercisable until March 27, 2028. The accounting treatment for the warrants is discussed within Note 10, *Warrants*.

The McKra Loan was amended, effective as of May 2023, including the following terms:

(i) Upon execution of the amendment, the Company paid the remainder of outstanding fees due.
(ii) Within 5 business days of the receipt of the first Additional Closing (as defined within the Securities Purchase Agreement, discussed in Note 7, Senior Secured Convertible Notes), the Company is required to pay $0.5 million towards its outstanding loans.
(iii) Within 5 business days of the second Additional Closing (as defined in Note 7, Senior Secured Convertible Notes), the Company is required to pay $0.5 million towards its outstanding loans plus any accrued unpaid interest.
(iv) In the event the Company raises additional equity through financing arrangements of at least $25.0 million, the Company is required to use the proceeds to repay the remainder of its outstanding loans plus any accrued unpaid interest.
(v) As consideration for entering into the amendment, the Company issued 25,000 shares of its common stock to McKra. The fair value of the shares issued are recorded in the Company's consolidated statements of operations as a loss on debt extinguishment.

During the fiscal year ended December 31, 2023, the Company recognized $0.3 million of interest expense on the McKra Loan, including $0.2 million related to the amortization of debt issuance costs.

Poseidon Demand Note

On October 2, 2023, the Company issued a demand promissory note to its largest stockholder and related party, Poseidon Bio, LLC ("Poseidon") for $0.7 million (the "Poseidon Demand Note"). The entire principal amount of the Poseidon Demand Note will be due and payable in full on demand, or on such earlier date the principal amount may become due and payable pursuant to certain triggering events (the "Maturity Date"). Interest accrues on the unpaid principal amount of the Poseidon Demand Note at a rate of 5% per annum and is payable on the Maturity Date. Interest expense related to the Poseidon Demand Note in the amount of $8 thousand is reflected in other income (expense) in the consolidated statement of operations for the fiscal year ended December 31, 2023.

See Note 3, *Business Combination and Backstop Agreement*, for information on the Underwriter Promissory Note and Note 7, *Senior Secured Convertible Notes*, for information on the 2023 Convertible Note.

7. Senior Secured Convertible Notes

Senior Secured Convertible Notes

In May 2023, the Company entered into a Securities Purchase Agreement (the "SPA") with an accredited investor (the "Investor") for the sale of up to three Senior Secured Convertible Notes (each, a "Note" and collectively, the "Notes"), which Notes are convertible into shares of the Company's common stock, in an aggregate principal amount of up to $27.0 million, in a private placement (the "Ayrton Convertible Note Financing"). In May 2023, the Company consummated the closing for the sale of (i) the initial note in the principal amount of $7.6 million (the "2023 Convertible Note") and (ii) a warrant to initially acquire up to 552,141 additional shares of the Company's common stock with an initial exercise price of $11.50 per share of common stock, subject to adjustment, exercisable immediately and expiring five years from the date of issuance (the "SPA Warrant"). Each Note will be sold at an original issue discount of 8%. Future issuances of Notes ("Additional Closings") are subject to satisfaction of certain conditions. At the closing of the first Additional Closing, $8.6 million in principal amount of Notes will be issued (the "First Additional Closing Date") and $10.8 million in principal amount of Notes will be issued at the closing of the second Additional Closing. So long as any Notes remain outstanding, the Company and each of its subsidiaries are prohibited from effecting or entering into an agreement to effect any subsequent placement involving a Variable Rate Transaction, as defined within the SPA, other than pursuant to the White Lion Common Stock Purchase Agreement.

The interest rate applicable to each Note is, as of any date of determination, the lesser of (i) 8% per annum and (ii) the greater of (x) 5% per annum and (y) the sum of (a) the "secured overnight financing rate," which from time to time is published in the "Money Rates" column of The Wall Street Journal (Eastern Edition, New York Metro), in effect as of such date of determination and (b) 2% per annum. Each Note will mature on the first anniversary of its issuance.

All or any portion of the principal amount of each Note, plus accrued and unpaid interest is convertible at any time, in whole or in part, at the noteholder's option, into shares of the Company's common stock at an initial fixed conversion price of $10.34 per share, subject to certain adjustments and alternative conditions. A noteholder will not have the right to convert any portion of a Note, to the extent that, after giving effect to such conversion, the noteholder (together with certain of its affiliates and other related parties) would beneficially own in excess of 9.99% of the shares of the Company's common stock outstanding immediately after giving effect to such conversion. Upon a change of control of the Company, noteholders may require the Company to redeem all, or any portion, of the Notes at a price stipulated by certain conditions as discussed within the SPA. At December 31, 2023, the principal amount outstanding under the 2023 Convertible Note was $7.6 million.

The Notes provide for certain events of default, including, among other things, any breach of the covenants described in the SPA and any failure of Dr. Chirinjeev Kathuria to be the chairman of the Company's Board of Directors. In connection with an event of default, the noteholders may require the Company to redeem all or any portion of the Notes, at a premium set forth in the SPA.

The Company is subject to certain customary affirmative and negative covenants regarding the rank of the Notes, the incurrence of indebtedness, the existence of liens, the repayment of indebtedness and the making of investments, the payment of cash in respect of dividends, distributions or redemptions, the transfer of assets, the maturity of other indebtedness, and transactions with affiliates, among other customary matters. The Company is also subject to financial covenants requiring that (i) the amount of the Company's available cash equals or exceeds $3.0 million at the time of each Additional Closing; (ii) the ratio of (a) the outstanding principal amount of the Notes, accrued and unpaid interest thereon, and accrued and unpaid late charges to (b) the Company's average market capitalization over the prior ten trading days, not exceeding 35%; and (iii) at any time any Notes remain outstanding, with respect to any given calendar month (each, a "Current Calendar Month") (x) the available cash on the last calendar day in such Current Calendar Month shall be greater than or equal to the available cash on the last calendar day of the month prior to such Current Calendar Month less $1.5 million.

The Company has elected to account for the Notes at fair value under the fair value option, under which the Notes were initially measured at fair value and subsequently re-measured during each reporting period. Changes in fair value are reflected within other income/(expense) in the consolidated financial statements, except for the portions, if any, related to the instrument specific credit risk which would be recorded in other comprehensive income.

Further, the Company concluded that the right to acquire additional Notes is separately exercisable from the 2023 Convertible Note and the SPA Warrant. If and when the additional Notes are issued, the Company will evaluate whether to account for such additional Notes at (a) fair value under the fair value option or (b) an amortized cost.

In addition, the Company determined that the SPA Warrant was (i) freestanding from the 2023 Convertible Note and (ii) classified as a derivative liability. Accordingly, upon issuance the SPA Warrant was measured at fair value with an offset to cash proceeds from the 2023 Convertible Note, with the remainder of $0.6 million recorded to other income/(expense) on the consolidated statements of operations. The Company reassess the classification of the SPA Warrant at each reporting period and records any changes to fair value to other income/(expense) on the consolidated statement of operations. To date, there have been no changes to the classification of the SPA Warrant.

In addition to the liabilities recorded for the 2023 Convertible Note and the SPA Warrant, the Company also recorded a liability for the Ayrton Note Purchase Option, which gives the Investor, at its option through 2025, the right to purchase from the Company additional Notes (up to the sum of the aggregate principal amount) at one or more Additional Closings. The initial recognition of this liability was measured at fair value utilizing the Black-Scholes Merton model and the fair value of $0.3 million was recorded to other income/(expense) on the consolidated statements of operations for the fiscal quarter ended June 30, 2023. The liability is remeasured at each reporting period and the Company records any changes to other income/(expense) on the consolidated statement of operations. As of December 31, 2023, it was determined that the fair value of the Ayrton Note Purchase Option was zero.

The Company issued 39,650 shares of its common stock to the Investor during the fiscal year ended December 31, 2023 as interest payments. A total of $0.2 million was recorded as fair value of non-cash stock issuances on the consolidated statement of operations or the shares issued based on the grant date fair values.

As of December 31, 2023, the Company is in default of its obligations with respect to Ayrton LLC as a result of, among other things, its delinquent SEC filings.

8. Commitments and Contingencies

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities, including the significant matters described below that could have a material impact on our results of operations and cash flows. In many proceedings, including the specific matters described below, it is inherently difficult to determine whether any loss is probable or even reasonably possible or to estimate the size or range of the possible loss, and accruals for legal matters are not recorded until a loss for a particular matter is considered probable and reasonably estimable. Given the nature of legal matters and the complexities involved, it is often difficult to predict and determine a meaningful estimate of loss or range of loss until we know, among other factors, the particular claims involved, the likelihood of success of our defenses to those claims, the damages or other relief sought, how discovery or other procedural considerations will affect the outcome, the settlement posture of other parties, and other factors that may have a material effect on the outcome. For such matters, unless otherwise specified, we do not believe it is possible to provide a meaningful estimate of loss at this time. Moreover, it is not uncommon for legal matters to be resolved over many years, during which time relevant developments and new information must be continuously evaluated.

Heller v. Ocean Biomedical, Inc. et al.:

On May 23, 2023, Jonathan Heller ("Heller") filed a civil action against the Company, Poseidon Bio LLC, Dr. Chirinjeev Kathuria and Elizabeth Ng (collectively, the "Defendants") in the District Court of Rhode Island. Heller has asserted claims alleging that he is entitled to earned salary and various other payments following his resignation from the Company. On July 27, 2023, Defendants filed their Answer and Affirmative Defenses. On September 3, 2024, Defendants filed a Motion to Dismiss numerous Counts included in the claims on the grounds that the Counts fail to state a claim upon which relief may be granted. If successful, this Motion would remove Dr. Kathuria and Ms. Ng as named defendants and will reduce the number of claims against the Company to three. The Court has not provided a hearing date for this Motion. The Company has concluded that a loss is probable and has recorded a liability of $0.5 million as of December 31, 2023 within Accounts Payable and Accrued Expenses on the consolidated balance sheets.

IPFS Corporation v. Ocean Biomedical, Inc.

On January 4, 2024, IPFS Corporation ("IPFS") filed an action against the Company in the U.S. District Court for the District of Delaware. IPFS claims amounts owed relating to financing provided to Aesther Healthcare Acquistion Corp for commercial insurance premiums in 2022, after the August 31, 2022 Merger Agreement but prior to closing of the Business Combination. IPFS filed a motion for a default judgment on February 16, 2024. Two default judgments have been entered in favor of IPFS; one entered April 19, 2024 related to the principal amount of $0.1 million and the other entered on May 21, 2024 related to costs and attorneys' fees incurred in the amount of $0.03 million. Both judgments accrue interest until paid. The Company has concluded that a loss is probable and has recorded a liability of $0.1 million as of December 31, 2023 within Accounts Payable and Accrued Expenses on the consolidated balance sheets.

Entoro Securities LLC v. Ocean Biomedical, Inc.

In June 2024, Entoro Securities LLC ("Entoro") filed an action against the Company in the Superior Court of Delaware. Entoro claims that its subcontractor introduced the Company to Aesther Healthcare Acquisition Corp. and claims that the Company is obligated to pay Entoro a finder's fee as a result of the Business Combination. Entoro seeks a finder's fee in the amount of $2 million and 4,750,000 shares of the Company's common stock. Discovery is underway. Based on the Company's investigation to date, the Company does not believe the allegations in the Complaint have merit. The Company has concluded at this time that a loss is not probable nor reasonably estimable, as such no liability has been recorded as of December 31, 2023.

Meteora Special Opportunity Fund I, LP, et al. v. Ocean Biomedical, Inc.

On May 22, 2024, Meteora Special Opportunity Fund I, LP, et al. (comprised of Meteora Special Opportunity Fund I, LP; Meteora Capital Partners, LP; and Meteora Select Trading Opportunities Master, LP, together "the Plaintiffs"), filed an action against the Company in the Supreme Court of the State of New York, New York County. The Plaintiffs claim that the Seller VWAP Triggering Event related to the Backstop Agreement as described in Note 2, Basis of Presentation and Summary of Significant Accounting Policies and Note 3, Business Combination and Backstop Agreement, occurred on November 3, 2023 when the Company's stock price traded below $4.00 per share for 30 of the preceding 45 trading days. The Plaintiffs set a Maturity Date for February 2024, at which time the Plaintiffs allege the entire Maturity Consideration became due and owed to the Plaintiffs in the amount of $6.3 million. The Company filed its opposition to the motion on September 6, 2024 and cross-moved for an extension of its time to answer or otherwise respond to the Complaint. Discussions with the Plaintiffs and the Court are on-going. The Company has concluded at this time that a loss is not probable nor reasonably estimable, as such no liability has been recorded as of December 31, 2023.

Leases

As of December 31, 2023, the Company is not a party to any leasing agreements.

License Fees

The Company has entered into license agreements with its academic research institution partners. Under these license agreements, the Company is required to make annual fixed license maintenance fee payments. The Company is also required to make payments upon successful completion and achievement of certain milestones as well as royalty payments upon sales of products covered by such licenses. The payment obligations under the license and collaboration agreements are contingent upon future events such as achievement of specified development, clinical, regulatory, and commercial milestones. As the timing of these future milestone payments are not known, the Company has not included these fees in the consolidated balance sheets as of December 31, 2023 and 2022.

For further discussion on license fees recorded during the period, refer to Note 12, *License and Manufacturing Agreements*.

Contingent Compensation and Other Contingent Payments

Under the management employment agreements, we have salaries and bonuses that are contingently payable upon financing, collectively called contingent compensation, that are contingently payable based only upon our first cumulative capital raise of at least $50 million. As of December 31, 2023, we have contingent compensation and bonuses in the amount of $12.4 million to certain members of senior management.

We also have $1.0 million of contingent vendor payments, which are also contingently payable based only upon our first cumulative capital raise of at least $50 million.

These amounts will not be paid if the contingencies do not occur. Since the payment of obligations under these agreements are contingent upon these future events, which are not considered probable as such future events are deemed outside of our control, we have not included these amounts in our consolidated financial statements. During the fiscal year ended December 31, 2023, $0.9 million of contingent compensation was paid and recorded in general and administrative expenses on the Company's consolidated statement of operations.

9. Equity

Common Stock

The holders of common stock of the Company are entitled to dividends when and if declared by the board of directors. The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. As of December 31, 2023, the Company had 300.0 million authorized shares with a par value of $0.0001 per share. As of December 31, 2022, the Company had 180.6 million authorized shares with a par value of $0.0001 per share.

Virion Contribution Agreement

On October 11, 2023, the Company entered into an Amended and Restated Contribution Agreement (the "Contribution Agreement") with Virion Therapeutics, LLC ("Virion") and Poseidon Bio LLC to provide financial, technical and operational assistance to further growth and development of Virion's Intelligent and Adaptable CD8+ T cell-based Immunotherapy ("VIACT") platform. Pursuant to the Contribution Agreement, the Company acquired a 50% membership interest in Virion and purchased one membership unit of Virion for an initial contribution of either a) $4.1 million in cash, or b) 750,000 shares of the Company's common stock, 250,000 of which were transferred to Virion by Poseidon Bio LLC, with the remaining 500,000 shares issued by the Company on December 1, 2023. The Company elected to fund the initial contribution via the issuance of shares of its common stock. In the case of an initial contribution in the form of shares of common stock, the Contribution Agreement provides for a post-closing true-up 18 months from the closing date, whereby the Company would be required to make a true-up contribution. This post-closing true-up amount would be equal to the difference between liquidation proceeds received by Virion from the sale of the 750,000 shares of common stock received in the initial contribution and $4.1 million. The post-closing true-up amount is payable, at the Company's discretion, in the form of additional shares of the Company's common stock, or cash. This investment has been reflected at the minimum amount to be contributed as of the post-closing true-up, or $4.1 million and is reflected in non-current assets on the Company's consolidated balance sheets as Investment in Virion. The Company initially recorded a liability of $2.8 million for the estimated amount of the post-closing true-up, reflecting the $4.1 million reduced by the fair market value of the common stock issued pursuant to the Contribution Agreement at the time of the contribution. The liability will remeasured at each reporting period and the Company will record any changes to other income/(expense) on the consolidated statement of operations. Based upon the closing price of the Company's common stock at December 31, 2023, the Company increased the liability for the post-closing true-up to $3.6 million and reflected and expense of $0.8 million for the change in the fair value of the Virion Contribution Liability in other income/(expense) on its consolidated statement of operations.

The investment in Virion is accounted for as an equity method investment under ASC 323 as the Company has significant influence over the investee. For the fiscal year ended December 31, 2023, Virion incurred a net loss of approximately $6.8 million. The Company recorded its share of this loss of approximately $0.8 million for its prorated share of the net loss from the date of Contribution Agreement thru December 31, 2023.

Stock Options

2022 Stock Option and Incentive Plan

The Company's Board of Directors ("the Board") approved and adopted the 2022 Stock Option and Incentive Plan and Form of Non-Qualified Stock Option Agreement for Non-Employee Directors (the "Incentive Plan") prior to the Closing of the Business Combination.

The maximum number of shares of common stock that may be initially issued or transferred pursuant to awards under the Incentive Plan equals 4,360,000 shares (the "Share Limit"). The Share Limit will automatically increase on the first trading day in January of each calendar year during the term of the Incentive Plan, with the first such increase to occur in January 2024, by an amount equal to the lesser of (i) three percent (3%) of the total number of shares of common stock issued and outstanding on December 31 of the immediately preceding calendar year or (ii) such number of shares of common stock as may be established by the Board.

The Incentive Plan authorizes stock options, stock appreciation rights, and other forms of awards granted or denominated in the Company's common stock or units of the Company's common stock, as well as cash bonus awards. The Incentive Plan retains flexibility to offer competitive incentives and to tailor benefits to specific needs and circumstances. Any award may be structured to be paid or settled in cash. Any awards under the Incentive Plan (including awards of stock options and stock appreciation rights) may be fully-vested at grant or may be subject to time- and/or performance-based vesting requirements.

The Incentive Plan does not limit the authority of the Board or any committee to grant awards or authorize any other compensation, with or without reference to the Company's common stock, under any other plan or authority. The Board may amend or terminate the Incentive Plan at any time and in any manner. Stockholder approval for an amendment will be required only to the extent then required by applicable law or deemed necessary or advisable by the Board. Unless terminated earlier by the Board and subject to any extension that may be approved by stockholders, the authority to grant new awards under the Incentive Plan will terminate on the tenth anniversary of its establishment.

Stock Options to Non-Employee Directors

Under the Non-employee Director Compensation Policy, upon initial election or appointment to the Board, each new nonemployee director will be granted under the Incentive Plan a one-time grant of a non-statutory stock option to purchase 75,000 shares of its common stock on the date of such director's election or appointment to the Board, issuable under the incentive plan. These will vest in substantially equal monthly installments over three years, subject to the director's continued service as a member of the Board through each applicable vesting date.

On February 15, 2023, 75,000 options were granted to each of the non-employee directors at a strike price of $10.00 per share.

The estimated fair value of a non-statutory stock option to purchase common stock on the grant date was $3.73 per share and was determined using the Black-Scholes Merton model. The valuation used the following assumptions:

Expected volatility: 75%

Expected term: 6.5 years

Risk-Free Interest Rate: 4%

Dividend Yield: The Company has not declared or paid dividends to date and does not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

The stock-based compensation expense recorded for the fiscal year ended December 31, 2023 was $0.6 million and was recorded within general and administrative expense in the Company's consolidated statements of operations, as discussed below.

The following table summarizes stock option activity during the fiscal year ended December 31, 2023:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2023	--	--	--	--
Options granted	600,000	$ 10.00	2.1	--
Options cancelled or forfeited	--	--	--	--
Outstanding at December 31, 2023	600,000	$ 10.00	2.1	--

The aggregate intrinsic value in the above table is calculated as the difference between the fair value of the Company's common stock as of December 31, 2023 and the exercise price of the stock options. As of December 31, 2023, the total unrecognized compensation related to unvested stock option awards granted was $1.6 million, which the Company expects to recognize over a weighted-average period of approximately 2.1 years. No stock options were exercised during the period.

2022 Employee Stock Purchase Plan

The Board approved and adopted the 2022 Employee Stock Purchase Plan (the "ESPP") prior to the Closing of the Business Combination.

Subject to adjustment, 2,180,000 shares of common stock are available for purchase pursuant to the exercise of options under the ESPP. Shares to be delivered upon exercise of options under the ESPP may be authorized but unissued stock, treasury stock, or stock acquired in an open-market transaction.

Subject to certain requirements and exceptions, all individuals classified as employees on the payroll records of the Company or its subsidiaries are eligible to participate in any one or more of the offerings under the ESPP.

The ESPP allows eligible employees to purchase shares of common stock during specified offering periods, with such offering periods not to exceed 27 months. During each offering period, eligible employees will be granted an option to purchase shares of common stock on the last business day of the offering period. The purchase price of each share of common stock issued pursuant to the exercise of an option under the ESPP on an exercise date will be 85% (or such greater percentage as specified by the administrator of the ESPP) of the lesser of: (a) the fair market value of a share of common stock date the option is granted, which will be the first day of the offering period, and (b) the fair market value of a share of common stock on the exercise date, which will the last business day of the offering period.

The Board has discretion to amend the ESPP to any extent and in any manner it may deem advisable, provided that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 of the U.S. Internal Revenue Code of 1986, as amended (the "Code") will require stockholder approval. The Board may suspend or terminate the ESPP at any time. No purchases were made as of December 31, 2023.

Profits Interests in Poseidon

Legacy Ocean's founder and then sole stockholder was issued 17,454,542 shares of Legacy Ocean's common stock ("Founders Shares") upon the formation of Legacy Ocean on January 2, 2019. After inception and prior to the Business Combination, the majority of the Founders Shares were contributed to Poseidon Bio, LLC ("Poseidon"), with Poseidon subsequently granting Class A and Class B profit interests to Legacy Ocean's founder and other certain executives and employees, respectively, and resulting in Legacy Ocean's founder holding 100% of the voting power of Poseidon. Further, after inception and prior to the Business Combination, Legacy Ocean implemented reverse stock splits which are appropriately reflected as applicable to the consolidated financial statements.

These profit interests grants to the Company's controlling shareholder were deemed to be transactions incurred by the shareholder and within the scope of ASC 718, *Stock Compensation*. As a result, the related transactions by the shareholder were pushed down into the Company's condensed consolidated financial statements. As of December 31, 2023, Legacy Ocean's founder held 100% of the voting power and 68% of the equity interests in Poseidon. The related stock-based compensation recognized is discussed below.

Stock-Based Compensation

The Company recognizes stock-based compensation costs for equity-based compensation awards granted to employees, nonemployees, and directors in accordance with U.S. GAAP. The Company estimates the fair value and the resulting amounts using the Black-Scholes option-pricing model. The fair value is recognized on a straight-line basis over the requisite service periods but accelerated to the extent that grants vest sooner than on a straight-line basis. Forfeitures are accounted for as they occur and requires management to make a number of other assumptions, including the volatility of the underlying shares, the risk-free interest rate, and expected dividends. Expected volatility is based on the historical share volatility of a set of comparable publicly traded companies over a period of time equal to the expected term of the grant or option.

Stock-based compensation for the fiscal year ended December 31, 2023 consisted of costs related to (i) stock options granted to non-employee directors in the first quarter of 2023 and (ii) warrants issued to advisors and consultants, as discussed below. Stock-based compensation for the fiscal year ended December 31, 2022 solely consisted of costs related to the profit interests in Poseidon.

The stock-based compensation allocation was based upon the grantees' vested interests and the amount of time spent in their respective operating department. The following table summarizes the allocation of stock-based compensation for the years ended December 31, 2023 and 2022:

(in thousands)	2023	2022
Research and development expense (1)	$ -	$ 8,231
General and administrative expense (2)	1,205	4,147
Total stock-based compensation expense	$ 1,205	$ 12,378

(1) As discussed above, certain executives and employees of the Company hold profit interests in Poseidon. The fair value of these profit interest was recorded on the grant dates at fair value utilizing an option-pricing model under which interests are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class, adjusted for a discount for the lack of marketability to account for a lack of access to an active public market. As of the end of fiscal 2022, the profit interests were fully amortized.

(2) In March 2023, the Company issued warrants to advisors and consultants as discussed below in Note 10, *Warrants*, which resulted in $0.6 million of stock-based compensation expense in 2023. Refer to discussion below for further detail. Also included in general and administrative expense is the stock-based compensation expense for the options awards to non-employee directors as discussed above.

As of December 31, 2023, there was $1.6 million of unamortized stock-based compensation expense, to be recognized over a weighted-average period of approximately 2.1 years.

10. Warrants

As of December 31, 2023 and 2022, the following warrants to purchase common stock were outstanding:

	December 31, 2023				
Lender/Name	**Issuance Date**	**Number of Shares Issuable**	**Exercise Price**	**Classification**	**Expiration**
Second Street Capital (1) (2)	February 2023	426,427	$ 8.06	(2)	3/8/2026
Second Street Capital (1)	February 2023	85,285	$ 8.06	Equity-classified	4/22/2026
Second Street Capital (1)	February 2023	102,342	$ 7.47	Equity-classified	9/30/2026
Second Street Capital	February 2023	75,000	$ 10.34	Equity-classified	2/15/2028
Second Street Capital	March 2023	200,000	$ 10.34	Equity-classified	3/29/2028
Second Street Capital	March 2023	150,000	$ 11.50	Equity-classified	3/31/2028
McKra Investments warrant	March 2023	200,000	$ 10.34	Equity-classified	3/28/2028
Special Forces F9 warrant	March 2023	150,000	$ 11.50	Equity-classified	3/7/2028
Public Warrants	(4)	5,250,000	$ 11.50	Equity-classified	2/14/2028
Private Warrants	(4)	5,411,000	$ 11.50	Equity-classified	2/14/2028
SPA Warrant (3)	May 2023	552,141	$ 11.50	Liability-classified	5/25/2028
		12,602,195			

	December 31, 2022				
Lender/Name	**Issuance Date**	**Number of Shares Issuable**	**Exercise Price**	**Classification**	**Expiration**
Second Street Capital (1) (2)	February 2022	312,500	$ 11.00	(2)	3/8/2026
Second Street Capital (1)	April 2022	62,500	$ 11.00	Equity-classified	4/22/2026
Second Street Capital (1)	September 2022	75,000	$ 10.20	Equity-classified	9/30/2026
		450,000			

(1) Upon Closing, and as discussed in Note 3, *Business Combination and Backstop Agreement*, Second Street Capital's warrants issued from Legacy Ocean in 2022 were terminated in exchange for the Converted Ocean Warrants.

(2) The Legacy Ocean warrant issued in February 2022 was issued with the right to put the warrant in exchange for a payment of $250,000. At the time of issuance, these warrants were recorded as a liability and as Second Street Capital had the intention to exercise the put option in the near-term, the Company determined that recording the liability at its fair value of $250,000 was appropriate.

(3) For further detail on the SPA Warrant, refer to Note 7, *Senior Secured Convertible Notes*.

(4) For further detail on the Public Warrants and Private Warrants, refer to the "Public and Private Warrants" discussion below.

In 2022 and 2023, the Company entered into certain agreements with Second Street Capital, Special Forces F9, LLC ("Special Forces"), and McKra for which it issued warrants exercisable to purchase the Company's common stock. For each of the warrants issued, the Company utilized the guidance within ASC 480, *Distinguishing Liabilities from Equity*, to determine whether the instruments should be recorded as liabilities or as equity. For warrants that are fully vested upon issuance with a fixed life term, the instrument is classified as equity and the Company recognizes the estimated fair value of the warrant within equity on the date of grant, with the offset be recorded within (i) other income/(expense) for those issued in conjunction with loans and (ii) stock-based compensation within operating expenses for those issued to advisors and consultants. Further, for any warrants that are issued in connection with a loan and are not fully vested upon issuance, the fair value of the debt issuance is amortized over the set term. The estimated fair value for the equity-classified warrants is determined utilizing the Black-Scholes Merton model, as described below. For the warrant with a put option, the Company recorded a corresponding liability in its consolidated balance sheets as discussed above.

In addition, the Company has Public Warrants and Private Warrants that were assumed in connection with the closing of the Business Combination. They are treated as equity-classified instruments, as discussed below.

The use of the Black-Scholes Merton model requires management to make the following assumptions:

Expected volatility: The Company estimates volatility for warrants issued by evaluating the average historical volatility of a peer group of companies for a period of time equal to the expected term of the warrants.

Expected term: Derived from the life of the warrants issued and is based on the simplified method which is essentially the weighted average of the vesting period and contractual term.

Risk-Free Interest Rate: The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues, with a term that is equal to the warrants' expected term at the grant date.

Dividend Yield: The Company has not declared or paid dividends to date and does not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

The fair value is recognized on a straight-line basis over the requisite service periods but accelerated to the extent that grants vest sooner than on a straight-line basis. Forfeitures are accounted for as they occur and requires management to make a number of other assumptions, including the volatility of the underlying shares, the risk-free interest rate, and expected dividends. Expected volatility is based on the historical share volatility of a set of comparable publicly traded companies over a period of time equal to the expected term of the grant.

Prior to the Business Combination, Legacy Ocean estimated the fair value of its common stock considering, among other things, contemporaneous valuations for its common stock prepared by third-party valuation firms and prices set forth in Legacy Ocean's previous filings with the SEC for a proposed IPO of its common stock that was not pursued by Legacy Ocean. Upon execution of the Business Combination Agreement in September 2022, the value of the Second Street Warrants was based on the closing price of AHAC's Class A common stock as reported on the Nasdaq Global Select Market on the grant date.

Following the Closing of the Business Combination, the value of warrants issued by the Company was based on the closing price of its common stock as reported on the Nasdaq Capital Market on the grant date. The Company estimates the fair value, based upon these values, using the Black-Scholes Merton model, which is affected principally by the life of the warrant, the volatility of the underlying shares, the risk-free interest rate, and expected dividends. Expected volatility is based on the historical share volatility of a set of comparable publicly traded companies over a period of time equal to the expected term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the warrant for time periods approximately equal to the expected term of the warrant. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company expenses the amount for warrants and stock-based awards within other income/(expense) and stock-based compensation within operating expenses, as applicable, in its consolidated statements of operations.

Second Street Warrants

In connection with the Second Street Loans discussed in Note 6, *Short-Term Loan Agreements*, the Company issued a total of eight warrants exercisable to purchase an aggregate of 1,039,054 shares of its common stock to Second Street Capital (including the Converted Ocean Warrants, as discussed above). During the fiscal years ended December 31, 2023 and 2022, the Company recognized $1.5 million and $0.8 million, respectively, in other income/(expense) in its consolidated statements of operations to record the issuance of warrants based on the estimated fair value of the awards on the date of grant.

The warrant issued in connection with the March Second Street Loan, exercisable for 200,000 shares of the Company's common stock, was treated as a debt discount and the respective fair value is being amortized over the life of the term of the loan. For those warrants issued in exchange for maturity extensions, the Company concluded that they met the accounting requirements for debt extinguishments and as such the fair values of the warrants, as well as related fees, were recorded in full to other income/(expense) in the period of issuance, with the offset to additional paid-in capital. As of December 31, 2023, all of the warrants remain outstanding.

McKra Investments III Warrant

In connection with the McKra Loan, discussed in Note 6, *Short-Term Loan Agreements,* the Company issued a warrant exercisable to purchase 200,000 shares of its common stock. The warrant is being treated as a debt discount and the fair value is being amortized over the life of the term of the warrant. During the fiscal year ended December 31, 2023, the Company recognized $0.8 million in other income/(expense) in its consolidated statements of operations based on the estimated fair value of the awards on the date of grant. As of December 31, 2023, the warrant remains outstanding.

Special Forces F9 Warrant

In connection with a strategic advisory agreement, dated March 19, 2023, between the Company and Special Forces, the Company issued to Special Forces a warrant to purchase 150,000 shares of its common stock with an exercise price of $11.50 per share exercisable until March 7, 2028. Warrants issued to advisors and consultants are also considered stock-based compensation. The estimated fair value of the warrant to purchase common stock on the grant date was $3.89 per share and was determined using the Black-Scholes Merton model.

In the first quarter of 2023, the full amount of the $0.6 million of the fair value of the warrant was recognized since the warrant was fully vested upon issuance. The fair value was recorded as stock-based compensation within general and administrative expense on the Company's consolidated statements of operations. As of December 31, 2023, the warrant remains outstanding.

SPA Warrant

In connection with the Ayrton Convertible Note Financing, the Company issued to an accredited investor a warrant exercisable for 552,141 shares of its common stock. Refer to Note 7, *Senior Secured Convertible Notes*, for further detail.

Public and Private Warrants

The Company has a total of 10,661,000 outstanding warrants to purchase one share of its common stock with an exercise price of $11.50 per share. Of these warrants, 5,250,000 were originally issued in AHAC's IPO (the "Public Warrants") and 5,411,000 were originally issued in a private placement in connection with the IPO (the "Private Warrants," and together with the Public Warrants, the "IPO Warrants").

Each whole IPO Warrant entitles the registered holder to purchase one share of common stock at a price of $11.50 per share, subject to adjustment as discussed within the underlying agreements, at any time commencing 30 days after the completion of the Business Combination. However, the IPO Warrants are not exercisable for cash unless the Company has an effective and current registration statement covering the shares of common stock issuable upon exercise of the IPO Warrants.

The Company may call the IPO Warrants for redemption, in whole and not in part, at a price of $0.01 per warrant:

- at any time after the warrants become exercisable;
- upon not less than 30 days' prior written notice of redemption to each warrant holder;
- if, and only if, the reported last sale price of the shares of common stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations and recapitalizations), for any 20 trading days within a 30-trading-day period commencing after the warrants become exercisable and ending on the third business day prior to the notice of redemption to warrant holders; and
- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants.

The right to exercise will be forfeited unless the IPO Warrants are exercised prior to the date specified in the notice of redemption. On and after the redemption date, a record holder of an IPO Warrant will have no further rights except to receive the redemption price for such holder's warrant upon surrender of such warrant. If the Company calls the IPO Warrants for redemption as described above, its management will have the option to require all holders that wish to exercise warrants to do so on a "cashless basis." In such event, each holder would pay the exercise price by surrendering the warrants for that number of shares of the Company's common stock equal to the quotient obtained by dividing (x) the product of the number of shares of common stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" for this purpose shall mean the average reported last sale price of the shares of common stock for the five trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants.

For accounting purposes, the Company accounts for the IPO Warrants (i) in accordance with the guidance contained in ASC 480-10-25-8 and ASC 815-40 and (ii) classified as an equity instrument. The fair values of the IPO Warrants were accounted for as deemed dividends. Since the entries to recognize the fair value of the IPO Warrants offset within additional paid-in capital, there is no inherent impact to the consolidated financial statements.

Additional Share Consideration

In connection with a Marketing Services Agreement, dated March 7, 2023, between the Company and Outside The Box Capital ("OTBC"), the Company issued to OTBC 13,257 shares of its common stock as consideration, pursuant to the Marketing Services Agreement, in the second quarter of 2023. The fair value of this stock issuance of $0.1 million was recorded within other income/(expense) in the Company's consolidated statements of operations.

11. Net loss Per Share

The Company computes basic loss per share using net loss attributable to stockholders and the weighted-average number of the Company's common stock shares outstanding during each period, less shares subject to repurchase under the Backstop Agreement. Diluted earnings per share include shares issuable upon exercise of outstanding stock options and stock-based awards where the conversion of such instruments would be dilutive. The Company's potentially dilutive securities, which include stock options, earnout shares, and warrants to purchase shares of common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to the Company's stockholders' is the same.

The net loss per share for the basic and diluted earnings calculations for the fiscal years ended December 31, 2023 and 2022 is as follows (in thousands, except share and per share data):

	2023	2022
Numerator:		
Net loss	$ (114,466)	$ (17,359)
Denominator:		
Weighted-average shares of common stock outstanding, basic and diluted	26,292,438	23,355,432
Net loss per common share, basic and diluted	$ (4.35)	$ (0.74)

As noted above, the following securities were excluded from the computation of diluted loss per share in the periods presented, as their effect would be anti-dilutive:

	2023	2022
Stock options	600,000	-
Warrants to purchase common stock	12,602,195	450,000

12. Income Taxes

Provision for income taxes

There is no provision for income taxes because the Company has incurred operating losses and capitalized certain items for income tax purposes since its inception and maintains a full valuation allowance against its net deferred tax assets. The reported amount of income tax expense for the period differs from the amount that would result from applying the federal statutory tax rate to net loss before taxes primarily because of the change in valuation allowance.

	For the Year Ended	
	December 31, 2023	December 31, 2022
Statutory federal income tax rate	21.0%	21.0%
Permanent items	(18.7)%	0.0%
Change in valuation allowance	(2.3)%	(21.0)%
Income tax provision (benefit)	0.0%	0.0%

Deferred tax assets and valuation allowance

Deferred tax assets reflect the tax effects of net operating losses, tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. At December 31, 2023 and 2022, the Company's deferred tax assets are the tax effects of amortization of organization and start-up costs, U.S. federal and state NOL carryforwards, and stock-based compensation.

The significant components of the net deferred tax assets are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Organization and start-up costs	$ 42	$ 46
Net operating loss carryforwards	5,962	1,338
Stock-based compensation	14,728	14,475
Losses-put option and warrant issuance	-	226
R&D tax credits	28	-
Total deferred income tax assets	20,760	16,085
Valuation allowance	(20,760)	(16,085)
Deferred tax asset, net of allowance	$ —	$ —

The Company may be entitled to claim additional federal and state income tax credits for its 2023 R&D activities, but these amounts have not yet been determined. Any R&D Credits generated by the Company in 2023 would result in an additional deferred tax asset that would be subject to a full valuation allowance. Future changes in ownership may limit the utilization of net operating loss carryforwards and R&D Credits due to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar provisions.

13. License and Manufacturing Agreements

Elkurt/Brown License Agreements

In 2020, the Company entered into four separate Exclusive License Agreements (the "Initial Brown License Agreements") with Elkurt, Inc.("Elkurt"), a licensee of Brown University, which were subsequently amended in 2022 and 2023. Elkurt is a company formed by the Company's scientific co-founders and members of our Board, Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., PhD, Chair of the Department of Pathology and Laboratory Medicine at Brown University. Under the Initial Brown License Agreements, Elkurt grants the Company exclusive, royalty-bearing licenses to patent rights and nonexclusive, royalty-bearing licenses to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in certain fields.

The latest amendment, executed on November 13, 2023, (i) extended the date after which Elkurt can terminate the license agreements if the Company has not raised at least $10.0 million in equity financing by May 1, 2024 and (ii) extended the dates of the commercialization plan of the license agreement to an additional three years.

For each of the Initial Brown License Agreements, as amended, the Company is required to pay Elkurt (i) a maintenance fee of $67,000 increased by interest at the rate of 1% per month from October 15, 2021 until paid and (ii) an annual license maintenance fee of $3,000 beginning on January 1, 2022, which increases to $4,000 on January 1, 2028. In addition, upon successful commercialization, the Company is required to pay Elkurt (i) between 0.5% to 1.5% of net sales based on the terms of each of the Initial Brown License Agreements and (ii) 25% of all non-royalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that the Company enters into sublicenses for the subject intellectual property. If net sales or non-royalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or nonroyalty sublicense income) shall be reduced by 50%. For the fiscal years ended December 31, 2023 and 2022, the Company recorded annual license maintenance fees of $12,000 in each year. For the fiscal year ended December 31, 2023, the Company recorded license fees of $0.3 million.

The Company is also required to pay Elkurt developmental and commercialization milestone payments for each of the Initial Brown License Agreements ranging from $50,000 for the filing of an Investigational New Drug Application ("IND"), or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. The Company is also responsible for reimbursement of patent costs. The Company records reimbursement of patent costs as general and administrative costs in the consolidated statements of operations as incurred. For the fiscal years ended December 31, 2023 and 2022, the Company incurred reimbursed patent costs expenses to Brown University in the amount of $0.1 million and $0.2 million, respectively. As of December 31, 2023, the Company reflected a balance due of $0.1 million in accrued expenses – related parties on its consolidated balance sheet.

The contract term for each of the Initial Brown License Agreements, as amended, continues until the later of (i) the date on which the last valid claim expires or (ii) ten years. Either party may terminate each of the Initial Brown License Agreements in certain situations, including Elkurt being able to terminate the Initial Brown License Agreements at any time and for any reason after May 1, 2024, as discussed above. For the oncology programs, three of the license agreements have been sublicensed to the Company's subsidiary, Ocean ChitoRx Inc, and for the fibrosis program, one license agreement has been sublicensed to the Company's subsidiary, Ocean ChitofibroRx Inc.

Brown Anti-PfGARP Small Molecules License Agreement

On September 13, 2022, the Company entered into an additional Exclusive License Agreement (the "Brown Anti-PfGARP Small Molecules License Agreement") with Elkurt. Under the Brown Anti-PfGARP Small Molecules License Agreement, Elkurt grants the Company an exclusive, royalty-bearing license to patent rights and a nonexclusive, royalty-bearing license to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in the field of malaria research.

For the Brown Anti-PfGARP Small Molecules License Agreement, the Company is required to pay Elkurt (i) an initial license fee of $70,000 which was paid during the second quarter of 2023 and (ii) an annual license maintenance fee of $3,000 beginning on September 13, 2023, which increases to $4,000 annually on September 13, 2028. Upon successful commercialization, based on the terms of the agreement, the Company is required to pay Elkurt (i) 1.25% of net sales and (ii) 25% of all nonroyalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that the Company enters into sublicenses for the subject intellectual property. If net sales or non-royalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or non-royalty sublicense income) shall be reduced by 50%. The Company also is required to pay Elkurt $0.1 million in the event that the Company or one of its sublicensees sublicenses this technology to a major pharmaceutical company or if the license agreement or any sublicense agreement for this technology is acquired by a major pharmaceutical company. A major pharmaceutical company is one that is publicly traded, with market capitalization of at least $5.0 billion and has been engaged in drug discovery, development, production and marketing for no less than 5 years.

The Company is also required to pay Elkurt developmental and commercialization milestone payments pursuant to the Brown Anti-PfGARP Small Molecules License Agreement ranging from $50,000 for the filing of an IND, or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. The Company is also responsible for reimbursement of patent costs.

The contract term for the Brown Anti-PfGARP Small Molecules License Agreement continues until the later of (i) the date on which the last valid claim expires or (ii) ten years. Either party may terminate the Brown Anti-PfGARP Small Molecules License Agreement in certain situations, including Elkurt being able to terminate the Brown Anti-PfGARP Small Molecules License Agreement at any time and for any reason after May 1, 2024 if the Company has not raised at least $10.0 million in equity financing by then.

Refer to Note 13, *Related Party Transactions*, for further detail on the Company's relationship to Elkurt.

Rhode Island License Agreement

In January 2021, the Company entered into an Exclusive License Agreement (the "Rhode Island License Agreement") with Elkurt, a licensee of Rhode Island Hospital, as subsequently amended throughout that year. Under the Rhode Island License Agreement, as amended, Elkurt grants the Company an exclusive, royalty-bearing license to patent rights and a nonexclusive, royalty-bearing license to know-how, solely to make, have made, market, offer for sale, use, and sell licensed products for use in a certain field.

For the Rhode Island License Agreement, the Company was required to pay Elkurt (i) $0.1 million, due within 45 days of an equity financing of at least $10.0 million or November 1, 2023, whichever comes first, and (i) an annual maintenance fee of $3,000 beginning on January 1, 2022, which increases to $4,000 annually on January 1, 2028.

Upon successful commercialization, under the terms of the agreement, the Company is also required to pay Elkurt (i) 1.5% of net sales and (ii) 25% of all nonroyalty sublicense income prior to the first commercial sale, and 10% of non-royalty sublicense income thereafter, in the event that the Company enters into sublicenses for the subject intellectual property. If net sales or nonroyalty sublicense income are generated from know-how products, the amounts otherwise due (royalty or non-royalty sublicense income) shall be reduced by 50%. The Company is also required to pay Elkurt developmental and commercialization milestone payments under the Rhode Island License Agreement, ranging from $50,000 for the filing of an IND, or the equivalent outside of the United States, to $0.3 million for enrollment of the first patient in a Phase 3 clinical trial in the United States or the equivalent outside of the United States. For the fiscal years ended December 31, 2023 and 2022, the Company has incurred reimbursed patent costs expenses to Rhode Island Hospital in the amount of $0.1 million and $0.3 million, respectively. As of December 31, 2023, the Company reflected a balance due of $0.2 million in accrued expenses – related parties on its consolidated balance sheet.

The contract term for the Rhode Island License Agreement began January 1, 2021 and will continue until the later of (i) the date on which the last valid claim expires or (ii) fifteen years. Either party may terminate the Rhode Island License Agreement in certain situations, and as discussed above, the next steps for the licensing agreements are still being negotiated. The Rhode Island License Agreement has been sublicensed to the Company's subsidiary, Ocean Sihoma Inc.

Refer to Note 13, *Related Party Transactions*, for further detail on the Company's relationship to Elkurt.

Development and Manufacturing Services Agreement

In December 2020, the Company entered into a Development and Manufacturing Services Agreement with Lonza AG and affiliate Lonza Sales AG ("Lonza"). The Company engaged Lonza pursuant to the development and manufacture of certain products and services along with the assistance in developing the product OCX-253. The agreement outlines the pricing for services and raw materials as incurred and payment terms. For the fiscal years ended December 31, 2023 and 2022, the Company has incurred expenses under this agreement of $0.2 million and $0.1 million, respectively. These costs are reflected in research and development costs on the Company's consolidated statement of operations.

The Development and Manufacturing Services Agreement will terminate on December 31, 2025. Either party may terminate the agreement within 60 days after it becomes apparent to either party that it will not be possible to complete the services for a scientific or technical reason after a good faith effort is made to resolve such problems. The agreement may be terminated by either party, immediately for any uncured material breach, insolvency, or liquidation. In the event of termination, the Company will pay Lonza all costs incurred through the termination date.

14. Related Party Transactions

License Agreements with Elkurt, Inc.

Elkurt/Brown Licenses

The Company is party to the License Agreements between Elkurt and Brown and the License Agreements between Elkurt and Rhode Island Hospital (see Note 12 *Licensing and Manufacturing Agreements* above). Elkurt is a company formed by the Company's scientific co-founders Jack A. Elias, M.D., former Dean of Medicine and current Special Advisor for Health Affairs to Brown University, and Jonathan Kurtis, M.D., PhD, Chair of the Department of Pathology and Laboratory Medicine at Brown University. Dr. Elias and Dr. Kurtis are members of the Company's Board.

Transactions with Legacy Ocean's Founder and Executive Chairman

The Legacy Ocean founder and executive chairman had paid certain expenses on behalf of the Company. He is reimbursed when the Company has sufficient working capital to do so. As of December 31, 2023, the amount due for these expenses was $0.1 million. These amounts were recorded as accrued expenses – related party on the consolidated balance sheets.

Transactions with Chief Accounting Officer

The Company's former Chief Accounting Officer previously provided consulting services to the Company with RJS Consulting, LLC, his wholly owned limited liability company through June 15, 2021, before becoming the Company's Chief Accounting Officer. As of December 31, 2023 and 2022, the Company owed RJS Consulting, LLC $0.2 million. The amounts were recorded as accounts payable on the consolidated balance sheets and were expensed as accounting fees in general and administrative expenses in 2021.

Transactions with Virion

As discussed in Note 9 – *Equity*, the Company entered into the Contribution Agreement with Virion on October 11, 2023, resulting in the Company acquiring a 50% membership interest in Virion. As a result, Virion is considered a related party, however, as of December 31, 2023 the Company has not engaged in any transactions with Virion with the exception of the Contribution Agreement.

15. Subsequent Events

The Company has evaluated subsequent events through November 25, 2024, the date that these consolidated financial statements were issued. Except for the matters disclosed below, no additional subsequent events had occurred that would require recognition or disclosure in these consolidated financial statements.

2023 Convertible Note

Between March 4, 2024 and March 8, 2024, the holder of the Company's 2023 Convertible Note sent Alternate Conversion Notices to the Company to convert the principal value and accrued and unpaid interest into shares of the Company's common stock pursuant to the Alternate Conversion Price mechanism in the 2023 Convertible Note. The Company is currently evaluating the situation and working with the noteholder to arrive at an equitable resolution.

Effective July 23, 2024, the Company entered into further arrangements to fund up to an additional $7.7 million in additional secured notes (the "2024 Notes") in conjunction with the 2023 Convertible Note. The first tranche of $1.1 million was funded to various vendors on behalf of the Company to address costs of the Company in preparing its 2023 financial statements and subsequent quarterly reporting requirements, among other things. The balance of the funds shall be released by the investor upon the Company reaching certain milestones over the next several months.

All prior defaults under the existing transaction documents have been deemed cured, and there is a late filing carveout until August 15, 2024. The current Notes have had an extension of the maturity date until December 15, 2024 and installment payments have been waived until the earlier of the date on which the Company's 2023 Form 10-K is filed and September 1, 2024, with subsequent installments continuing to be due on the first of each month thereafter. No payments have been made.

The Company shall issue to the investor 3,844,466 restricted shares of its common stock in settlement of all past defaults and penalty shares to be issued in conjunction therewith, subject to a leak out of 15% of daily trading value unless the sales price of such shares is above $5.00 per share. The Company is also issuing the investor 1,332,806 warrants which shall be exchangeable on a one for one basis into restricted shares of common stock on or after August 1, 2024.

The Company also confirmed that the principal amount of the Existing Note is $9.7 million, after giving effect to the Event of Default Interest to date and Redemption Premium.

As part of the agreement, Chirinjeev Kathuria, the Company's Chairman, and Poseidon Bio, LLC, an entity controlled by Dr. Kathuria, also agreed to grant a proxy on all of their shares of the Company's common stock to an independent third party, to vote them as that party sees fit, until such time as the Notes are paid in full.

On November 22, 2024, the Company issued a Note to an institutional investor upon the same terms as those notes issued in the July 23, 2024 transaction. The principal amount of the Note is $2,712,214, and the purchase price is $2,511,225.70. In conjunction therewith, the Company also lowered the conversion price on $25,000 of its Existing Notes to $0.01 per share, and it issued a warrant to the investor for 1,580,975 shares of its common stock.

All securities are being issued in private placement transactions exempt from registration under Section 4(a)(2) under the Securities Exchange Act of 1934 as amended.

Amendment to Earnout Shares Agreement

Pursuant to the Business Combination Agreement, the Company's premerger shareholders were to receive up to 19,000,000 shares of the Company's common stock in three tranches over a three year period, assuming the Company reached certain milestones. The Company's Board has amended this agreement so that the Earnout Shares are to be issued in restricted shares in three tranches of 6,000,000 shares each, with the first tranche to be issued in the near future (the "initial issuance") and the remaining tranches to be issued on the first and second year anniversaries of the date of the initial issuance. Additionally, the Sponsor will be issued 1,000,000 shares of the Company's stock for each issuance of Earnout Shares, as contemplated in the Business Combination Agreement.

All securities are being issued in private placement transactions exempt from registration under Section 4(a)(2) under the Securities Exchange Act of 1934 as amended.

Issuance of Shares in Payment of Note

In 2024, the Company entered into a settlement agreement with Second Street Capital and McKra Investments III with regard to $2.7 million principal amount of promissory notes, plus accrued and unpaid interest and fees. The Company will satisfy payment of past due loan fees by the issuance of 225,000 shares of restricted common stock. The Company will also satisfy the amount due for the principal amount of the notes and accrued and unpaid interest through (i) the issuance of $1.7 million worth of restricted common stock (at a price per share equal to the 30 day vwap of a share of Company common stock as of July 22, 2024), and (ii) payment of the remaining balance of $1.7 million in cash at the time of closing of the Company's next financing with net proceeds to the Company of more than $10 million either in a public offering or private transaction, or if such a closing does not occur on or before September 30, 2024, in shares of restricted Common Stock of the Company (at a price per share equal to the 30 day vwap of a share of Company common stock as of September 30, 2024). Since the Company did not close a financing with net proceeds to the Company of more than $10 million prior to September 30, 2024, the Company did not pay the remaining balance of $1.7 million in cash.

All securities are being issued in private placement transactions exempt from registration under Section 4(a)(2) under the Securities Exchange Act of 1934 as amended.

Virion Agreement

In September 2024, the Company entered into an amendment to the contribution agreement with Virion. In the amendment, the Company agreed to contribute $9.0 million in cash and/or shares of the Company's common stock (the "Aggregate Capital Contribution") in exchange for additional limited liability company units in an amount sufficient to cause the Company's ownership interest in Virion to equal 22% of Virion's issued and outstanding membership units, on a fully diluted basis. The Aggregate Capital Contribution will be credited for: a) $1.0 million for amounts already received by Virion in connection with the original contribution agreement; and b) the aggregate proceeds actually received by Virion in connection with the sale of 500,000 shares of the Company's common stock. If the actual cash received by Virion from the proceeds of the sale of the Company's shares of common stock (the "Actual Contributions") does not equal the Aggregate Capital Contribution as of April 1, 2025 (the "Final Contribution Date"), the Company shall have the option, but not the obligation, to make additional capital contributions to Virion, up to an amount equal to the difference between the Aggregate Capital Contributions and the Actual Contributions (the "Final Contribution Amount"). The Final Contribution Amount may be paid, at the Company's election, in cash, through the issuance of additional shares of the Company's common stock or a combination of both and shall be made no later than 1 business day following the "Final Contribution Date"). The ownership interest of Virion held by the Company shall be determined based upon the Actual Contributions made, plus any Final Contribution paid to Virion as of the date such calculation is made.

On November 13, 2024, the Company received a notice of default with regard to its 2023 promissory note with EF Hutton, which alleges that $2,076,223.64 is due under the promissory note.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws to be in effect immediately prior to the completion of this offering that limit or eliminate the personal liability of our directors and officers to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director or officer, except for liability for:

- any breach of the director's or an officer's duty of loyalty to us or our stockholders; any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director or officer liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

On February 14, 2023, we entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director or officer. Nonetheless, our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We will maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by us, Aesther and Legacy Ocean within the three years preceding the filing of this registration statement that were not registered under the Securities Act. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(a) Issuances of Capital Stock

In September 2021, the Sponsor purchased an aggregate of 2,625,000 shares of Aesther's Class B common stock, par value $0.0001 per share, for an aggregate offering price of $25,000. These securities were issued pursuant to Section 4(a)(2) of the Securities Act.

In March and April 2021, Legacy Ocean issued 41,828 shares of its common stock to certain persons who were accredited investors (consisting of friends and family of our employees), at an aggregate offering price of $1.0 million. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Closing of the Business Combination, on February 14, 2023, the Company, Legacy Ocean and Polar entered into a subscription agreement in which Polar agreed to purchase 1,350,000 newly-issued shares of our Common Stock at a per share purchase price of $10.56 and an aggregate purchase price of $14.3 million (the "Polar Subscription"). The Polar Subscription was the method by which Polar exercised its right to purchase "Additional Shares" pursuant to the Backstop Agreement to which Polar acquired a portion of the rights from Vellar pursuant to the Polar Agreement. The shares acquired by Polar as part of the Polar Subscription are subject to the restrictions for "Additional Shares" set forth in the Backstop Agreement. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Closing of the Business Combination, on February 14, 2023, the registrant issued to Sponsor 1,365,000 shares of Aesther's Class A common stock in connection with Sponsor obtaining two (2) three-month extensions beyond the September 16, 2022 deadline to complete an initial business combination. Such shares were reclassified as Ocean Biomedical Common Stock in connection with the Business Combination pursuant to the Amended Certificate. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Loan Modification Agreement, on March 22, 2023, we issued to NPIC Limited 50,000 shares of our Common Stock in exchange for the extension of the maturity date of the loan made pursuant to the Loan and Transfer Agreement between the registrant, the Sponsor and NPIC Limited dated December 13, 2022. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Loan Modification Agreement, on April 19, 2023, we issued to NPIC Limited an additional 50,000 shares of our Common Stock in exchange for the extension of the maturity date of the loan made pursuant to the Loan and Transfer Agreement between the registrant, the Sponsor and NPIC Limited dated December 13, 2022. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Loan Modification Agreement, on May 12, 2023, we issued to NPIC Limited an additional 50,000 shares of our Common Stock in exchange for the extension of the maturity date of the loan made pursuant to the Loan and Transfer Agreement between the registrant, the Sponsor and NPIC Limited dated December 13, 2022. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Marketing Services Agreement, dated March 7, 2023, between us and Outside The Box Capital ("OTBC"), we issued to OTBC 13,257 shares of our Common Stock as consideration, pursuant to the Marketing Services Agreement, in May 2023.

In connection with the McKra Loan Amendment, on June 5, 2023, we issued to McKra 25,000 shares of our Common Stock in exchange for the extension of the maturity date of the loan made pursuant to the McKra Loan. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

In connection with the Second Street Loans Amendment, on June 5, 2023, we issued to Second Street Capital 25,000 shares of our Common Stock in exchange for the extension of the maturity dates of the loans made pursuant to the Second Street Loan, the Second Street Loan 2, and the March Second Street Loan. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

(b) Issuance of Warrants

On September 17, 2021, Aesther issued 5,411,000 Private Placement Warrants to purchase shares of Aesther Class A common stock to Sponsor for aggregate gross proceeds of $5.4 million.

On February 22, 2022, Legacy Ocean entered into a Loan Agreement with Second Street Capital (the "February 2022 Second Street Loan"), where Legacy Ocean borrowed $0.6 million, which was used to pay a $15,000 loan fee and certain accrued expenses of Legacy Ocean. The February 2022 Second Street Loan accrues interest at the rate of 15% per annum, with principal and interest due at maturity. Legacy Ocean was required to repay the February 2022 Second Street Loan on the earlier of (i) 5 business days after Legacy Ocean's next financing or (ii) May 23, 2022. Legacy Ocean issued to Second Street Capital a warrant to purchase 312,500 shares of Legacy Ocean's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. For a period of 180 days from the closing of our next financing, Second Street Capital has the right to put the warrants to us in exchange for a payment of $0.3 million. On April 22, 2022, the February 2022 Second Street Loan was amended whereas the maturity date was extended from May 23, 2022 to November 18, 2022. Legacy Ocean recognized a loss and recorded the liability of $0.3 million for the put option in its consolidated financial statements for the period ended September 30, 2022.

In April 2022, Legacy Ocean entered into a second Loan Agreement with Second Street Capital (the "April 2022 Second Street Loan"), where Legacy Ocean borrowed $0.2 million, which was used to pay a $15,000 loan fee, $15,000 fee for amending the February 2022 Second Street Loan to extend the maturity date, and $20,000 next day loan fee. The April 2022 Second Street Loan accrues interest at the rate of 15% per annum, with principal and interest due at maturity. Legacy Ocean issued to Second Street Capital a warrant to purchase 62,500 shares of Legacy Ocean's common stock, with an exercise price of $11.00 per share, exercisable until February 22, 2026. There is no put option associated with this loan. Legacy Ocean was required to repay the April 2022 Second Street Loan on the earlier of (i) 5 business days after Legacy Ocean's next financing or (ii) November 18, 2022. Legacy Ocean recognized a loss of $388,938 for the warrant issued based on the estimated fair value of the awards on the date of grant in Legacy Ocean's consolidated financial statements for the period ended September 30, 2022.

On September 30, 2022, the February 2022 Second Street Loan and April 2022 Second Street Loan were amended whereas the maturity date was extended from November 18, 2022 to December 30, 2022. In consideration of the extension, Legacy Ocean issued to Second Street Capital a warrant to purchase 75,000 shares of Legacy Ocean's common stock with an exercise price of $10.20 per share exercisable until September 30, 2026. Legacy Ocean recognized a loss of $0.4 million for the warrant issued based on the estimated fair value of the awards on the date of the grant in Legacy Ocean's consolidated financial statements for the period ended September 30, 2022. Legacy Ocean recognized a total expense in the amount of $1.1 million of which $0.3 million was for the put option and $0.8 million was for the warrants issued for the fiscal year end December 31, 2022.

On November 17, 2022, Legacy Ocean, Aesther and Second Street Capital entered into a Warrant Exchange Agreement, pursuant to which Legacy Ocean and Aesther agreed as of the Closing of the Business Combination to replace the warrants previously issued by Legacy Ocean to Second Street Capital with new warrants. As of the Closing, the new warrants consisted of three warrants for the number of shares of common stock equal to the economic value of the warrants previously issued to Second Street Capital in exchange for the termination of such previously issued warrants. The new warrants are exercisable for a total of 511,712 shares of our Common Stock at an exercise price of $8.06 per share and 102,342 shares of our Common Stock at an exercise price of $7.47 per share. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

On February 15, 2023, the February 2022 Second Street Loan and April 2022 Second Street Loan were further amended whereas the maturity dates were extended from February 15, 2023 to March 31, 2023. We were required to repay the principal and accrued interest of the February 2022 Second Street Loan and April 2022 Second Street Loan the earlier of (i) 5 business days after our next financing or closing of the Business Combination or (ii) March 31, 2023. In consideration of the extension of the February 2022 Second Street Loan, we paid a $50,000 extension fee and issued to Second Street Capital a warrant to purchase 50,000 shares of our Common Stock with an exercise price of $10.34 per share exercisable until February 15, 2028. In consideration of the extension of the April 2022 Second Street Loan, we paid a $25,000 extension fee and issued to Second Street Capital a warrant to purchase 25,000 shares of our Common Stock with an exercise price of $10.34 per share exercisable until February 15, 2028. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

Dated as of March 19, 2023, we entered into a Strategic Advisory Agreement with Special Forces F9, LLC ("Special Forces"). We issued a warrant to Special Forces for 150,000 shares of our Common Stock, exercisable until March 7, 2028 at an exercise price of $11.50 per share. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

Dated as of March 28, 2023, we entered into a Loan Agreement with McKra Investments III pursuant to which we borrowed $1.0 million to pay certain accrued expenses. The loan bears interest at 15% per annum and is due within three business days of our next financing or receipt of proceeds from the Backstop Agreement or, if earlier, 45 days from the date of the advance. We issued a warrant to the lender for 200,000 shares of our Common Stock, exercisable for five years at an exercise price of $10.34 and will pay $0.2 million in loan fees at maturity. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

Dated as of March 29, 2023, we entered into a Loan Agreement with Second Street Capital pursuant to which we borrowed $1 million to pay certain accrued expenses. The loan bears interest at 15% per annum and is due within three business days of our next financing or receipt of proceeds from the Backstop Agreement or, if earlier, 45 days from the date of the advance. We issued a warrant to the lender for 200,000 shares of our Common Stock, exercisable for five years at an exercise price of $10.34 and will pay $0.2 million in loan fees at maturity. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

On March 31, 2023, the February 2022 Second Street Loan and April 2022 Second Street Loan were further amended whereas the maturity dates were extended from March 31, 2023 to May 31, 2023. We were required to repay the principal and accrued interest of the February 2022 Second Street Loan and April 2022 Second Street Loan the earlier of (i) 5 business days after our next financing or closing of the Business Combination or (ii) March 31, 2023. In consideration of the extension of the February 2022 Second Street Loan, we paid a $60,000 extension fee and issued to Second Street Capital a warrant to purchase 100,000 shares of our Common Stock with an exercise price of $11.50 per share that expires in five years. In consideration of the extension of the April 2022 Second Street Loan, we paid a $35,000 extension fee and issued to Second Street Capital a warrant to purchase 50,000 shares of our Common Stock with an exercise price of $11.50 per share that expires in five years. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

On May 25, 2023, we issued a warrant to Alto Opportunity Master Fund, SPC – Segregated Master Portfolio B (the "Ayrton Warrant") in connection with the Ayrton Convertible Note Financing. The Ayrton Warrant is exercisable for 552,141 shares of our Common Stock at an exercise price of $11.50 per share, exercisable until May 25, 2028. The warrant can be exercised by payment of the exercise price or through a cashless exercise if, at the time of exercise, a registration statement is not effective (or the prospectus contained therein is not available for use) for the resale by the holder of all of the shares underlying the warrant. These transactions were effected without registration under the Securities Act in reliance on the exemption from registration provided under Section 4(a)(2) promulgated thereunder.

Elkurt Brown License Agreements: On June 13, 2024, we amended the Initial Brown License Agreements such that $0.2 million of past due license fees were paid on July 17, 2024, and $0.2 million of past due license fees and $0.1 million in past due patent expenses were to be paid by October 1, 2024, which remain unpaid and are subject to negotiation between the parties.

Elkurt RIH License Agreements: Only July 17, 2024, we entered into an amendment to pay $0.1 million by July 22, 2024, which was paid.

(c) Grants and Exercises of Stock Options and Restricted Stock

None.

SIGNATURES

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

November 25, 2024

Ocean Biomedical, Inc.

By: */s/ Michelle Berrey*
Name: Michelle Berrey
Title: Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Elizabeth Ng and Jolie Kahn, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Michelle Berrey Michelle Berrey	Director and Chief Executive Officer *(Principal Executive Officer)*	November 25, 2024
/s/ Jolie Kahn Jolie Kahn	Chief Financial Officer *(Principal Financial Officer)*	November 25, 2024
/s/ Chirinjeev Kathuria Chirinjeev Kathuria	Director	November 25, 2024
/s/ Jack A. Elias Jack A. Elias	Director	November 25, 2024
/s/ Elizabeth Ng Elizabeth Ng	Director	November 25, 2024
/s/ Jonathan Kurtis Jonathan Kurtis	Director	November 25, 2024
/s/ Amy Griffith Amy Griffith	Director	November 25, 2024
/s/ Michael L. Peterson Michael L. Peterson	Director	November 25, 2024
/s/ Michelle Berrey Michelle Berrey	CEO and Director	November 25, 2024
/s/ Suren Ajjarapu Suren Ajjarapu	Director	November 25, 2024
/s/ William Owens William Owens	Director	November 25, 2024

Exhibit 31.1

Certification of Chief Executive Officer

I, Michelle Berrey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ocean Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 25, 2024

/s/ Michelle Berrey

Michelle Berrey
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer

I, Jolie Kahn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ocean Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 25, 2024

/s/ Jolie Kahn

Jolie Kahn
Chief Financial Officer (Principal Accounting/Financial Officer)

Exhibit 32.1

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

I, Elizabeth Ng, Chief Executive Officer of Ocean Biomedical, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Annual Report on Form 10-K of Ocean Biomedical, Inc. for the year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, and

(ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Dated: November 25, 2024

/s/ Michelle Berrey
Michelle Berrey
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

I, Jolie Kahn, Chief Financial Officer of Ocean Biomedical, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

(i) The Annual Report on Form 10-K of Ocean Biomedical, Inc. for the year ended December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, and

(ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Dated: November 25, 2024

/s/ Jolie Kahn
Jolie Kahn
Chief Financial Officer
(Principal Accounting/Financial Officer)