PHARMACYTE BIOTECH

2024 ANNUAL REPORT

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended April 30, 2024

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-40699

PHARMACYTE BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Nevada	**62-1772151**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3960 Howard Hughes Parkway, Suite 500 **Las Vegas, NV 89169**	
(Address of principal executive offices)	**(917) 595-2850** (Registrant's telephone number, including area code)

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

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, Par Value $0.0001 Per Share	PMCB	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 precedent 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of October 31, 2023: $18,203,997.

As of August 8, 2024, the registrant had 7,709,459 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K ("Report") includes "forward-looking statements" within the meaning of the federal securities laws. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements other than statements of historical fact are "forward-looking statements" for purposes of this Report, including any projections of earnings, revenue or other financial items, any statements regarding the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, any statements regarding expected benefits from any transactions and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by use of terminology such as "may," "will," "should," "believes," "intends," "expects," "plans," "anticipates," "estimates," "goal," "aim," "potential" or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Thus, investors should refer to and carefully review information in future documents we file with the U.S. Securities and Exchange Commission ("Commission"). Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risk and uncertainties, including, but not limited to, the risk factors set forth in "Part I, Item 1A – Risk Factors" set forth in this Report and for the reasons described elsewhere in this Report.

Among others, these include:

- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- whether the United States ("U.S.") Food and Drug Administration ("FDA") approves our Investigational New Drug Application ("IND") after we complete the FDA's requested studies and submit a response to the FDA's clinical hold, so that we can commence our planned clinical trial involving locally advanced, inoperable, non-metastatic pancreatic cancer ("LAPC");
- the success and timing of our preclinical studies and clinical trials;
- the potential that results of preclinical studies and clinical trials may indicate that any of our technologies and product candidates are unsafe or ineffective;
- our dependence on third parties in the conduct of our preclinical studies and clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates;
- the material adverse impact that the coronavirus pandemic may have on our business, including our planned clinical trial involving LAPC, which could materially affect our operations as well as the business or operations of third parties with whom we conduct business; and
- whether the FDA will approve our product candidates after our clinical trials are completed, assuming the FDA allows our clinical trials to proceed after submission and review of our response to the FDA's clinical hold.

All forward- looking statements and reasons why results may differ included in this Report are made as of the date hereof, and we do not intend to update any forward-looking statements except as required by law or applicable regulations. New risk factors emerge from time to time, and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements.

Except where the context otherwise requires, in this Report, the "Company," "we," "us" and "our" refer to PharmaCyte Biotech, Inc., a Nevada corporation, and, where appropriate, its subsidiaries.

PART I

ITEM 1. BUSINESS.

We are a biotechnology company focused on developing cellular therapies for cancer based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." The Cell-in-a-Box® technology is intended to be used as a platform upon which therapies for several types of cancer, including LAPC, will be developed. The current generation of our product candidate is referred to as "CypCaps™."

During the year ended April 30, 2024, we determined that research and development in the treatment of diabetes would no longer be pursued.

On August 15, 2022, we entered into a Cooperation Agreement (the "Cooperation Agreement") with Iroquois Master Fund Ltd. and its affiliates, pursuant to which we elected a reconstituted board of directors (the "Board"). On November 17, 2023, the Board formed the Strategic Scientific Committee (the "Scientific Committee"), chaired by Dr. Michael Abecassis. The Scientific Committee and our independent consultants are reviewing many of the risks relative to our business. In addition, the Board is reviewing risks associated with our development programs and our relationship with SG Austria Pte. Ltd ("SG Austria"), including that all licensed patents have expired and that know-how relating to our Cell-in-a-Box® technology solely resides with SG Austria. The Board has reduced spending on our programs, including pre-clinical and clinical activities, until the review by the Scientific Committee and the Board is complete and the Board has determined the actions and plans to be implemented. The Scientific Committee's recommendations will include potentially seeking a new framework for our relationship with SG Austria and its subsidiaries. We are reevaluating those programs which are dependent on SG Austria and the U.S. Food and Drug Administration's (the "FDA") acceptance of its technologies, including our development programs for locally advanced, inoperable, non-metastatic pancreatic cancer ("LAPC"). Our reevaluation for addressing the FDA concerns has resulted in delays stemming from the review of the non-clinical package provided by SG Austria and changes to the FDA review process.

The Cell-in-a-Box® encapsulation technology is designed to present genetically engineered live human cells to targeted tissues. The technology is intended to result in the formation of pinhead-sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated, grown to confluence and maintained in a cryopreserved (frozen) state until shortly before they are injected into an appropriate patient. In a laboratory setting, this proprietary live cell encapsulation technology has been shown to create a micro-environment in which encapsulated cells survive and flourish. Encapsulated cells are protected from environmental challenges, such as the shear forces associated with bioreactors and passage through catheters and needles, which we believe enables greater cell growth and production of the active molecules. The capsules are largely composed of cellulose (cotton) and are bioinert. During the past year, SG Austria has generated data and reports to support submission to the FDA concerning the safety of the microcapsules.

We have been developing therapies for pancreatic tumors by using genetically engineered live human cells that we believe are capable of converting a cancer prodrug into its cancer-killing form. We encapsulate those cells using the Cell-in-a-Box® technology and place those capsules in the body as close as possible to the tumor. In this way, we believe that when a cancer prodrug is administered to a patient with a particular type of cancer that may be affected by the resulting active drug, the killing of the patient's cancerous tumor may be optimized both by enhanced potency and limited exposure away from the target tumor. We believe that the prodrug/activator technology is well suited to address the shift from cure/enhanced survival to creating a zone of clearance around blood vessels adjacent to tumor. This zone of clearance improves the probability of successful surgical resection of LAPC, which has been shown to improve survival.

In addition to reengaging SG Austria, the Company is also identifying alternative approaches to expand the prodrug/activator technology for cancer treatment. These discussions may expand our prodrug/activation options to use highly toxic cancer-killing drugs in tightly controlled perivascular spaces.

Until the Strategic Scientific Committee completes its evaluation of our programs and we enter into a new framework for its relationship with SG Austria, spending on our development programs has been curtailed.

Investigational New Drug Application and Clinical Hold

On September 1, 2020, we submitted an IND to the FDA for a planned clinical trial in LAPC. On October 1, 2020, we received notice from the FDA that it had placed our IND on clinical hold. On October 30, 2020, the FDA sent us a letter setting forth the reasons for the clinical hold and providing specific guidance on what we must do to have the clinical hold lifted.

In order to address the clinical hold, the FDA has requested that we:

- Provide additional sequencing data and genetic stability studies;
- Conduct a stability study on our final formulated product candidate as well as the cells from our Master Cell Bank ("MCB");
- Evaluate the compatibility of the delivery devices (the prefilled syringe and the microcatheter used to implant the CypCaps™) with our product candidate for pancreatic cancer;
- Provide additional detailed description of the manufacturing process of our product candidate for pancreatic cancer;
- Provide additional product release specifications for our encapsulated cells;
- Demonstrate comparability between the 1st and 2nd generation of our product candidate for pancreatic cancer and ensure adequate and consistent product performance and safety between the two generations;
- Conduct a biocompatibility assessment using the capsules material;
- Address specified insufficiencies in the Chemistry, Manufacturing and Controls information in the cross-referenced Drug Master File;
- Conduct an additional nonclinical study in animals to assess the safety, activity, and distribution of the product candidate for pancreatic cancer; and
- Revise the Investigators Brochure to include any additional preclinical studies conducted in response to the clinical hold and remove any statements not supported by the data we generated.

The FDA also requested that we address the following issues as an amendment to our IND:

- Provide a Certificate of Analysis for pc3/2B1 plasmid that includes tests for assessing purity, safety, and potency;
- Perform qualification studies for the drug substance filling step to ensure that the product candidate for pancreatic cancer remains sterile and stable during the filling process;
- Submit an updated batch analysis for the product candidate for the specific lot that will be used for manufacturing all future product candidates;
- Provide additional details for the methodology for the Resorufin (CYP2B1) potency and the PrestoBlue cell metabolic assays;
- Provide a few examples of common microcatheters that fit the specifications in our Angiography Procedure Manual;
- Clarify the language in our Pharmacy Manual regarding proper use of the syringe fill with the product candidate for pancreatic cancer; and
- Provide a discussion with data for trial of the potential for cellular and humoral immune reactivity against the heterologous rat CYP2B1 protein and potential for induction of autoimmune-mediated toxicities in our study population.

We assembled a scientific and regulatory team to address the FDA requests. That team has been working diligently to complete the items requested by the FDA.

The following provides a detailed summary of our activities to have the clinical hold lifted:

- Stability Studies on Our Clinical Trial Product Candidate for Pancreatic Cancer. We have successfully completed the required product stability studies. The timepoints were 3, 6, 9, 12, 18 and 24 months of our product candidate for pancreatic cancer being stored frozen at -80C. These studies included container closure integrity testing for certain timepoints.

- Additional Studies Requested by the FDA. We have successfully completed various additional studies requested by the FDA, including a stability study on the cells from our MCB used to make our CypCaps™.

- Determination of the Exact Sequence of the Cytochrome P450 2B1 Gene. We have completed the determination of the exact sequence of the cytochrome P450 2B1 gene inserted at the site previously identified on chromosome 9 using state-of-the-art nanopore sequencing. This is a cutting edge, unique and scalable technology that permits real-time analysis of long DNA fragments. The result of this analysis of the sequence data confirmed that the genes are intact.

- Confirmation of the Exact Sequence of the Cytochrome P450 2B1 Gene Insert. An additional, more detailed analysis of the integration site of the cytochrome P450 2B1 gene from the augmented HEK293 cell clone that is used in our CypCaps™ was found to be intact. In this new study, we were able to confirm the previously determined structure of the integrated transgene sequence using more data points. These studies also set the stage for a next step analysis to determine the genetic stability of the cytochrome P450 2B1 gene at the DNA level after multiple rounds of cell growth. This new study has been completed in which our original Research Cell Bank ("RCB") cells were compared with cells from the MCB. The analysis confirmed that the cytochrome P450 2B1 and the surrounding sequence has remained stable with no changes detected at the DNA level.

- Biocompatibility Studies. We have been involved with 10 biocompatibility studies requested by the FDA, eight of which have been completed successfully. To enable the biocompatibility studies to be performed, we had Austrianova Singapore Pte. Ltd. ("Austrianova") manufacture an additional 400 syringes of empty capsules.

- Systemic Toxicity Testing. We evaluated the potential toxicity of the capsule component of our product candidate for pancreatic cancer and determined there is no evidence of toxicity in any of the parameters examined. The study also confirmed previous data that shows our capsule material is bioinert.

- Micro-Compression and Swelling Testing. This testing is underway. We are developing and optimizing two reproducible methods for testing and confirming the physical stability and integrity of our CypCaps™ under extreme pressure. These studies required the acquisition of new equipment by Austrianova as well as validation and integration into Austrianova's Quality Control laboratory.

- Break Force and Glide Testing. We are in the process of developing a protocol to measure whether the syringe, attached to the catheter when used to expel the capsules, will still have a break and glide force that is within the specifications we have established. We are setting the specifications based on the syringe/plunger manufacturer's measured break and glide forces, or alternatively, accepted ranges for glide forces routinely used in the clinic.

- Capsules Compatibility with the Syringe and Other Components of the Microcatheter Delivery System. We are in the process of showing that CypCaps™ are not in any way adversely affected by the catheters used by interventional radiologists to deliver them into a patient. Compatibility data is being generated to demonstrate that the quality of the CypCaps™ is maintained after passage through the planned microcatheter systems.

- CypCaps Capsules and Cell Viability after Exposure to Contrast Medium. We have commenced testing to show that exposure of CypCaps™ to the contrast medium interventional radiologists used to implant the CypCaps™ in a patient has no adverse effect on CypCaps™. Contrast medium is used to visualize the blood vessels during implantation.

- Master Drug File Information. Austrianova is providing additional detailed confidential information on the manufacturing process, including information on the improvements and advancements made to our product candidate for pancreatic cancer since the last clinical trials were conducted with respect to reproducibility and safety. However, Austrianova has not changed the overall physical characteristics of CypCaps™ between the 1st and 2nd generations.

- Submission of Data to FDA. We are in the process of providing these data to the FDA. The clinical hold did not reflect any deficiencies of the clinical trial proposed. We seek to resolve these non-clinical issues to enable FDA review of a new clinical protocol that reflects the standard of care for LAPC.

History of the Business

In 2013, we restructured our operations to focus on biotechnology. On January 6, 2015, we changed our name from "Nuvilex, Inc." to "PharmaCyte Biotech, Inc." to reflect the nature of our business.

We are a biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer using our live cell encapsulation technology. This resulted from entering into the following agreements.

Commencing in May 2011, we entered into a series of agreements and amendments with SG Austria Pte. Ltd. ("SG Austria") to acquire certain assets from SG Austria as well as an exclusive, worldwide license to use, with a right to sublicense, the Cell-in-a-Box® technology and trademark for the development of therapies for cancer ("SG Austria APA").

In June 2013, we and SG Austria entered a Third Addendum to the SG Austria APA ("Third Addendum"). The Third Addendum materially changed the transaction contemplated by the SG Austria APA. Under the Third Addendum, we acquired 100% of the equity interests in Bio Blue Bird and received a 14.5% equity interest in SG Austria. We paid: (i) $500,000 to retire all outstanding debt of Bio Blue Bird; and (ii) $1.0 million to SG Austria. We also paid SG Austria $1,572,193 in exchange for a 14.5% equity interest of SG Austria. The transaction required SG Austria to return to us the 66,667 shares of our common stock held by SG Austria and for us to return to SG Austria the 67 shares of common stock of Austrianova we held.

Effective as of the same date we entered the Third Addendum, we and SG Austria also entered a Clarification Agreement to the Third Addendum ("Clarification Agreement") to clarify and include certain language that was inadvertently left out of the Third Addendum. Among other things, the Clarification Agreement confirmed that the Third Addendum granted us an exclusive, worldwide license to use, with a right to sublicense, the Cell-in-a-Box® technology and trademark for the development of therapies for cancer.

With respect to Bio Blue Bird, Bavarian Nordic A/S ("Bavarian Nordic") and GSF-Forschungszentrum für Umwelt u. Gesundheit GmbH (collectively, "Bavarian Nordic/GSF") and Bio Blue Bird entered into a non-exclusive License Agreement ("Bavarian Nordic/GSF License Agreement") in July 2005, whereby Bio Blue Bird was granted a non-exclusive license to further develop, make, have made (including services under contract for Bio Blue Bird or a sub-licensee, by Contract Manufacturing Organizations, Contract Research Organizations, Consultants, Logistics Companies or others), obtain marketing approval, sell and offer for sale the clinical data generated from the pancreatic cancer clinical trials that used the cells and capsules developed by Bavarian Nordic/GSF (then known as "CapCells™") or otherwise use the licensed patent rights related thereto in the countries in which patents had been granted. Bio Blue Bird was required to pay Bavarian Nordic a royalty of 3% of the net sales value of each licensed product sold by Bio Blue Bird and/or its Affiliates and/or its sub-licensees to a buyer. The term of the Bavarian Nordic/GSF License Agreement continued on a country-by-country basis until the expiration of the last valid claim of the licensed patent rights.

Bavarian Nordic/GSF and Bio Blue Bird amended the Bavarian Nordic License Agreement in December 2006 ("First Amendment to Bavarian Nordic/GSF License Agreement") to reflect that: (i) the license granted was exclusive; (ii) a royalty rate increased from 3% to 4.5%; (iii) Bio Blue Bird assumed the patent prosecution expenses for the existing patents; and (iv) to make clear that the license will survive as a license granted by one of the licensors if the other licensor rejects performance under the Bavarian Nordic License Agreement due to any actions or declarations of insolvency.

In October 2016, Bavarian Nordic/GSF and Bio Blue Bird further amended the Bavarian Nordic License Agreement ("Second Amendment to Bavarian Nordic/GSF License Agreement") in order to: (i) include the right to import in the scope of the license; (ii) reflect ownership and notification of improvements; (iii) clarify which provisions survive expiration or termination of the Bavarian Nordic License Agreement; (iv) provide rights to Bio Blue Bird to the clinical data after the expiration of the licensed patent rights; and (v) change the notice address and recipients of Bio Blue Bird.

In May 2018, we entered into a series of binding term sheet amendments ("Binding Term Sheet Amendments"). The Binding Term Sheet Amendments provides that our obligation to make milestone payments to SG Austria for therapies for cancer be eliminated in their entirety.

One of the Binding Term Sheet Amendments required us to pay $900,000 to Austrianova. The Binding Term Sheet Amendments also provide that Austrianova receives 50% of any other financial and non-financial consideration received from our sublicensees of the Cell-in-a-Box® technology.

Market Opportunity and Competitive Landscape

We are developing for live cell encapsulation-based therapies for cancer.

The Cell-in-a-Box® capsules are comprised of cotton's natural component – cellulose. Other materials used by competitors include alginate, collagen, chitosan, gelatin and agarose. Alginate appears to be the most widely used of these. We believe the inherent strength and durability of our cellulose-based capsules provides us with advantages over the competition. They do so with no evidence of rupture, damage, degradation, fibrous overgrowth or immune system response. The cells within the capsules also remained alive and functioning during these studies. Other encapsulating materials degrade in the human body over time, leaving the encapsulated cells open to immune system attack. Damage to surrounding tissues has also been reported to occur over time when other types of encapsulation materials begin to degrade.

The cells encapsulated using the Cell-in-a-Box® technology can be frozen for extended periods of time. When thawed, the cells are recovered with approximately 85% viability. We are unaware of any other cell encapsulation material that is capable of protecting their encapsulated cells to this degree. The implications of this property of the Cell-in-a-Box® technology are obvious – long-term storage of encapsulated cells and shipment of encapsulated cells over long distances.

We believe our live cell encapsulation technology may have new opportunities for us in numerous and developing ways. For example:

- Cancerous diseases may be treated by placing encapsulated drug-converting cells that convert a chemotherapy prodrug near the cancerous tumor;

- Confinement and maintenance of therapeutic cells that activate a chemotherapy prodrug may be placed at the site of implantation in a blood vessel near the cancerous tumor results in "targeted chemotherapy";

- Increased efficacy of a chemotherapy prodrug may allow for lower doses of the prodrug to be given to a patient, significantly reducing or even eliminating side effects from the chemotherapy;

- Multi-layered trade secret protection and marketing exclusivity for our technology exists and is being expanded;

- Cell-in-a-Box® capsules can prevent immune system attack of functional cells inside them without the need for immunosuppressive drug therapy; and

- Promising data with the Cell-in-a-Box® technology and the cells used with our technology from animal and initial human clinical trials.

Pancreatic cancer is increasing in most industrialized countries. The American Cancer Society estimated that in 2023 there were 64,000 people in the U.S. diagnosed with pancreatic cancer. It also estimated 51,000 patients with pancreatic cancer died in 2023. Pancreatic cancer accounts for about 3% of all cancers in the U.S. and about 7% of all cancer deaths.

Our goal is to satisfy a clear unmet medical need for patients with LAPC whose tumors no longer respond after 4-6 months of treatment with the chemotherapy combination of Abraxane® plus gemcitabine or the four-drug combination known as FOLFIRINOX. For these patients, there is currently no effective therapy. We believe there will be no therapy comparable to our Cell-in-a-Box® plus low dose of ifosfamide combination therapy when it is used in these patients.

We face intense competition in the field of treating pancreatic cancer. There are dozens of startups, smaller biotech companies, big pharma, and several academic institutions and cancer centers all trying to improve the outcome for pancreatic cancer patients. There are several drugs already available and in the pipelines of pharmaceutical companies worldwide, not the least of which is the combination of the drugs of Abraxane® and gemcitabine. This is the primary FDA-approved combination of drugs for treating advanced pancreatic cancer. In Europe and in the U.S., the 4-drug combination FOLFIRINOX has also found use as a first-line treatment for advanced pancreatic cancer. Some of our competitive strengths include the Orphan Drug Designation we have been granted by the FDA and the European Medicines Agency for our pancreatic cancer therapy. Yet many of our competitors have substantially greater financial and marketing resources than we do. They also have stronger name recognition, better brand loyalty and long-standing relationships with customers and suppliers. Our future success will be dependent upon our ability to compete.

Material Agreements

Third Addendum to the SG Austria APA

In June 2013, we and SG Austria entered the Third Addendum and the Clarification Agreement. The Third Addendum required us to make the following payments for the purchased assets; these payments were timely made in full under the payment deadlines set forth in the Third Addendum:

- A $60,000 payment due under the SG Austria APA;
- A payment of Stamp Duty estimated to be $10,000-17,000 to the Singapore Government;
- $500,000 to be used to pay off the existing debt of Bio Blue Bird; and
- $1,000,000 to SG Austria.

Pursuant to the Third Addendum, we agreed to and have entered a manufacturing agreement with SG Austria for the manufacture of the pancreatic cancer clinical trial product to treat LAPC. The Manufacturing Framework Agreement required us to pay Austrianova a one-time manufacturing setup fee in the amount of $647,000, of which 50% is required to be paid on the effective date of the Manufacturing Framework Agreement and 50% is required to be paid three months later. We have paid the full amount of the manufacturing setup fee.

The Manufacturing Framework Agreement also requires us to pay a fee for producing the final encapsulated cell product of $647 per vial of 300 capsules after production, with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product. The fees under the Manufacturing Framework Agreement are subject to annual increases according to the annual inflation rate in the country in which the encapsulated cell products are manufactured.

The Third Addendum also requires us to make future royalty and milestone payments as follows:

- Two percent royalty on all gross sales received by us or our affiliates;
- Ten percent royalty on gross revenues received by us or our affiliates from a sublicense or right to use the patents or the licenses granted by us or our affiliates;
- Milestone payments of $100,000 within 30 days after enrollment of the first human patient in the first clinical trial for each product; $300,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial for each product; and $800,000 within 60 days after having a NDA or a BLA approved by the FDA or a MAA approved by the EMA in Europe, or its equivalent based on the country in which it is accepted for each product; and
- Milestone payments of $50,000 due 30 days after enrollment of the first veterinary patient in the first trial for each product and $300,000 due 60 days after having a BLA, a NDA or a MAA or its equivalent approved based on the country in which it is accepted for each veterinary product.

On May 14, 2018, we entered into amendments to the Third Addendum. For a full description of these amendments, see Item 1. “History of the Business.”

Sources and Availability of Raw Materials

The entire encapsulation process relating to the encapsulation of the cells for the oncology is to be carried out by Austrianova. Austrianova is the sole source of our product candidates. Austrianova is responsible for acquiring all of the necessary raw materials used in this process, including the cellulose sulfate necessary for encapsulating the live cells, a process proprietary to Austrianova. Austrianova from time to time has experienced significant supply chain delays, and we believe Austrianova may also be experiencing liquidity issues as well. If Austrianova is unwilling or unable to perform such manufacturing for us, we may not be able to locate a replacement manufacturer for our product candidates.

Intellectual Property and Trade Secrets

Intellectual property and patent protection are of paramount importance to our business, as are the trade secrets and other strategies we have employed with Austrianova to protect the proprietary Cell-in-a-Box® technology. Although we believe we take reasonable measures to protect our intellectual property and trade secrets and those of Austrianova, we cannot guarantee we will be able to protect and enforce our IP or obtain patent protection for our product candidates as needed. We license technology and trademarks relating to two areas: (i) live cell encapsulation with cells that express cytochrome P450 where the capsule is permeable to prodrug molecules and the cells are retained within the capsules and (ii) treatment of solid cancerous tumors.

Litigation may be required to protect our product candidates, intellectual property rights or to determine the validity and scope of the proprietary rights of others. Establishment, maintenance and enforcement of our intellectual property utilizes financial and operational resources. In addition, the possibility exists that our intellectual property could be discovered to be owned by others, be invalid or be unenforceable – potentially bringing unforeseen challenges to us.

Human Capital

As of April 30, 2024, we had two full-time employees and several consultants who devote substantial time to us. The consultants are physicians, scientists, regulatory experts, clinical operation experts and cGMP experts. All of our research and development ("R&D") work is handled by our consultants.

Our Corporate Information

We are a Nevada corporation incorporated in 1996. In 2013, we restructured our operations to focus on biotechnology. The restructuring resulted in us focusing our efforts to develop a novel, effective and safe way to treat cancer. In January 2015, we changed our name from Nuvilex, Inc. to PharmaCyte Biotech, Inc. to reflect the nature of our current business.

Our corporate headquarters are located at 3960 Howard Hughes Parkway, Suite 500, Las Vegas, Nevada 89169. Our telephone number is (917) 595-2850. We maintain a website at www.pharmacyte.com to which we post copies of our press releases as well as additional information about us. Our filings with the Commission are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the Commission. Information contained in our website is not a part of, nor incorporated by reference into, this Report or our other filings with the Commission, and should not be relied upon.

Government Regulation and Product Approval

As a development-stage biotechnology company that operates in the U.S., we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising, promotion, marketing and sale of our product candidates. Although the discussion below focuses on regulation in the U.S., we anticipate seeking approval for, and marketing of, our product candidates in other countries. Our activities in other countries will also be the subject of extensive regulation, although there can be important differences with the U.S. The process of obtaining regulatory marketing approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations will require the expenditure of substantial time and financial resources and may not be successful.

Regulatory approval, when obtained, may be limited in scope which may significantly limit the uses for which a product may be placed in the market. Further, approved drugs or biologic products, as well as their manufacturers, are subject to ongoing post-marketing review, inspection and discovery of previously unknown issues regarding the safety and efficacy of such products or the manufacturing or quality control procedures used in their production. These may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure or delay by us, our suppliers of manufactured drug product, collaborators or licensees in obtaining regulatory approvals could adversely affect the marketing of our product candidates and our ability to receive product revenue, license revenue or profit-sharing payments. For more information, see Item 1A. "Risk Factors."

U.S. Government Regulation

The FDA is the main regulatory body that controls pharmaceuticals and biologics in the U.S. Its regulatory authority is based in the FDCA and the Public Health Service Act. Pharmaceutical products and biologics are also subject to other federal, state and local statutes and regulations. A failure to comply with any applicable requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include, among other things, the imposition by the FDA or by an Institutional Review Board ("IRB") of a hold on clinical trials, FDA refusal to approve pending marketing applications or supplements, withdrawal of previously granted approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The steps required before a new drug or biologic may be marketed in the U.S. generally include:

- completion of preclinical studies and formulation studies in compliance with the FDA's Good Laboratory Practices ("GLP"), protocols and regulations;
- submission to the FDA of an IND to support human clinical testing in the U.S.;
- approval by an IRB at each clinical site before a trial may be initiated at that site;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices ("GCP") and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product candidate for each target indication;
- submission to the FDA of a New Drug Application ("NDA") for a drug or Biologics License Application ("BLA") for a biologic for marketing approval, including payment of application user fees
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the investigational product candidate is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites to assure compliance with GCP and the integrity of the clinical data submitted in support of the NDA or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval of the NDA or BLA.

Clinical Development

Before a drug or biological product candidate may be tested in human subjects, it must undergo preclinical testing. Preclinical tests generally include laboratory evaluations of a product candidate's chemical and biological activities, formulation and stability, as well as studies to evaluate toxicity in animals and potential for other adverse events, which support subsequent clinical testing and rationale for subsequent therapeutic use.

The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended both the FDCA and PHSA to specify that nonclinical testing for drugs and biologics, respectively, may, but is not required to, include *in vivo* animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or *in vivo* animal tests. The results of these studies must be submitted, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an IND which must be reviewed by the FDA for safety and other considerations and become effective before testing can begin in humans. Some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug or biologic candidate is submitted to the FDA and human clinical trials have been initiated.

An IND is a request for authorization from the FDA to administer an investigational product candidate to humans. This authorization is required before interstate shipping and administration can commence for any drug or biologic product candidate destined for use in humans in the U.S. A 30-day waiting period after the submission of each IND is required before commencement of clinical testing in humans. 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 clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds may also be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

A clinical trial involves the administration of the investigational product candidate to patients under the supervision of qualified investigators following GCP standards, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial (unless the consent requirement has been waived by an IRB) along with the requirement to ensure that the data and results reported fom the clinical trials are credible and accurate. GCP requirements are meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. A clinical trial is conducted under a protocol that details, among other things, the objectives of the trial, the criteria for determining subject eligibility, the dosing plan, the parameters to be used in monitoring safety, the procedure for timely reporting of adverse events, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

In addition, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and re-approve the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health, or NIH, for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's complementary policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has begun enforcing those requirements against non-compliant clinical trial sponsors.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1 Clinical Trial: The product candidate is initially introduced into health human subjects and tested for safety, and such trials typically include a preliminary determination of a product candidate’s safe dosage range. A Phase 1 clinical trial also determines how a drug is absorbed, distributed, metabolized and excreted by the body and, therefore, the potential duration of its action. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

Phase 2 Clinical Trial: A Phase 2 clinical trial is conducted on a limited number of patients; these patients can have a specific targeted disease. The product candidate is administered to such patients to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific indications and to determine dosage tolerance and optimal dosage. Phase 2 clinical trials are typically well-controlled and closely monitored.

Phase 3 Clinical Trial: Such trials are undertaken with an expanded patient population to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Congress also recently amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other “pivotal study” of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor’s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if the FDA objects to a sponsor’s diversity action plan, it may delay trial initiation.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The decision to terminate development of an investigational product candidate may be made by either a health authority body, such as the FDA, by IRB/ethics committees, or by the sponsor for various reasons. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the patients enrolled in the trial. 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 clinical protocol, GCP, or other IRB requirements or if the product candidate has been associated with unexpected serious harm to patients.In some cases, a clinical trial is overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board (or DSMB). This group provides authorization for whether a trial may move forward at designated checkpoints based on access that only the group maintains to available data from the study.

A sponsor may be able to request a special protocol assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the Phase 3 trial protocol design, clinical endpoints and statistical analysis that will form the primary basis of an efficacy claim. A sponsor meeting the regulatory criteria may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. A SPA request must be made before the proposed trial begins. All open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins, except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the product candidate was identified after the testing began. A SPA is not binding if new circumstances arise, such as if the FDA identifies, after the clinical trial begins, new information that may cause the scientific community and the agency to question or reject the assumptions supporting the SPA, or if the sponsor fails to follow the protocol that was agreed upon with the FDA, and there is no guarantee that a study trial will ultimately be adequate to support an approval even if the study is subject to a SPA. Having a SPA does not guarantee that a product candidate will receive FDA approval.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product and 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 candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. For biological products in particular, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help reduce the risk of the introduction of adventitious agents. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product candidate information is submitted to the FDA in the form of an NDA or BLA to request regulatory approval for the product in the specified indication.

New Drug Applications and Biologic Licensing Applications

To obtain approval to market a drug or biologic in the U.S., a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing and controls, as well as proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from several alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product candidate to the satisfaction of the FDA.

In most cases, the NDA, in the case of a drug, or BLA, in the case of a biologic, must be accompanied by a substantial user fee. These fees are typically adjusted annually, but exemptions and waivers may be available under certain, narrow circumstances. The FDA will initially review the NDA or BLA for completeness before it accepts the application for filing. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing, in which case, the application must be resubmitted with the requested information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the NDA or BLA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), for original NDAs and BLAs, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with "priority review." For all BLAs and new molecular entity ("NME") NDAs, the ten and six-month time periods run from the filing date; for all other original applications, the ten and six-month time periods run from the submission date. However, the FDA can extend such review periods by three months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP standards. The FDA may refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee. This is typically a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities substantially comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Manufacturers of human cellular or tissue-based biologics also must comply with the FDA's Good Tissue Practices ("GTP"), as applicable, and with the general biological product standards. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

FDA also may require the development of a risk evaluation and mitigation strategy ("REMS") if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. 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 a BLA without a REMS, if required.

Under the Pediatric Research Equity Act as amended ("PREA"), a NDA, BLA, or supplement to an NDA or BLA must contain data that are adequate to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric population for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers from such requirements. Under the law, a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP") within sixty 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 trial 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 pre-clinical studies, early phase clinical trials or other clinical development programs.

After the FDA evaluates the NDA or BLA and the product manufacturing facilities, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product 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 generally outlines the deficiencies in the submission and may require substantial additional testing or information, which may include data from further preclinical studies or clinical trials, for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

FDA Review and Approval Process for Combination Products

A combination product is a product composed of a combination of two or more FDA-regulated product constituent parts or products, e.g., drug-device or biologic-device. Such products often raise regulatory, policy and review management challenges because they integrate constituent parts that are regulated under different types of regulatory requirements and by different FDA Centers, namely, the Center for Drug Evaluation and Research, or CDER, the Center for Devices and Radiological Health, or CDRH, or the Center for Biologics Evaluation and Research, or CBER. Differences in regulatory pathways for each constituent part can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated constituent parts that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug, biologic, or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, biologic, or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, biologic, or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, biologic, or device where both are required to achieve the intended use, indication, or effect.

The FDA's Office of Combination Products, or OCP, was established to provide prompt determination of the FDA Center with primary jurisdiction over the review and regulation of a combination product; ensure timely and effective premarket review by overseeing the timeliness of and coordinating reviews involving more than one center; ensure consistent and appropriate post-market regulation; resolve disputes regarding review timeliness; and review/revise agreements, guidance and practices specific to the assignment of combination products.

OCP determines which Center will have primary jurisdiction for the combination product, referred to as the Lead Center, based on the combination product's "primary mode of action," or PMOA. A mode of action is the means by which a product achieves an intended therapeutic effect or action. The PMOA is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. The Lead Center has primary responsibility for the review and regulation of a combination product; however a second Center is often involved in the review process, especially to provide input regarding the "secondary" component(s). In most instances, the Lead Center applies its usual regulatory pathway. For example, a drug-biologic combination product assigned to CDER will typically be reviewed under an NDA, while a drug-biologic combination product assigned to CBER is typically reviewed under through a BLA.

Often it is difficult for OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which Center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product. A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which Center will regulate the combination product. If the sponsor objects to that decision, the sponsor may request that OCP reconsider its decision.

Combination products are subject to FDA user fees based on the type of application submitted for the product's premarket approval or clearance. For example, a combination product for which an NDA is submitted is subject to the NDA fee under PDUFA.

Since a combination product incorporates two or more constituent parts that have different regulatory requirements, a combination product manufacturer must comply with all cGMP requirements that apply to each constituent part. The FDA has issued a combination product cGMP regulation, along with final guidance, describing two approaches a combination product manufacturer may follow to demonstrate compliance. Under these two options, the manufacturer demonstrates compliance with: (1) All cGMP regulations applicable to each separate regulated constituent part included in the combination product; or (2) either the drug cGMP or the QSR (if there is a device constituent part), as well as with specified provisions from the other of these two sets of requirements (also called the "streamlined approach").

Post Approval Regulations

After regulatory approval of a drug or biologic is obtained, a company is required to comply with pervasive and continuing FDA requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing, including a Phase 4 clinical trial and surveillance to further assess and monitor the product's safety and effectiveness after commercialization has begun. In addition, NDA and BLA holders are subject to regulations governing, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities.If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or an NDA/BLA supplement, which may require the applicant to develop additional data or conduct additional nonclinical 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. 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 also require drug and biologic manufacturers to implement and maintain quality control and manufacturing procedures that conform to cGMP standards to assure and preserve the long-term stability of the approved product. The FDA periodically inspects The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and other entities involved in the production and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and such facilities are subject to periodic unannounced or scheduled inspections by the FDA and certain state agencies to assess compliance with cGMP standards. In addition, FDA regulations require investigation and correction of any deviations from cGMP standards and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in production and quality control to maintain compliance with cGMP standards and other aspects of regulatory compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMPs, 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 voluntary recall and regulatory sanctions as described below.

Once an approval of a drug or biologic is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market surveillance 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 product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and/or
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical and biological products is subject to the Prescription Drug Marketing Act ("PDMA") which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act ("DSCSA") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the U.S., including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors and dispensers over a 10-year period, which culminated in November 2023. Most recently, the FDA announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, FDA released proposed regulations in February 2022 to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a state program, each of which is mandated by the DSCSA.

It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Advertising and Promotion

The FDA and other federal regulatory agencies tightly regulate the marketing and promotion of drugs and biologics through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. A drug or biological product cannot be commercially promoted for any indication before it is approved for such indication. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are legally permitted to prescribe drugs or biologics for "off-label" uses (uses not approved by the FDA and therefore not described in the approved labeling for the drug or biologic) because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a product for any off-label use, but may engage in non-promotional, balanced communication to licensed healthcare professionals regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice ("DOJ"), the U.S. Department of Health and Human Services Office of Inspector General ("HHS-OIG") and state authorities. Such enforcement action may lead to a range of penalties that could have a significant commercial impact, including civil and criminal fines and/or agreements that materially restrict the manner in which a company promotes or distributes its approved drug and biological products.

U.S. Patent Extension

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). The Hatch-Waxman Act permits a patent extension term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The length of the patent term extension is related to the length of time the drug, biologic or medical device is under regulatory review. It is calculated as half of the period of time comprising the testing phase (the time between the IND becoming effective and the NDA or BLA submission date) plus all the FDA review phase (the time between NDA or BLA submission and approval dates), up to a maximum extension of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office ("USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension.

Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug, biologic or medical device. In the future, if any of our product candidates receive FDA approval, we expect to apply for patent term extension on patents covering those products that may be eligible for such patent term restoration.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the U.S. and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request by the FDA does not require the sponsor to undertake the described studies.

Reference Product Exclusivity for Biological Products

March 2010, the Patient Protection and Affordable Care Act was enacted in the U.S. and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Since that time, the FDA has approved numerous biosimilar products, issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilar, and created a public database that contains information on all FDA-licensed biological products, including biosimilars, called the Purple Book.

A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that 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. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of market exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. As part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period.

If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, the 12-year exclusivity period will be extended for an additional six months. In addition, the 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. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change 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.

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

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for influencing any act or decision of the foreign entity to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring such companies 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. In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects less than 200,000 individuals in the U.S., or more than 200,000 individuals and for which the cost of developing and making available the product is not reasonably expected to be recovered from sales of the product in the U.S. 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. The benefits of orphan drug designation include research and development tax credits and exemption from FDA prescription drug user fees. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Upon the approval of the first NDA or BLA for a drug or biologic designated as an Orphan Drug for a specified indication, the sponsor of that NDA or BLA is entitled to seven years of exclusive marketing rights in the U.S. for the drug or biologic for the particular indication, during which time the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances. However, Orphan Drug exclusivity for an approved indication does not prevent the approval of a different drug for the same rare disease or condition, nor does it block the approval of the same drug for different conditions. Additionally, if a drug designated as an orphan product receives marketing approval for an indication broader than what was designated, it may not be entitled to orphan drug exclusivity. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA for treatment of the same indication.

Recent court cases have challenged FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Our product candidate for pancreatic cancer received Orphan Drug status in the U.S. and European Union.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to grant designations, including fast track designation, priority review designation, and breakthrough therapy designation, to certain drugs or biologics intended for the treatment of a serious or life-threatening disease or condition and demonstrate the potential to address an unmet medical need. The designation programs are intended to expedite the process for the development and review of such products, and ultimately, to provide important new drugs or biologics to patients earlier than under standard FDA review procedures.

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. In addition, the FDA may review sections of the NDA or BLA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

The FDA may give a priority review designation to a drug or biologic that that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug or biologic represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation means that the goal for the FDA to take action on an NME NDA or original BLA submission within six months after the filing date, rather than the standard review period of ten months under current PDUFA guidelines.

Finally, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies may also eligible for accelerated approval. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings and providing advice, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

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 decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process. We may explore some of these opportunities for our product candidates as appropriate.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug or biologic that is intended to treat a serious or life-threatening condition and that provides meaningful therapeutic advantage to patients over existing treatments based upon adequate and well-controlled clinical trials establishing that the drug or biologic has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality("IMM") and that is reasonably likely to predict an effect on IMM or other clinical benefit, considering the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs or biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug or biologic.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug or biologic, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs or biologics for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. In addition, as part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these recent amendments to the FDCA, the agency may require a sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports will be published on FDA's website. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, allows the FDA to withdraw approval of the drug or biologic. Congress also recently amended the FDCA to give the agency the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Regulation Outside of the U.S.

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before we may commence clinical trials or market products in those countries or areas. With the United Kingdom withdrawal from the European Union on January 31, 2020, UK licensing decisions were transferred from EMA to The Medicines and Healthcare Products Regulatory Agency, or MHRA, the UK Regulatory Body. For a period of three years following January 1, 2021, the UK continued to adopt decisions taken by the European Commission on the approval of new marketing authorizations. However, companies will be required to submit an identical application to the MHRA upon the Committee for Medicinal Products for Human Use, or CHMP, positive opinion of the application. The MHRA will then wait for the European Commission decision on approval. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Union drug development, review and approval

In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if marketing authorization from the competent regulatory agencies has been obtained. Similar to the U.S., the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP, and the related national implementing provisions of the individual EU Member States previously governed the system for the approval of clinical trials in the European Union. Under this system, an applicant had to obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant could only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion.

In 2014, the new Clinical Trials Regulation, (EU) No 536/2014, Clinical Trials Regulation, was adopted and it became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all of the EU Member States, as it repealed the Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation depends on when the Clinical Trials Regulation became applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation became applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" or Clinical Trial Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. Use of the CTIS became mandatory for new clinical trial application submissions as of February 1, 2023.

To obtain a marketing authorization of a drug in the European Union, we may submit marketing authorization applications, or MAA, either under the so-called centralized or national authorization procedures.

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency, or EMA, that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA 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. 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 an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

National authorization procedures

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Under the above-described procedures, before granting the marketing authorization, 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.

Conditional approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

European Union regulatory exclusivity

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven 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 held to bring a significant clinical benefit in comparison with existing therapies.

European Union orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the European Union, are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

PRIME designation

The EMA grants access to the Priority Medicines, or PRIME, program to investigational medicines for which it determines there to be preliminary data available showing the potential to address an unmet medical need and bring a major therapeutic advantage to patients. As part of the program, the EMA provides early and enhanced dialogue and support to optimize the development of eligible medicines and speed up their evaluation, aiming to bring promising treatments to patients sooner.

Periods of authorization and renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union's General Data Protection Regulation (" GDPR"), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. 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. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the European Union to the U.S. – the EU-U.S. Data Privacy Framework, which provides individuals in the European Union with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised by the Court of Justice of the European Union in its decision on a case known as *Schrems II*, which invalidated the previous EU-U.S. Privacy Shield. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the U.S. along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of European Union data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Following the United Kingdom's withdrawal from the European Union, the GDPR has been implemented in the United Kingdom (as the U.K. GDPR). The U.K. GDPR sits alongside the amended United Kingdom Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the U.K. GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or to monitor their behavior will be subject to the U.K. GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover. On June 28, 2021, the European Commission issued a decision that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the European Union to the United Kingdom. In June of 2021, the European Commission issued a decision, which will sunset on June 27, 2025 without further action, that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom. The Parliament of the United Kingdom is currently considering the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, U.K. GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework. In addition, as of January 2024, the Parliament of the United Kingdom is considering the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, the U.K. GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework.

Rest of the world regulation

For other countries outside of the European Union and the U.S., 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 jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP 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.

Healthcare Reform

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. For example, Congress must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 but without any substantive policy changes. 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 otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

As previously mentioned, the primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Legislative and regulatory changes under the ACA are possible, but it is unknown what form any such changes or any law would take and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the U.S.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Notably, the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94), which became law on December 20, 2019, includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the CREATES Act). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the U.S. remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

In addition to the IRA's drug price negotiation provisions, President Biden's Executive Order 14087, issued in October 2022, called for the CMS Innovation Center to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. In February 2023, CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of February 2024, the CMS Innovation Center continues to test the proposed models and has started to roll out plans for access model testing of certain product types (e.g., cell and gene therapies) by states and manufacturers.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that appears to be leading to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

In the European Union, many member states have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new medicinal products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for medicinal products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services. Moreover, 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, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all the FDA-approved drugs for a certain indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates, if approved, may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Medicare is a federal healthcare program administered by the federal government that covers individuals aged 65 and over as well as individuals with certain disabilities. Drugs may be covered under one or more sections of Medicare depending on the nature of the drug and the conditions associated with and site of administration. For example, under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage for outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. 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.

Medicare Part B covers most injectable drugs given in an in-patient setting and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for a Part B-covered drug based on a percentage of manufacturer-reported average sales price, which is regularly updated.

Different pricing and reimbursement schemes exist in other countries. In the European Union governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, and particularly on prescription drugs, has become more intense.

The marketability of any product for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Also, an increasing emphasis on managed care in the U.S. has increased and will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services ("HHS"), such as HHS-OIG and the Office for Civil Rights, which has jurisdiction over matters relating to individuals' privacy and protected health information, as well as the DOJ, individual U.S. Attorney offices within the DOJ and state and local governments. Although we currently do not have any drug or biological products on the market, our business activities and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to regulation and enforcement by such federal, as well as state, regulatory and law enforcement authorities. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order, or the referral to another for the furnishing or arranging for the furnishing of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare program. The Anti-Kickback Statute has been interpreted broadly to proscribe arrangements and conduct where only one purpose of the remuneration between the parties was to induce or reward referrals. The term remuneration has been interpreted broadly to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting some business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all the criteria for safe harbor protection from federal Anti-Kickback Statute liability. Failure to meet all the requirements of an applicable safe harbor or statutory exemption, however, does not make the arrangement or conduct *per se* unlawful under the Anti-Kickback Statute; instead, in such cases, the legality of the arrangement would be evaluated on a case-by-case basis based on a consideration of all the facts and circumstances to ascertain the parties' intent. Moreover, the intent standard under the Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below. The federal Civil Monetary Penalties Law imposes fines against any person or entity that, among other things, is determined to have knowingly presented, or caused to be presented, a claim to a federal healthcare 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.

The federal civil False Claims Act ("FCA") prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. Intent to deceive is not required to establish liability under the FCA. Actions under the FCA may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, FCA lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices and promoting off label uses. FCA liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal healthcare programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud payors or to 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, a healthcare benefit program, including private third-party payors, in connection with the delivery or payment for healthcare benefits, 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 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. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, imposes requirements on covered entities relating to the privacy, security, and transmission of individually identifiable health information, known as protected health information. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to "business associates," defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and individuals. It also 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 these actions. We are not a covered entity or a business associate under HIPAA, however, we are indirectly affected by HIPAA because the protected health information held by investigators conducting our clinical trials are subject to HIPAA and can only be used for our research consistent with HIPAA requirements imposed on those investigators. In addition, other federal and state laws, such as the California Consumer Privacy Act (CCPA), govern the privacy and security of the personal information of California residents and may, in certain circumstances, apply to health information. Other states have implemented laws protecting identifiable health and personal information, many of which laws differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act under the ACA and its implementing regulations also require 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 make annual reports to CMS regarding payments and other transfers of value made to or at the request of covered recipients, such as, but not limited to physicians, certain advanced non-physician healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family. Failure to submit timely, accurately and complete information in compliance with the law may result in significant civil monetary penalties. CMS makes the reported information publicly available.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate sponsors' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require sponsors to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. Furthermore, to distribute products commercially, we must comply with state laws requiring the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors that ship products into the state even if such manufacturers or distributors have no place of business within the state. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases, typically as consumer protection laws. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties or other enforcement actions. These include criminal and civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts and non-procurement transactions such as grants, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or the curtailment or restructuring of our operations. Any of these could adversely affect our ability to operate our business and our results of operations. To the extent any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Smaller Reporting Company

We qualify as a smaller reporting company in accordance with Rule 12b-2 under the Exchange Act, and have elected to follow certain of the scaled back disclosure accommodations within this Annual Report on Form 10-K.

Financial Information Concerning Geographic Areas

We had no revenues in the fiscal years ended April 30, 2024, and 2023, including no revenues from foreign countries. We have long-lived assets, other than financial instruments, located in the following geographical areas:

	FY 2024	FY 2023
U.S.:	$ 1,557,115	$ 5,129,308
All foreign countries, in total:	$ 0	$ 0

We operate globally and are attempting to develop products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in overseeing foreign operations;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third-party disputes over ownership of intellectual property and infringement of third-party intellectual property by our product candidates;
- risks resulting from our extensive supply chain exposure to Asia; and
- general social, economic and political conditions in these foreign markets.

We are dependent on business relationships with parties in multiple countries, as disclosed in Item 1A. "Risk Factors—Risks Related to Our Dependence on Third Parties."

ITEM 1A. RISK FACTORS

You should carefully consider these factors that may affect future results, together with all the other information included in this Report in evaluating our business. The risks and uncertainties described below are those that we currently believe may materially affect our business and results of operations. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial also may become important factors that affect our business and results of operations. Our shares of common stock involve a high degree of risk and should be purchased only by investors who can afford a loss of their entire investment. Prospective investors should carefully consider the following risk factors concerning our business before making an investment.

In addition, you should carefully consider these risks when you read "forward-looking" statements elsewhere in this Report. These are statements that relate to our expectations for future events and time periods. Generally, the words "anticipate," "expect," "intend," and similar expressions identify forward-looking statements. Forward-looking statements involve risks and uncertainties, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements.

Forward-Looking Statements and Associated Risks

We operate in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this Report are based on assumptions management believes are reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise.

Summary of Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company. These risks are described in more detail in the section titled "Risk Factors" in Item 1A of this Report. These risks include, but are not limited to, the following:

- We are a biotechnology company with limited resources, a limited operating history and no products approved for clinical trials or commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- As a result of the clinical hold that has been placed on our IND by the FDA, it has taken and may continue to take considerable time and expense to respond to the FDA, and no assurance can be given that the FDA will remove the clinical hold in which case our business and prospects will likely suffer material adverse consequences.
- We contract with Austrianova for the manufacture of our product candidates for preclinical studies and clinical trials, if allowed to proceed, and expect to continue to do so for commercialization. This reliance on Austrianova increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations and the financial condition of the third parties on which we rely, including Austrianova.
- The recent and ongoing COVID-19 pandemic has affected and could continue to affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health pandemics in regions where we or third parties on which we rely have significant business operations.
- If we are unable to successfully raise sufficient capital, our future clinical trials and product development could be limited, and our long-term viability may be threatened.
- Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We currently have no commercial revenue and may never become profitable.
- If we are unable to obtain, or if there are delays in obtaining, required approval from the applicable regulatory agencies, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.
- If allowed to proceed with our clinical development program, we intend to conduct clinical trials for certain of our product candidates at sites outside of the U.S., and the U.S. regulatory agencies may not accept data from trials conducted in such locations.
- Promising results in previous clinical trials of our encapsulated live cell and ifosfamide combination for advanced pancreatic cancer may not be replicated in future clinical trials which could result in development delays or a failure to obtain marketing approval.
- We may not be able to protect our intellectual property rights throughout the world.
- We rely and expect to continue to rely heavily on third parties to conduct our preclinical studies, plan to rely on third parties to conduct our and clinical trials, assuming they are allowed to proceed, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies and trials.
- Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations and the financial condition of the third parties on which we rely, including Austrianova.
- You may experience future dilution as a result of future equity offerings.
- If we fail to comply with the continuing listing standards on Nasdaq, our securities could be delisted which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.
- We may experience volatility in our stock price, which may adversely affect the trading price of our common stock.
- A large number of shares may be issued and subsequently sold upon the exercise of existing options and warrants and the conversion of preferred shares.
- We are a "smaller reporting company" under the Commission's disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.
- As a non-accelerated filer, we are not required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.

Risks Related to Our Financial Position, FDA Clinical Hold, Need for Additional Capital and Overall Business

We are a biotechnology company with limited resources, a limited operating history, and no products approved for clinical trials or commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a biotechnology company focused on developing cellular therapies for cancer based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." In recent years, we have devoted substantially all our resources to the development of our product candidates for LAPC. We have limited resources, a limited operating history, no products approved for clinical trials or commercial sale and therefore have not produced any revenues. We have generated significant operating losses since our inception. Our net losses attributable to common stockholders for the years ended April 30, 2024, and 2023 were approximately $17.2 million and $4.3 million, respectively. As of April 30, 2024, we had an accumulated deficit of approximately $115.6 million. Substantially all our losses have resulted from expenses incurred relating to our research and development programs and from general and administrative expenses and operating losses associated with our business.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses will increase as we continue our research and development of, and, if approved by the FDA, commence clinical trials for, our product candidates. In addition to budgeted expenses, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We have no facilities to conduct fundamental research and we have performed our research and development activities by collaboration with contract service providers, and contract manufacturers and by designing and developing research programs in collaboration with university-based experts who work with us to evaluate mechanism(s) of disease for which we have designed and developed product candidates. We have not maintained a principal laboratory or primary research facility for the development of our product candidates.

Biotechnology product development is a highly uncertain undertaking and involves a substantial degree of risk. We have not commenced or completed clinical trials for any of our product candidates, obtained marketing approval for any product candidates, manufactured a commercial scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of biotechnology product development, we may never commence or complete clinical trials for any of our product candidates, obtain marketing approval for any product candidates, 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.

Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biotechnology companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, operating results and financial condition will suffer.

As a result of the clinical hold that has been placed on our IND by the FDA, it has taken and may continue to take considerable time and expense to respond to the FDA and no assurance can be given that the FDA will remove the clinical hold in which case our business and prospects will likely suffer material adverse consequences.

On October 1, 2020, we received notice from the FDA that it had placed our IND for a planned clinical trial in LAPC on clinical hold. As part of the clinical hold process, the FDA has asked for additional information, tasks to be performed by us and new preclinical studies and assays. It has taken and may continue to take a considerable period of time, the length of which is not certain at this time, for us to conduct such tasks and preclinical studies and to generate and prepare the requested information. It is possible that the service providers that we will utilize for such work may have considerable backlogs and/or are suffering from slowdowns as a result of COVID-19 and supply chain disruptions and may not be able to perform such work for an extended period of time. Even if we are able to fully respond to the FDA's requests, the agency may subsequently make additional requests that we would need to fulfill prior to the lifting of the clinical hold and we may never be able to begin our clinical trial in LAPC, obtain regulatory approval or successfully commercialize our product candidates. An inability to conduct our clinical trial in LAPC as a result of the clinical hold or otherwise, would likely force us to terminate our clinical development plans. It is possible that we will be unable to fully respond to the FDA in a satisfactory manner, and as a result the clinical hold may never be lifted. If the clinical hold is not lifted or if the lifting takes an extended period of time, our business and prospects will likely suffer material adverse consequences.

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

We do not currently own or operate manufacturing facilities to produce our encapsulated live cell product candidates for cancer. We rely on and expect to continue to rely on Austrianova to manufacture supplies of our product candidates for preclinical studies and clinical trials, if allowed to proceed, as well as for commercial manufacture of our product candidates, and these must be maintained for us to receive marketing approval for our product candidates.

Our encapsulated live cell product candidates must be manufactured through complex, multi-step synthetic processes that are time-consuming and involve special conditions at certain stages. Biologics and drug substance manufacture requires high potency containment, and containment under aseptic conditions. Any performance failures on the part of our existing or future manufacturers could delay clinical development or marketing approval of our product candidates. Moreover, the facilities that produce our Cell-in-a-Box® capsules are unique to us and would not be replicable or replaceable promptly, if at all, if those facilities become unavailable or are damaged or destroyed through an accident, natural disaster, labor disturbance or otherwise.

If Austrianova should become unavailable to us for any reason, we may incur additional cost or delay in identifying or qualifying a replacement manufacturer. At this time, we are unaware of any available substitute manufacturer other than Austrianova. In addition, while we believe that our existing manufacturer, Austrianova, can produce our product candidates, if approved, in commercial quantities, we may also need to identify a third-party manufacturer capable of providing commercial quantities of our product candidates. If we are unable to arrange for such a third-party manufacturing source or fail to do so on commercially reasonable terms and in a timely manner, we may not be able to successfully produce and market our encapsulated live cell and ifosfamide product, if approved, or any other product candidate or may be delayed in doing so.

Even if we can establish such arrangements with another third-party manufacturer, reliance on a new third-party manufacturer entails additional risks, including:

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

A new third-party manufacturer may not be able to comply with cGMP standards or the requirements of a regulatory agency. Our failure, or the failure of our third-party manufacturer, to comply with these practices or requirements could result in sanctions being imposed on us, including additional clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Delays in the cGMP certification of the Austrianova manufacturing facility in Bangkok, Thailand could affect its ability to manufacture encapsulated live cells on a timely basis and could adversely affect supplies of our product candidates for clinical trials and to market.

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

In addition, we expect to rely on Austrianova to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies, if allowed to proceed. There are a small number of suppliers for certain equipment and raw materials that are used in the manufacture of our product candidates. Such suppliers may not sell these raw materials to Austrianova at the times we need them or on commercially reasonable terms. For example, there is from time to time a limited supply of acceptable cell media for production of our MCB. We do not have any control over the process or timing of the acquisition of these raw materials by Eurofins or Austrianova. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Austrianova from time to time has experienced significant supply chain disruptions, some of which may be related to COVID-19, and we believe it is experiencing liquidity issues. Any further significant delay in the supply of a product candidate or the raw material components thereof our clinical trials, if allowed to proceed, due to the need to replace a third-party supplier of these raw materials could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates, if approved, would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations and the financial condition of the third parties on which we rely, including Austrianova.

The disruptions to the global economy in recent years have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. Austrianova, a third-party supplier on whom we rely, from time to time has experienced significant supply chain disruptions, some of which may be related to COVID-19, and we believe it may be experiencing liquidity issues. Despite any actions we have undertaken to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain, inflationary pressures, and delays our third parties face will not have a material adverse effect on our business, financial condition and results of operations.

The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health pandemics in regions where we or third parties on which we rely have significant business operations.

We face the ongoing risk that the coronavirus pandemic may slow our operations, our preclinical studies or the eventual enrollment of our planned clinical trial. In order to prioritize patient health and that of the investigators at clinical trial sites, we may need monitor enrollment of patients in our clinical study. In addition, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. These and other factors outside of our control could delay our ability to conduct clinical trials or release clinical trial results. In addition, the effects of the ongoing coronavirus pandemic may also increase non-trial costs such as insurance premiums, increase the demand for and cost of capital, increase loss of work time from key personnel, and negatively impact our key clinical trial vendors. We cannot guarantee that COVID-19 or any other public health crisis will not cause delays or impact on our business or proposed clinical trial.

If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited, and our long-term viability may be threatened.

We have experienced negative operating cash flows since our inception and have funded our operations primarily through sales of our equity securities. We may need to seek additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings to complete our product development initiatives. These financings could result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

Our operating and capital requirements during this fiscal year and thereafter will vary based on several factors, including whether we can complete the studies requested by the FDA with respect to our IND filing, whether the FDA allows us to commence our planned clinical trial for LAPC, how quickly enrollment of patients in our such trial can be commenced, the duration of the clinical trial and any change in the clinical development plans for our product candidates and the outcome, timing and cost of meeting regulatory requirements established by the FDA and the EMA or other comparable foreign regulatory authorities.

Our present and future capital requirements will be significant and will depend on many factors, including:

- our ability to complete the studies requested by the FDA with respect to our IND filing;
- whether the FDA lifts the clinical hold on our IND filing for LAPC;
- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- market acceptance of our product candidates;
- the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay or reduce the scope of or eliminate some or all of our development programs. Further, if we do not have, or are not able to obtain, sufficient funds, we may be required to delay planned and future clinical trials, including the pig study, and development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing lead programs and ensuring replenishment of our portfolio. Until such time, if ever, as the FDA lifts its clinical hold on our IND related to our planned clinical trial in LAPC, our Cell-in-a-Box® encapsulation technology is validated in our planned clinical trial, and sufficient additional funding is available, we have halted spending on behalf of our development program with respect to cannabinoids.

Due to the significant resources required for the development of our programs, we must focus our programs on specific diseases and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. If we make incorrect determinations regarding the viability or market potential of any or all of our programs or product candidates or misread trends in the biotechnology industry, our business, prospects, financial condition and results of operations could be materially adversely affected.

We currently have no commercial revenue and may never become profitable.

Even if we can successfully achieve regulatory approval for our product candidates, we do not know what the reimbursement status of our product candidates will be or when any of these products will generate revenue for us, if at all. We have not generated, and do not expect to generate, any product revenue for the foreseeable future. We expect to continue to incur significant operating losses for the foreseeable future due to the cost of our research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates. The amount of future losses is uncertain and will depend, in part, on the rate of growth of our expenses.

Our ability to generate revenue from our product candidates also depends on numerous additional factors, including our ability to:

- successfully complete development activities, including the remaining preclinical studies and planned clinical trials for our product candidates;
- complete and submit NDAs or BLAs to the FDA and MAAs to the EMA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, other foreign regulatory authorities;
- manufacture any approved products in commercial quantities and on commercially reasonable terms;
- develop a commercial organization, or find suitable partners, to market, sell and distribute approved products in the markets in which we have retained commercialization rights;
- achieve acceptance among patients, clinicians and advocacy groups for any products we develop;
- obtain coverage and adequate reimbursement from third parties, including government payors; and
- set a commercially viable price for any products for which we may receive approval.

We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we can complete the processes described above, we anticipate incurring significant costs associated with commercializing our product candidates.

To date, we have generated no revenue. Our ability to generate revenue and become profitable depends upon our ability to obtain regulatory approval for, and successfully commercialize, our product candidates that we may develop, in-license or acquire in the future.

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. Such competition may arise from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are entirely different from our approach. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are numerous companies developing or marketing therapies for cancer, including many major pharmaceutical and biotechnology companies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain 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 can enter the market.

Many of the companies against which we are competing or against which we may compete in the future 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 pharmaceutical and biotechnology sectors may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our future revenues are unpredictable which causes potential fluctuations in operating results.

Because of our limited operating history as a biotech company; we are currently unable to accurately forecast our revenues. Future expense levels will likely be based largely on our marketing and development plans and estimates of future revenue. Any sales or operating results will likely generally depend on volume and timing of orders, which may not occur and on our ability to fulfill such orders, which we may not be able to do. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenues in relation to planned expenditures could have an immediate adverse effect on our business, prospects, financial condition and results of operations. Further, as a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service or marketing decisions that could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may experience significant fluctuations in future operating results due to a variety of factors, many of which are outside of our control. Factors that may affect operating results include: (i) the ability to obtain and retain customers; (ii) our ability to attract new customers at a steady rate and maintain customer satisfaction with products; (iii) our announcement or introduction of new products by us or our competitors; (iv) price competition; (v) the level of use and consumer acceptance of its products; (vi) the amount and timing of operating costs and capital expenditures relating to expansion of the business, operations and infrastructure; (vii) governmental regulations; (viii) general economic conditions; (ix) delays or disruptions in our supply chain; and (x) the adverse impacts caused by COVID-19.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Risks Related to Regulatory Matters

If we are unable to obtain, or if there are delays in obtaining, required approval from the applicable regulatory agencies, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates must obtain marketing approval from the FDA for commercialization in the U.S. and from foreign regulatory agencies for commercialization in countries outside the U.S. The process of obtaining marketing approvals in the countries in which we intend to sell and distribute our product candidates is expensive and can take many years if approval is obtained at all. This process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing that product candidate. To date, we have not received approval to market any of our product candidates from regulatory agencies in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the regulatory agencies for each product candidate to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory agencies.

Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed after such therapies. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

If allowed to proceed with our clinical development programs, we intend to conduct clinical trials for certain of our product candidates at sites outside of the U.S., and the U.S. regulatory agencies may not accept data from trials conducted in such locations.

The acceptance of data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions or may not be accepted at all, and other comparable non-U.S. regulatory authorities may have similar restrictions and conditions with respect to clinical trials conducted outside of their respective jurisdictions. In cases where data from clinical trials conducted wholly outside of the U.S. are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not accept such foreign trial data unless (i) the data are determined to be applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the FDA is able to validate the data through an onsite inspection, if necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many comparable non-U.S. regulatory authorities have similar approval requirements.

In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the U.S. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the U.S., it would likely result in the need for additional trials that would be costly and time-consuming and delay or permanently halt the development of our product candidate.

In addition, the conduct of clinical trials outside the U.S. could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- Foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- Administrative burdens of conducting clinical trials under multiple foreign regulatory schemes;
- Foreign exchange fluctuations; and
- Diminished protection of intellectual property in some countries.

Our plan to first pursue a clinical trial before a pivotal Phase 3 trial will likely result in additional costs to us and resultant delays in the FDA review process and any future commercialization and marketing if regulatory approval is obtained.

If the FDA allows us to begin a clinical trial by lifting its clinical hold on our IND, we have determined that the data contained in previous clinical trial reports using the Cell-in-a-Box® and its Associated Technologies are not sufficient to advance the program to a Phase 3 pivotal trial. Therefore, we are designing a clinical trial that, if successful, we believe will provide the information necessary to plan a Phase 3 pivotal trial. Our determination to first conduct a clinical trial before conducting a pivotal Phase 3 clinical trial will likely result in additional costs to us and resultant delays in the regulatory review process and any future commercialization and marketing if regulatory approval is obtained. The same is true to a greater extent if the FDA requires us to commence a Phase 1 or other Phase 2 clinical trial instead of the planned Phase 2b clinical trial currently under clinical hold.

Development of a biologic involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing or be unable to complete the development and commercialization of our product candidates.

Our Cell-in-a-Box® and ifosfamide combination product candidate has not begun clinical development, and, like others' candidates in a similar phase of development, the risk of failure is high. It is impossible to predict when or if this product candidate or any other product candidate will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory agencies for the sale of any product candidate, if allowed to proceed, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take several years to complete and are uncertain as to their outcome. A failure of one or more clinical trials can occur at any stage of a clinical trial. The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of medically or commercially unacceptable or severe adverse events, failure to comply with protocols or applicable regulatory requirements or determination by the regulatory agencies that a drug or biologic product is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation because of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, because of the same factors, our clinical trials if allowed to proceed, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials if allowed to proceed, we may fail to detect toxicity of, or intolerability caused by, our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not, in fact, the case.

The design of a clinical trial can determine whether its results will support approval of a product; however, flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the regulatory agencies may disagree and may not grant marketing approval of our product candidates or may require that we conduct additional clinical studies; the latter would require that we incur significantly increased costs and would significantly extend the clinical development timeline for our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 1, Phase 2 or Phase 3 clinical trial we may conduct may not demonstrate the efficacy or safety necessary to obtain regulatory approval to market our product candidates.

Additionally, any positive results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the results of later-stage clinical trials, such that drug candidates may reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and early-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier phases of the trials. Therefore, the results of any ongoing or future clinical trials we conduct may not be successful.

We may experience significant delays in pursuing any clinical trials, and any planned clinical trials may not begin on time, may require redesign, may not enroll sufficient healthy volunteers or patients in a timely manner and may not be completed on schedule, if at all.

Our clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay in reaching, or failure to reach, agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable volunteers or patients to participate in a trial;
- delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis;
- failure of trial participants to complete a trial or return for post-treatment follow-up;
- inability to monitor trial participants adequately during or after treatment;
- clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable foreign regulatory authority due to observed safety findings or other reasons;
- negative or inconclusive results in our clinical trials, and our decision to or regulators' requirement that we conduct additional non-clinical studies, clinical trials or that we abandon one or more of our product development programs; or
- inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials.

Further, we may also encounter delays if a clinical trial is suspended or terminated by us, by any IRB or ethics committee, by a DSMB, or by the FDA or other regulatory authority. A suspension or termination may occur due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate or changes in governmental regulations or administrative actions. We cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates.

If we experience delays in the commencement or completion of, or suspension or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be harmed, and our ability to generate product revenues from the drug candidate may be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize regulatory approval of our drug candidates and our ability to commence sales and generate revenues. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly.

We are seeking FDA approval to commence clinical trials in the U.S. of certain of our product candidates based on clinical data that was obtained in trials conducted outside the U.S., and it is possible that the FDA may not accept data from trials conducted in such locations or conducted nearly 20 years ago.

In support of our IND application to commence a clinical trial in LAPC using genetically engineered live human cells encapsulated using our Cell-in-a-Box® technology in combination with ifosfamide we are relying on a Phase 1/2 clinical trial and a clinical trial previously conducted using the same technology in combination with ifosfamide between 1998 and 1999 and between 1999 and 2000, respectively. The Phase 1/2 clinical trial was carried out at the Division of Gastroenterology, University of Rostock, Germany, and the Phase 2 clinical trial was carried out at four centers in two countries in Europe: Berne, Switzerland, and in Rostock, Munich and Berlin, Germany.

Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. There is a risk that the FDA may not accept the data from the two previous trials. In that case, we may be required to conduct a Phase 1 or a Phase 1/2b clinical trial rather than the planned Phase 2b clinical trial in LAPC, currently under clinical hold. This may result in additional costs to us and resultant delays in the regulatory review process and any future commercialization and marketing if regulatory approval is obtained. It is not known whether the FDA would be likely to reject the use of such clinical data due to the significant time that has elapsed since the earlier clinical trials were conducted or because the clinical trial material for our proposed clinical trial is different from that used in the earlier clinical trials because of cloning the cells used in the earlier trials and certain other modifications and improvements that have been made to the Cell-in-a-Box® technology since the time of the earlier trials.

Results in previous clinical trials of our encapsulated live cell and ifosfamide combination for pancreatic cancer may not be replicated in future clinical trials which could result in development delays or a failure to obtain marketing approval.

Results in the previous Phase 1/2 and Phase 2 clinical trials of the encapsulated live cell and ifosfamide combination product may not be predictive of similar results in future clinical trials such as our planned clinical trial in LAPC, if allowed to proceed. The previous Phase 1/2 and Phase 2 clinical trials had a relatively limited number of patients in each trial. These trials resulted in outcomes that were not statistically significant and may not be representative of future results. In addition, interim results obtained after a clinical trial has commenced do not necessarily predict results in future clinical trials. Numerous companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage clinical development. Our clinical trials, if allowed to proceed, may produce negative or inconclusive results and we may decide, or regulatory agencies may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain the approval for their products by the regulatory agencies.

The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our drug candidates from applicable regulatory authorities, we will not be able to market and sell those drug candidates in those countries or regions and our business could be substantially harmed.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the U.S. and by the respective regulatory agencies in other countries where regulations differ. We are not permitted to market our product candidates in the U.S. until we receive the respective approval of an NDA or BLA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory agencies in such countries. The time required to obtain approval, if any, by the FDA, EMA, and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory agencies and the type, complexity and novelty of the product candidates involved. Regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. We have not submitted a marketing application to the FDA, EMA or any similar regulatory agency in any other jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third-party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory agencies for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing and packaging facilities by the regulatory agencies. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our third-party manufacturers that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following:

- the FDA or comparable foreign regulatory agencies may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory agencies that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory agencies may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of a NDA, BLA, or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory agency may find our record keeping or the record keeping of our clinical trial sites to be inadequate;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA or comparable foreign regulatory agencies;
- the FDA or comparable foreign regulatory agencies may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the change of the medical standard of care or the approval policies or regulations of the FDA or comparable foreign regulatory agencies may significantly change in a manner that renders our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, for the product candidates we are currently developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory agencies may approve any of our product candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials (referred to as "conditional" or "accelerated" approval depending on the jurisdiction), or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate or that includes significant warnings or contraindications. Any of the foregoing circumstances could materially harm the commercial prospects for our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, we may not achieve our clinical development timeline and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll enough eligible patients to participate in our clinical trials. In particular, for some diseases and conditions we are or will be focusing on, our pool of suitable patients may be smaller and more selective and our ability to enroll a sufficient number of suitable patients may be limited or take longer than anticipated. In addition, some of our competitors may have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and volunteers or patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment is a significant factor in the overall duration of a clinical trial and is affected by many factors, including:

- The size and nature of the patient population;
- The severity of the disease under investigation;
- The proximity of patients to clinical sites;
- The eligibility criteria for the trial;
- Our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- The design of the clinical trial;
- Efforts to facilitate timely enrollment;
- The patient referral practices of physicians;
- Competing clinical trials for the same patient population; and
- Clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Our inability to enroll enough patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from our product candidates., if approved Any of the foregoing could cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

We may request priority review for our product candidates in the future. FDA may not grant priority review for any of our product candidates. Moreover, even if FDA designated such products for priority review, that designation may not lead to a faster regulatory review or approval process and, in any event, does not assure regulatory approval of the product.

We may be eligible for priority review designation for our product candidates if the regulatory agencies determine such product candidates offer major advances in treatment of a serious disease or condition or provide a treatment for a serious disease or condition where no adequate therapy exists. For a description of priority review designation, see "Government Regulation – Fast Track, Breakthrough Therapy and Priority Review Designations."

FDA has broad discretion with respect to whether to grant priority review status to a product candidate, so even if we believe a product candidate is eligible for such designation or status, FDA may decide not to grant it. Thus, while FDA has granted priority review to other oncology products, our product candidates, should we request priority review designation for them, may not receive such designation. Moreover, even if one of our product candidates is designated for priority review, such a designation does not change the standards for product approval and does not necessarily mean a faster overall regulatory review process or necessarily confer any advantage with respect to approval compared to the standard FDA review process.

Receiving priority review from the regulatory agencies does not guarantee approval within an accelerated timeline or thereafter.

In some instances, we believe we may be able to secure approval from FDA to use accelerated development pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate which could increase the expense of obtaining and delay the receipt of necessary marketing approvals.

We anticipate that we may seek an accelerated approval pathway for certain of our product candidates. For a description of the accelerated approval pathway, see "Government Regulation – Accelerated Approval Pathway."

Prior to requesting accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our eligibility to use the accelerated approval pathway. There can also be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or a BLA, as applicable, for accelerated approval or any other form of designation or program intended to expedite the product development, review or approval processes. Similarly, there can be no assurance that after subsequent feedback from the FDA that we will continue to pursue or apply for accelerated approval or any other form of designation or expedited program, even if we initially decide to do so. Furthermore, if we decide to apply for accelerated approval or under another expedited regulatory designation (such as the Breakthrough Therapy designation or Fast Track designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis or at all. The FDA could also require us to conduct further studies prior to considering or grantingour application or granting approval of any type and may require us to have a confirmatory trial to verify the clinical benefit of the product underway and partially or fully enrolled before granting approval. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trials, submission to the FDA of periodic progress reports on confirmatory trials, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw any product approval granted through the accelerated approval pathway for multiple reasons, including if we fail to conduct any required post-market study with due diligence; a post-market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or we disseminate promotional materials that are found by the FDA to be false and misleading. Under the Consolidated Appropriations Act for 2023, the FDA may use expedited procedures to withdraw any product for which we receive accelerated approval if our confirmatory trials fail to verify the purported clinical benefits.

A failure to obtain accelerated approval or any other form of designation or program intended to expedite product development, review or approval for any of our product candidates that we determine to seek accelerated approval or designation for would result in a longer time to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We currently have Orphan Drug designation for our product candidate for the treatment of pancreatic cancer, and may seek Orphan Drug designation for additional product candidates, and we may be unsuccessful in obtaining or maintaining such designations.

The FDA or EMA may designate drugs for relatively small patient populations as Orphan Drugs. We have been granted Orphan Drug designation for our product candidate for the treatment of pancreatic cancer in the U.S. and European Union. For a description of orphan drug designation in the U.S., see "Government Regulation – Orphan Drug Status." For a description of orphan drug designation in the European Union, see "Government Regulation – Regulation Outside of the U.S. – European Union orphan designation and exclusivity."

Although we have received Orphan Drug designation for our pancreatic cancer product candidate, there is no guarantee that the product candidate will be successfully approved by the FDA or the EMA for such indication, that the product, if approved, will be commercially successful in the marketplace, or that another product will not be approved for the same indication ahead of our product candidate. Orphan Drug exclusivity may be lost if a regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Marketing exclusivity for a product designated as an Orphan Drug may not effectively protect the product candidate from competition because different drugs can be approved for the same rare disease or condition, and the same drug may be approved for a different condition that may be used off-label for an orphan indication. Even after an Orphan Drug is approved and granted exclusivity, the regulatory agency can subsequently approve the same drug or biological substance in a different product for the same condition if they conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

A Fast Track by the FDA or similar designation by another regulatory agency, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Fast Track designation by the FDA or similar designation by another regulatory agency for any of our product candidates but intend to seek such designation based upon the data generated from our clinical trials, if allowed to proceed and if successful. For a description of Fast Track designation, see Government Regulation Fast Track, Breakthrough Therapy and Priority Review Designations.

Even if we believe a product candidate is eligible for Fast Track or any similar designation, we cannot assure you that FDA or any other regulatory agency would decide to grant it. Even if we do receive Fast Track or similar designation, we may not experience a faster development process, review or approval compared to conventional procedures adopted by a regulatory agency. In addition, a regulatory agency may withdraw Fast Track or any similar designation if it believes that the designation is no longer supported by data from our clinical development program. Many product candidates that have received Fast Track designation have failed to obtain marketing approval.

A Breakthrough Therapy designation by the FDA or similar designation by another regulatory agency, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Breakthrough Therapy designation by the FDA or similar designation by another regulatory agency for any of our product candidates but intend seek such designation based upon the data we generate during our clinical trials, if successful. For a description of Breakthrough Therapy designation, see "Government Regulation – Fast Track, Breakthrough Therapy and Priority Review Designations."

A Breakthrough Therapy or similar designation is within the discretion of the FDA or other applicable regulatory agencies. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy or other similar designation, a regulatory agency may disagree and instead determine not to grant such designation. In any event, the receipt of a Breakthrough Therapy or other similar designation for a product candidate may not result in a faster development process, review or approval compared to drugs or biologics considered for approval under conventional procedures of a regulatory agency and does not ensure the designated product's ultimate approval. In addition, even if one or more of our product candidates receives Breakthrough Therapy designation or other similar designations, a regulatory agency may later decide that such product candidates no longer meet the conditions for the designation.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

To market and sell our product candidates in Europe and many other jurisdictions outside the U.S., we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval in the U.S. The regulatory approval process outside the U.S. generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approval from a regulatory agency outside the U.S. on a timely basis, if at all. Approval by FDA does not ensure approval by a regulatory agency in other countries or jurisdictions, and approval by one regulatory agency outside the U.S. does not ensure approval by a regulatory agency in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any market.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market. We may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of our product candidates are approved.

Our product candidates and the activities associated with their development and commercialization, if approved, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive and ongoing regulation by regulatory agencies. The requirements that result from such regulations include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by regulatory agencies, requirements regarding the distribution of samples to physicians and recordkeeping.

In addition, regulatory agencies may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product candidate. Regulatory agencies tightly regulate the post-approval marketing and promotion of drugs and biologics to ensure the products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. They also impose stringent restrictions on manufacturers' communications regarding use of their products. If we promote any of our product that may receive regulatory approval beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the laws relating to the promotion of prescription drugs or biologics may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

Also, later discovery of previously unknown adverse events or other problems with our product candidates or any products that may receive regulatory approval, or our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Restrictions on such products, approved manufacturers or manufacturing processes;
- Restrictions on the labeling or marketing of a product;
- Restrictions on product distribution or use;
- Requirements to conduct post-marketing studies or clinical trials;
- Notices of noncompliance, such as warning or untitled letters from the FDA, or inspectional observations;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall of products;
- Fines, restitution or disgorgement of profits or revenues;
- Suspension or withdrawal of marketing approvals;
- Clinical hold or suspension of any of our ongoing clinical trials;
- Refusal to permit the import or export of products;
- Product seizure; or
- Injunctions, consent decrees, or the imposition of civil or criminal penalties

Non-compliance with European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with EU requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacture, and sale of a biologic is a long, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacture, and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture, and sell our biological product candidates, or any biological component of our product candidates, would adversely impact our business and future results of operations.

Our relationships with customers 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, substantial civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments in the U.S. as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other healthcare providers, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable federal and state 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 products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations include the following:

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

The False Claims Act imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the Federal governments; and

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The Physician Payments Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family, which includes data collection and reporting obligations. Such information reported to CMS is made publicly available on a searchable website.

Analogous state and foreign 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 reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law 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, imprisonment, exclusion of our product candidates from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found 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.

Recently enacted and future legislation could increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the U.S. and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates or any of our potential future product candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Congress also must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the law's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the U.S.

Further, over the past several years there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The probability of success of these policies, many of which have been subjected to legal challenge in the federal court system, and their potential impact on the U.S. prescription drug marketplace is unknown. There are likely to be continued political and legal challenges associated with implementing these reforms as they are currently envisioned.

Additionally, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94) and includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples of a reference listed drug, to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in recent years, several states have formed PDABs. Much like the IRA's drug price negotiation program, these PDABs have attempted to implement UPLs on drugs sold in their respective states in both public and commercial health plans. In August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or EU member state level may result in significant additional requirements or obstacles that may increase our operating costs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Even if we are able to commercialize any of our drug candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

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

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the U.S., reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal healthcare programs or private health plans in the U.S. For example, a number of cancer drugs are generally covered and paid for in the U.S. but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. 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 payments for particular products. For example, payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA, or other comparable regulatory agencies. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs and biologics may be reduced by mandatory discounts or rebates required by federal healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In the U.S., third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U.S. Starting in 2023, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product's price increases faster than the rate of inflation. This calculation is made on a drug product-by-drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, the Centers for Medicare & Medicaid Services, or CMS, will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain biopharmaceutical products or additional pricing pressures.

In some foreign countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

Serious adverse events or undesirable side effects or other unexpected properties of our encapsulated live cell plus ifosfamide product candidate or any of our other product candidates may be identified during development that could delay or prevent the product candidates' marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an IRB or a regulatory agency to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label or the delay or denial of marketing approval by a regulatory agency. If any of our product candidates is associated with serious adverse events or undesirable side effects or has properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many drugs that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the drug.

Even if one of our product candidates 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 and the market opportunity for the product candidate may be smaller than we anticipated.

We have never commercialized a drug or biologic product. Even if one of our product candidates is approved by a regulatory agency for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable.

The degree of market acceptance of our encapsulated live cell plus ifosfamide product candidate or any of our other product candidates, if approved for commercial sale, will depend on several factors, including:

- The efficacy and safety of the product;
- The potential advantages of the product compared to alternative treatments;
- The prevalence and severity of any side effects;
- The clinical indications for which the product is approved;
- Whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- Limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- Our ability to offer the product for sale at competitive prices;
- Our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;
- The product's convenience and ease of administration compared to alternative treatments;
- The willingness of the target patient population to try, and of physicians to prescribe, the product;
- The strength of sales, marketing and distribution support;
- The approval of other new products for the same indications;
- Changes in the standard of care for the targeted indications for the product;
- The timing of market introduction of our approved products as well as competitive products and other therapies;
- Availability and amount of reimbursement from government payors, managed care plans and other third-party payors;
- Adverse publicity about the product or favorable publicity about competitive products; and
- Potential product liability claims.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

If any of our product candidates receives marketing approval and we or others later discover that the therapy is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the therapy could be compromised.

Clinical trials of our product candidates, if allowed to proceed, will be conducted in carefully defined subsets of patients who have provided informed consent to enter a clinical trial. Consequently, it is possible that our clinical trials, if allowed to proceed, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we or others discover that the product candidate is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following could occur:

- A regulatory agency may withdraw its approval of the product candidate or seize the product candidate;
- We may be required to recall the product candidate or change the way the product is administered;
- Additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product candidate;
- We may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- A regulatory agency may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- We may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution of our product candidate to patients;
- We could be sued and held liable for harm caused to patients;
- The product candidate may become less competitive; and
- Our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

If we are unable to establish sales, marketing and distribution capabilities or enter acceptable sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidate that we develop when a product candidate is approved.

We do not have any sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product candidate, we must either develop a sales and marketing organization, outsource these functions to third parties or license our product candidates to others. If approved by the FDA, the EMA or comparable foreign regulatory agencies, we expect to license our encapsulated live cell plus ifosfamide product candidate for pancreatic cancer to a large pharmaceutical company with greater resources and experience than us.

We may not be able to license our encapsulated live cell plus ifosfamide product candidate on reasonable terms, if at all. If other product candidates are approved for smaller or easily targeted markets, we expect to commercialize them in the U.S. directly with a small and highly focused commercialization organization. The development of sales, marketing and distribution capabilities will require substantial resources and will be time-consuming, which could delay any product candidate launch.

We expect that we will commence the development of these capabilities prior to receiving approval of any of our product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. Such a delay may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel.

In addition, we may not be able to hire or retain a sales force in the U.S. that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our product candidates, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product candidate independently.

We expect to seek one or more strategic partners for commercialization of our product candidates outside the U.S. Because of entering arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales and marketing capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

Risks Related to Our Dependence on Third Parties

We rely heavily on third parties to conduct our preclinical studies and plan to rely on third parties to conduct our clinical trials, assuming they are allowed to proceed, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies and trials.

We currently rely heavily on third parties to conduct our preclinical studies and plan to rely on third parties to conduct our clinical trials, assuming they are allowed to proceed, including Austrianova in which we own an equity interest. We expect to continue to rely heavily on third parties, such as contract research organizations ("CROs"), clinical data management organizations, medical institutions (including academic medical centers), clinical investigators and others to plan for and conduct our clinical trials. Our agreements with these third parties generally allow the third party to terminate our agreement with them at any time. Switching or adding third parties to conduct our studies involves substantial cost and requires extensive management time and focus. We may be forced to seek an engagement with a substitute or new third party and may be unable to enter into arrangements with such third parties on commercially reasonable terms, or at all. If we are required to enter alternative arrangements because of any such termination, the development, marketing authorization, or introduction of our product candidates to market could be delayed.

Our reliance on these third parties for R&D activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical trials and will remain responsible for ensuring that each is conducted in accordance with the general investigational plan and protocol for the trial. Moreover, regulatory agencies require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Regulatory agencies enforce GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our contractors fail to comply with applicable GCP regulations, the clinical data generated in the applicable trial may be deemed unreliable and regulatory agencies may require us to perform additional clinical trials before approving a drug candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from future sales of such drug candidate.We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database of regulatory agencies within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, and we will be unable to control whether or not our contracted third parties devote sufficient time and resources to our preclinical and clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with the requirements of a regulatory agency or our protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, disruptions in the global economy and supply chains could adversely affect the financial conditions of the third parties on which we rely, resulting in delays in preclinical studies and clinical trials that could adversely affect our business, financial condition and results of operations. For instance, Austrianova from time to time has experienced significant supply chain delays, some of which may be related to COVID-19, and we believe it may be experiencing liquidity issues.

We rely on numerous consultants for a substantial portion of our R&D related to our product candidates. If there are delays or failures to perform their obligations, our product candidates would be adversely affected. If our collaboration with these consultants is unsuccessful or is terminated, we would need to identify new research and collaboration partners for our preclinical and clinical development. If we are unsuccessful or significantly delayed in identifying new collaboration and research partners, or unable to reach an agreement with such a partner on commercially reasonable terms, development of our product candidates will suffer, and our business would be materially harmed.

In addition, if any of these consultants change their strategic focus, or if external factors cause any one of them to divert resources from our collaboration, or if any one of them independently develops products that compete directly or indirectly with our product candidates using resources or information it acquires from our collaboration, our business and results of operations could suffer.

Future preclinical and clinical development collaborations may be important to us. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development of our product candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any 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 several 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 our potential development schedule or increase our expenditures and undertake preclinical and clinical development activities at our own expense. If we fail to enter collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

Future collaborations we may enter may involve the following risks:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not perform their obligations as expected;
- Changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- Collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon preclinical or clinical development of a product candidate or must repeat or conduct new preclinical and clinical development of a product candidate;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;
- Product candidates 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 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 termination of the preclinical or clinical development or commercialization of product candidates. This 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 intellectual property rights licensed to us 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; and
- Collaborations may be terminated at the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of our product candidates.

In addition, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our 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. If we are unable to maintain our collaborations, development of our product candidates could be delayed, and we may need additional resources to develop them.

We rely on Prof. Günzburg and Dr. Salmons for the development of our product candidates. If they decide to terminate their relationship with us, we may not be successful in the development of our product candidates.

We rely on Prof. Walter H. Günzburg and Dr. Brian Salmons, officers of Austrianova, for the development of our product candidates. If they decide to terminate their relationship with us, we may not be successful in the development of our product candidates.

Prof. Günzburg and Dr. Salmons are involved in almost all our scientific endeavors underway and being planned by us. These endeavors include preclinical and clinical studies involving our cancer therapy for LAPC to be conducted in the U.S. and elsewhere on our behalf. They also provide professional consulting services to us through the respective consulting agreements we have entered with the consulting companies through which they provide services. The consulting agreements may be terminated for any reason at any time upon one party giving the other written notice prior to the effective date of the termination. If that occurs, we may not be successful in the development of our product candidates which could have a material adverse effect on us.

The manufacture of our product candidates is complex, and difficulties may be encountered in production. If such difficulties are encountered or failure to meet regulatory standards occurs, our ability to provide supply of our product candidates for clinical trials, if allowed to proceed, or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our product candidates are complex, expensive, highly regulated and subject to multiple risks. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Further, as product candidates are developed through preclinical studies to potential future clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. We expect to rely on third-party manufacturers for the manufacturing of our products. However, there can be no assurance that we will be able to maintain our relationships with such third-party manufacturers on commercially reasonable terms, if at all. If we are unable to maintain those relationships, we could experience delays in our development efforts as we locate and qualify new third-party manufacturers.

In order to conduct planned or future clinical trials of our product candidates, or supply commercial products, if approved, we will need to have them manufactured in small and large quantities. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and potential clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

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

Furthermore, our third-party manufacturers are subject to inspection and approval by regulatory agencies before we can obtain regulatory approval and commercially launch of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in enforcement actions, such as the issuance of inspectional observations or notices of noncompliance, or sanctions being imposed on us, including clinical holds, injunctions, civil penalties, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any such failure by us or any of our third-party manufacturers would significantly impact our ability to develop, obtain regulatory approval for or, if approved, market our products.

Risks Related to our Intellectual Property

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

Filing, prosecuting and defending patents or establishing other intellectual property rights to our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. or non-existent. For example, the Melligen cells are protected by patents only in the U.S. and Europe and we are only pursuing patent protection for our pancreatic cancer product candidate in the U.S., Australia and Canada.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or misappropriation of our intellectual property rights generally. Proceedings to enforce our patent and other intellectual property 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 or intellectual property rights 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.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our ability to pursue strategic alternatives, including identifying and consummating transactions with potential third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates, and consequently our potential revenue opportunities.

Our intellectual property and data and market exclusivity may not be sufficient to block others from commercializing identical or competing products.

Our success depends in large part on our ability to obtain and maintain both intellectual property rights and data and market exclusivity for our product candidates in order to block others from commercializing identical or competing products. Establishing intellectual property rights includes filing, prosecuting, maintaining and enforcing patents that cover our product candidates and variations of our product candidates and protecting our trade secrets and other proprietary information related to our product candidates from unauthorized use.

The foundational patents relating to the Cell-in-the-Box® technology that were formerly licensed from Bavarian Nordic/GSF covering capsules encapsulating cells expressing cytochrome P450 and treatment methods using the same expired on March 27, 2017. We may not be able to obtain protection for our product candidates or variations of our product candidates. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage or our patents may expire before or shortly after our product candidate is approved. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Confidential know-how and trade secrets are only protectable to the extent a third party utilizes the confidential know-how or trade secret in an unauthorized manner; however, if a third party is able to independently duplicate the technology, such as through reverse engineering, without access to or use of our confidential know-how or trade secret, we would have no recourse.

In addition, data exclusivity that is provided through the BPCIA in the U.S. and equivalents in foreign countries is limited in both time and scope. The BPCIA bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval, however it does not bar the FDA from approving an identical or similar product that is the subject of its own BLA. Finally, upon the approval of the first BLA for a biologic designated as an Orphan Drug for a specified indication, the sponsor of that BLA is entitled to 7 years of exclusive marketing rights in the U.S. for biologic for the particular indication unless the sponsor cannot assure the availability of sufficient quantities to meet the needs of persons with the disease. In Europe, this exclusivity is 10 years. However, Orphan Drug status for an approved indication does not prevent another company from seeking approval of a biologic that has other labeled indications that are not under orphan or other exclusivities. In addition, in the U.S., the FDA is not prevented from approving another biologic for the same labeled Orphan indication if the company can demonstrate that the other biologic is clinically superior to first approved product.

Even if we are able to obtain patents, maintain confidential information, trade secrets, obtain data, and market exclusivity for our product candidates, our competitors may be able to develop and obtain approval of identical or competing products.

If we are unable to obtain and maintain intellectual property protection for our technology and product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patents in the U.S. and abroad related to our product candidates. Our patent portfolio relating to the Cell-in-the-Box® technology was formerly licensed from Bavarian Nordic/GSF. The Bavarian Nordic/GSF patents covered capsules encapsulating cells expressing cytochrome P450 and treatment methods using the same. The patents are issued in the U.S. and Europe and expire in August 2028. Currently, we do not have any issued patents in any countries covering our product candidate for the treatment of cancer; we have pending applications in the U.S., Australia and Canada and relating to our product candidate for the treatment of pancreatic cancer. If issued, such patents would expire in March 2038.

We cannot estimate the financial or other impact of the expiration of the Bavarian Nordic/GSF patents or the failure of the USPTO or similar regulatory authorities in other countries denying the claims we pursue in the U.S. and other countries.

The patent prosecution and/or patent maintenance process is expensive and time-consuming. We may not be able to file and prosecute or maintain all necessary or desirable patent applications or maintain the existing patents at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and preclinical development output before it is too late to obtain patent protection.

Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, India does not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 or more months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Consequently, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Any future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our owned or licensed patent applications and the enforcement or defense of our owned or licensed patents. On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes several significant changes to patent law in the U.S. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act. Many of the substantive changes to patent law associated with the Leahy-Smith Act, such as the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or licensed patent applications and the enforcement or defense of our owned or licensed patents, all of which could have a material adverse effect on our business and financial condition.

Also, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter-party review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current our future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and 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. Thus, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license. Moreover, our licensors may fail to take the steps that we believe are necessary or desirable to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

If we do not obtain patent and/or data exclusivity for our product candidates, our business may be materially harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property protection and/or data exclusivity under the BPCIA in the U.S. and other countries with respect to our proprietary technology, product candidates and our target indications.

If we are unable to obtain patents covering our product candidates or obtain data and/or marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products, such as a biosimilar, earlier than might otherwise be the case.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with numerous procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue because our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents associated with our business at risk of being invalidated or interpreted narrowly. We may also elect to enter license agreements to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

If we breach any of our license or collaboration agreements, it could compromise our development and commercialization efforts for our product candidates.

We have licensed rights to intellectual property from third parties to commercialize our product candidates, including our Cell-in-a-Box® Technology for LAPC. If we materially breach or fail to perform any provision under these license and collaboration agreements, including failure to make payments to a licensor or collaborator when due for royalties and failure to use commercially reasonable efforts to develop and commercialize our product candidates, such licensors and collaborators have the right to terminate our agreements, and upon the effective date of such termination, our right to practice the licensed intellectual property would end. Any uncured, material breach under the agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under the agreements and could result in the loss of our ability to develop or commercialize our product candidates.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. Although we believe that licenses to these patents may be available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or are not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO and various governmental patent agencies outside of the U.S. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we could obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be successful in obtaining or maintaining necessary rights for its development pipeline through acquisitions and licenses from third parties.

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. We may be unable to acquire or in-license any compositions, methods of use or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and numerous established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering confidentiality agreements with our employees and consultants; however, we cannot be certain that such agreements have been entered with all relevant parties.

Moreover, to the extent we enter such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets to unaffiliated third parties. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

The majority of the technology that we license and use for our product candidates is not protected by patents, but rather is based upon confidential know-how and trade secrets. Confidential know-how and trade secrets are only protectable to the extent a third party utilizes the confidential know-how or trade secret in an unauthorized manner; however, if a third party is able to independently duplicate the technology, such as through reverse engineering, without access to or use of our confidential know-how or trade secret, we would have no recourse.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals and use consultants and independent contractors who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to ensure that our employees and our consultants and independent contractors 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 trade secrets, or other confidential information of our employees', consultants' or independent contractors' former employers, clients or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and others working for us.

In addition, while it is our policy to require our employees, consultants and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make compositions that are the same as or like our product candidates, but that are not covered by the claims of any patents that we may own or exclusively license;
- others may be able to make product that is like the product candidates we intend to commercialize that is not covered by any patents that we might own or exclusively license and have the right to enforce;
- we, our licensors or any collaborators might not have been the first to make the inventions covered by issued patents or pending patent applications that we may own;
- we, our licensors or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own may not provide us with any competitive advantages, or may be held invalid or unenforceable because of legal challenges;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to Our Business Model and Operations

Development of brand awareness is critical to our success.

For certain market segments that we plan to pursue, the development of our brand awareness is essential for us to reduce our marketing expenditures over time and realize greater benefits from marketing expenditures. If our brand-marketing efforts are unsuccessful, growth prospects, financial condition and results of operations would be adversely affected. Our brand awareness efforts have required, and will most likely continue to require, additional expenses and time of the current senior management team.

Any weakness in our internal controls could have a material adverse effect on us.

As discussed in Item 9A. "Controls and Procedures," the senior management has identified a material weakness in our internal controls over financial reporting and cannot assure you that additional material weaknesses will not be identified in the future. We cannot assure you that these steps will be successful in preventing material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. In addition, any such failure could adversely affect our ability to report financial results on a timely and accurate basis, which could have other material effects on our business, reputation, results of operations, financial condition or liquidity. Material weaknesses in internal controls over financial reporting or disclosure controls and procedures could also cause investors to lose confidence in our reported financial information which could have an adverse effect on the trading price of our securities.

The insurance coverage and reimbursement status of newly approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our products, if approved will depend substantially, both domestically and abroad, on the extent to which the costs of our products, if approved, will be paid 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. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we can charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the U.S. and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, thus, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures with the sale of any of our products, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become very intense. Because of this, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. Many private payors may also contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

Our employees, consultants and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could subject us to significant liability and harm our reputation.

We are exposed to the risk of fraud and other misconduct by those who work for us. Misconduct by employees, consultants or independent contractors could include failures to comply with the FCPA or with the DEA, the FDA or the EMA regulations or similar regulations of other foreign regulatory authorities or to provide accurate information to the DEA, the FDA, the EMA or other foreign regulatory authorities. In addition, misconduct could include failures to comply with certain manufacturing standards, to comply with U.S. federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Misconduct by those who work for us could also involve the improper use of information obtained during our clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have implemented and will enforce a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct by those who work for us. 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 such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our transactions and relationships outside the U.S. will be subject to the FCPA and similar anti-bribery and anti-corruption laws.

As we pursue international clinical trials, licensing and, in the future, sales arrangements outside the U.S., we will be heavily regulated and expect to have significant interaction with foreign officials. Additionally, in many countries outside the U.S., the healthcare providers who prescribe pharmaceuticals are employed by the government and the purchasers of pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers would be subject to regulation under the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Compliance with these laws and regulations may be costly and may limit our ability to expand into certain markets. There is no certainty that all our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- Decreased demand for any product candidates or products that we may develop;
- Injury to our reputation and significant negative media attention;
- Withdrawal of clinical trial participants;
- Significant costs to defend the related litigation;
- Substantial monetary awards to trial participants or patients;
- Loss of revenue;
- Reduced resources of our management to pursue our business strategy; and
- The inability to commercialize any products that we may develop.

We currently do not have product liability insurance because we do not have any products to market. We will need such insurance for clinical trials, if allowed to proceed, and for commercialization of our products, if approved. Product liability insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We incur increased costs because of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and are continuing to incur significant legal, accounting and other expenses. These expenses may increase. We are subject to, among others, the reporting requirements of the Exchange Act of 1934, as amended ("Exchange Act"), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the Commission. Our management and other personnel devote a substantial amount of time to these compliance initiatives.

Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time-consuming and costlier. The increased costs have increased our net loss. These rules and regulations may make it more difficult and more expensive for us to maintain sufficient director and officer liability insurance coverage. We cannot predict or estimate the amount or timing of additional costs we may continue to incur to respond to these requirements. The ongoing impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers.

Risk Factors Related to Our Stock and Financial Condition

Our common stock is currently listed on Nasdaq. Market prices for our shares of common stock will be influenced by several factors, including, but not limited to:

- The issuance of new shares pursuant to future offering;
- Changes in interest rates;
- New services or significant contracts and acquisitions;
- Variations in quarterly operating results;
- Change in financial estimates by securities analysts;
- The depth and liquidity of the market for the shares;
- Investor perceptions of us and of investments based in the countries where we do business or conduct research; and
- General economic and other national and international conditions.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional common stock or other securities convertible into or exchangeable for our common stock at prices lower than that paid by existing investors. Investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing investors.

We may not be able to meet the continued listing requirements for Nasdaq or another nationally recognized stock exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

In order to remain listed on Nasdaq, we will be required to meet the continued listing requirements of Nasdaq or any other U.S. or nationally recognized stock exchange to which we may apply and be approved for listing. We may be unable to satisfy these continued listing requirements, and there is no guarantee that our common stock will remain listed on Nasdaq or any other U.S. or nationally recognized stock exchange. If, after listing, our common stock is delisted from Nasdaq or any other U.S. or nationally recognized stock exchange, we could face significant material adverse consequences, including:

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

A large number of shares may be issued and subsequently sold upon the exercise of existing options and warrants and upon the conversion of the Company's Series B convertible preferred stock (the "Series B Preferred Shares").

As of August 8, 2024, there were 925,164 shares of common stock issuable under outstanding options, 18,570,847 shares of common stock issuable upon exercise of outstanding warrants at various exercise prices and 3,765,105 shares of common stock reserved for issuance upon conversion of the Preferred Shares. To the extent that holders of existing options or warrants sell the shares of common stock issued upon the exercise of warrants, the market price of our common stock may decrease due to the additional selling pressure in the market. The risk of dilution from issuances of shares of common stock underlying existing options and warrants may cause shareholders to sell their common stock, which could further decline in the market price.

The requirement that we redeem the Series B Preferred Shares in cash could adversely affect our business plan, liquidity, financial condition, and results of operations.

If not converted, we are required to redeem some or all of the outstanding shares of Series B Preferred Shares for cash under certain circumstances. These obligations could have important consequences on our business. In particular, they could:

- limit our flexibility in planning for, or reacting to, changes in our businesses and the industries in which we operate;
- increase our vulnerability to general adverse economic and industry conditions; and
- place us at a competitive disadvantage compared to our competitors.

No assurances can be given that we will be successful in making the required payments to the holders of the Series B Preferred Shares or that we will be able to comply with the financial or other covenants contained in the Certificate of Designations. If we are unable to make the required cash payments or otherwise comply with the Certificate of Designations:

- dividends will accrue on the Series B Preferred Shares at 15% per annum;
- the holders of the Series B Preferred Shares could foreclose against our assets; and/or
- we could be forced into bankruptcy or liquidation.

The terms of the Series B Preferred Shares could limit our growth and our ability to finance our operations, fund our capital needs, respond to changing conditions and engage in other business activities that may be in our best interests.

The Certificate of Designations contains a number of affirmative and negative covenants regarding matters such as the payment of dividends, maintenance of our properties and assets, transactions with affiliates, and our ability to issue other indebtedness.

Our ability to comply with these covenants may be adversely affected by events beyond our control, and we cannot assure you that we can maintain compliance with these covenants. The financial covenants could limit our ability to make needed expenditures or otherwise conduct necessary or desirable business activities.

We may obtain additional capital through the issuance of preferred stock, which may limit your rights as a holder of our common stock.

Without any stockholder vote or action, our Board may designate and approve for issuance shares of our preferred stock. The terms of any preferred stock may include priority claims to assets and dividends and special voting rights which could limit the rights of the holders of our common stock. The designation and issuance of preferred stock favorable to current management or stockholders could make any possible takeover of us or the removal of our management more difficult.

We may experience volatility in our stock price, which may adversely affect the trading price of our common stock.

We have experienced significant volatility from time to time in the market price of our shares of common stock. Factors that may affect the market price include the following:

- Announcements of regulatory developments or technological innovations by us or our competitors;
- Changes in our relationship with our licensors and other strategic partners;
- Our quarterly operating results;
- Litigation involving or affecting us;
- Shortfalls in our actual financial results compared to our guidance or the forecasts of stock market analysts;
- Developments in patent or other technology ownership rights;
- Acquisitions or strategic alliances by us or our competitors;
- Public concern regarding the safety of our products; and
- Government regulation of drug pricing.

The price of our common stock is volatile, which substantially increases the risk that our investors may not be able to sell their shares at or above the price that the investors have paid for their shares.

Because of the price volatility in our shares, we have observed since its inception, investors in our common stock may not be able to sell their shares when they desire to do so at a price the investors desire to attain. During the year ended April 30, 2024, shares of our common stock were quoted and traded at a high of $3.23 per share and a low of $1.92 per share. The inability to sell securities in a rapidly declining market may substantially increase the risk of loss because the price of our common stock may suffer greater declines due to the historical price volatility of our shares. Certain factors, some of which are beyond our control, which may cause our share price to fluctuate significantly include, but are not limited to, the following:

- Variations in our quarterly operating results;
- Loss of a key relationship or failure to complete significant product candidate milestones timely or at all;
- Additions or departures of key personnel; and
- Fluctuations in the stock market price and volume.

In addition, in recent years the stock market in general, and the over-the-counter markets in particular, have experienced extreme price and volume fluctuations. In some cases, these fluctuations are unrelated or disproportionate to the performance of the underlying company. These market and industry factors may materially and adversely affect our share price, regardless of our performance or whether we meet our business objectives. In the past, class action litigation often has been brought against companies following periods of volatility in the market price of those companies' common stock. If we become involved in this type of litigation in the future, it could result in substantial costs and diversion of management attention and resources, which could have a material adverse effect on us and the trading price of our common stock.

We have no plans to pay dividends in the foreseeable future, and investors may not expect a dividend as a return of or on any investment in us.

We have not paid dividends on our shares of common stock and do not anticipate paying such dividends in the foreseeable future. In addition, the terms of the certificate of designations governing our Preferred Shares presently restricts our ability to pay dividends.

We are a "smaller reporting company" under the Commission's disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.

We are a "smaller reporting company" under the Commission's disclosure rules, meaning that we have either:

- a public float of less than $250 million; or
- annual revenues of less than $100 million during the most recently completed fiscal year; and
- no public float; or
- a public float of less than $700 million.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our Commission filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our Commission filings will result in less information about our company being available than for other public companies.

If investors consider our common stock less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile.

As a non-accelerated filer, we are not required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.

We are a non-accelerated filer under the Exchange Act, and we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common stock less attractive because we are not required to comply with the auditor attestation requirements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and trading price for our common stock may be negatively affected.

We face risks related to owning securities issued by other public companies.

We own securities of other public companies, including the Notes, the MYMD Preferred Shares, the Femasys Warrants and the MyMD Warrants. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Femasys Transaction" and "– MyMD Transaction" for more information regarding these securities. Defined terms used in this risk factor are defined in such section.

The Notes are convertible at a conversion price of $1.18 per share. To the extent we convert the Notes when the market price of the Femasys Shares is lower than the conversion price, we may realize a loss equal to the difference between the conversion price and the market price. Femasys may require us to convert our Notes into Femasys Shares if the closing price of the Femasys Shares exceeds $2.36 per share for 10 consecutive trading days and the daily dollar trading volume of the Femasys Shares exceeds one million dollars ($1,000,000) per day during the same period and certain equity conditions described in the Notes are satisfied. If we are forced to mandatorily convert the Notes, we may realize additional loss.

The MyMD Preferred Shares are convertible at a conversion price of $1.816 per share. To the extent we convert the MyMD Preferred Shares when the market price of the MyMD Common Shares is lower than the conversion price, we may realize a loss equal to the difference between the conversion price and the market price.

The Series A Warrants are exercisable at an exercise price of $1.18 per share, and the Series B Warrants are exercisable at an exercise price of $1.475. There can be no assurance that the Femasys Warrants will be in the money when exercisable, and as such they may expire worthless.

The MyMD Warrants are exercisable at an exercise price of $1.816 per share. There can be no assurance that the MyMD Warrants will be in the money when exercisable, and as such they may expire worthless.

Our ownership of securities of other companies creates a risk that we will be categorized as an investment company that is subject to registration under the Investment Company Act of 1940 (the "1940 Act"). If we are deemed to be an investment company under the 1940 Act, we may be required to institute burdensome compliance requirements and our activities may be restricted, which may make it difficult for us to continue operating our business.

Section 3(a)(1)(A) of the 1940 Act defines an "investment company" as any issuer that is or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities. Section 3(a)(1)(C) of the 1940 Act defines "investment company" to mean any issuer that is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having a value exceeding 40% of the value of such issuer's total assets. Such investment companies are required to register and meet other requirements promulgated under the 1940 Act. Our purchases of securities of other companies, including pursuant to the Femasys Transaction and the MyMD Transaction (each as defined below), could give rise to a determination that we are or were an investment company subject to registration under the 1940 Act. Such a determination could have a material adverse effect on our business operations, projected revenues and earnings, and growth prospects.

We believe that we are not an investment company, and we have conducted and intend to continue to conduct our operations so that we will not be deemed to be an investment company. However, if we were deemed to be an investment company under the 1940 Act, our future activities may be restricted, including:

- restrictions on the nature of our investments; and
- restrictions on the issuance of securities, each of which may make it difficult for us to conduct our business and raise working capital.

In addition, we may have imposed upon us burdensome requirements, including:

- registration as an investment company with the Commission;
- adoption of a specific form of corporate structure different from our current operating structure; and
- reporting, record keeping, voting, proxy and disclosure requirements and other rules and regulations that we are currently not subject to.

Compliance with these additional regulatory burdens would require additional expenses for which we have not allotted funds and may hinder our ability to operate our business, and make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Employee and Tax Matters, Managing Growth and Macroeconomic Conditions

We have experienced significant management changes which could increase our control risks and have a material adverse effect on our ability to do business and our results of operations.

We have recently experienced a number of changes in our management, including changes in our Chief Executive Officer and Board. The magnitude of these changes and the short time interval in which they have occurred add to the risks of control failures, including a failure in the effective operation of our internal control over financial reporting or our disclosure controls and procedures. Control failures could result in material adverse effects on our financial condition and results of operations. It may take time for the new management team to become sufficiently familiar with our business and each other to effectively develop and implement our business strategies. The turnover of key management positions could further harm our financial performance and results of operations. Management attention may be diverted from regular business concerns by reorganizations.

We have a limited number of employees and are highly dependent on our Chief Executive Officer and Chief Financial Officer. Our future success depends on our ability to retain these officers and other key personnel and to attract, retain and motivate other needed qualified personnel.

We are an early-stage biotechnology company with a limited operating history. As of April 30, 2024, we had 2 full-time employees and numerous consultants. We are highly dependent on the R&D, clinical and business development expertise of the principal members of our management, scientific and clinical teams, specifically, on our Interim Chief Executive Officer and Chief Financial Officer. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our Interim Chief Executive Officer and Chief Financial Officer or other key employees or consultants could severely impede the achievement of our R&D and commercialization of our product candidates and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers and key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on other consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, preclinical and clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of April 30, 2024, we had federal net operating loss carryforwards of approximately $57 million, and approximately $27 million for state net operating losses, which will begin to expire in varying amounts beginning in 2024. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes will be limited to approximately $20 million and $11 million for federal and state, respectively.

We experienced ownership changes in the past and could experience one or more ownership changes in the future, some of which are outside our control. Our net operating loss carryforwards are subject to limitation under state laws. Further, our ability to utilize net operating loss carryforwards of companies that we may acquire in the future may also be subject to limitations. There is also a risk that due to tax law changes, such as suspensions on the use of net operating loss carryforwards, or other unforeseen reasons, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation or expire.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities. Thus, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis related to COVID-19 caused extreme volatility and disruptions in the capital and credit markets. Also, geopolitical tensions and the conflicts between Russia and Ukraine and between Israel and Palestine continue to escalate, and numerous jurisdictions have imposed harsh sanctions on certain industry sectors and parties in Russia, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets and financial services industry.

A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could adversely impact our business.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our third-party service providers on whom we rely on are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party service providers. While we and, to our knowledge, our third-party service providers have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of our third-party service providers, it could result in a material disruption of our drug development programs. If any disruptions occur, they could have a material adverse effect on our business.

We are subject to legal, regulatory, financial and other risks with our operations outside the U.S.

We operate globally and are attempting to develop products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in overseeing foreign operations;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third-party disputes over ownership of intellectual property and infringement of third-party intellectual property by our products; and
- general social, economic and political conditions in these foreign markets.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our Board is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. In general, we seek to address cybersecurity risks by utilizing reputable third party vendors and service providers to manage and maintain our information systems and assets in accordance with strong cybersecurity policies, standards, processes and practices, and by preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain policies to ensure our systems are effective and prepared for information security risks. For example, our PharmaCyte Information Security Policy, which applies to all employees, contractors and third parties granted access to our systems and provides guidelines for maintaining information security, including safeguarding personal and company-issued digital devices, learning to detect phishing and other attacks, restricting data transfer, and ensuring the judicious use of the internet and social media. We also maintain a more general Risk Management Strategy that sets forth our procedures for identifying, assessing, responding to, monitoring, and reporting risks, including any cyber-related risks.

Our approach to addressing cybersecurity threat risks also includes mitigating risk associated with our use of third-party service providers. For example, when we enter into contracts with third-party collaborators or vendors pursuant to which sensitive business or personal data will be shared or accessible, we include provisions safeguarding the protection of confidential information. We also utilize a third-party service provider to maintain our information systems and assets and to employ technical safeguards that are designed to protect our information systems from cybersecurity threats.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. We maintain an Information Security Incident Response form that directs a detector of any incident to report such incident to our Information Security Officer, whom we contract through a third-party service provider. Following notice of any such incident, our Information Security Officer would then work with our Chief Financial Officer and our Board to establish an appropriate response plan and to determine the materiality of the incident and any disclosure obligations.

As discussed in more detail under “Cybersecurity Governance” below, our Board provides oversight of our risk management and strategy processes.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading “We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure,” which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is part of our overall risk management processes. In general, our Board oversees risk management activities designed and implemented by our management, and considers specific risks, including, for example, risks associated with our strategic plan, business operations, and capital structure. Any cybersecurity incident that occurs would be brought to the immediate attention of the Board.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by a contracted third-party Information Security Officer. Such individual has over 25 years of experience in information technology, including over 14 years of experience in cybersecurity, and has a master's degree in cybersecurity. Our Information Security Officer is informed about and monitors our cybersecurity risk through his participation in the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan.

ITEM 2. PROPERTIES

Our principal office is located at 3960 Howard Hughes Parkway, Suite 500, Las Vegas, Nevada 89169 and we lease this space on a month-to-month arrangement. This space consists of approximately 100 square feet of office space plus the use of certain shared facilities, such as a lobby, conference rooms, a kitchen and open workspaces. We believe this space will be adequate for our operations for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on our financial condition or operating results.

On December 4, 2023, H.C. Wainwright & Co., LLC ("Wainwright") filed a complaint against us in the Supreme Court of the State of New York, County of New York, asserting a single cause of action for breach of contract and alleging that we breached an April 2021 engagement agreement with Wainwright by failing to pay a purported "tail fee" allegedly due in connection with a private placement transaction that closed in 2023. Wainwright seeks damages of not less than $1,950,000, warrants to purchase an aggregate of 656,250 shares of our common stock at an exercise price of $5.00 per share, and attorney's fees. On February 28, 2024, we responded to the complaint with an answer and affirmative defenses. We intend to vigorously defend against Wainwright's complaint and do not believe that any potential loss is reasonably probable at this time.

To our knowledge, there are no other material legal proceedings pending against us or any material litigation against any of our officers or directors in their capacity as such, and no such litigation is contemplated by any governmental authorities.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our shares of common stock are listed on the Nasdaq Capital Market ("Nasdaq"), where they have traded under ticker symbol "PMCB" since initial listing on August 10, 2021.

The following table sets forth the high and low bid quotations reported on Nasdaq through April 30, 2024 for our shares for each quarter during the two fiscal years ("FYs") ended April 30, 2024 and 2023. The prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	Bid Price	
FY 2024	HIGH	LOW
First Quarter	$ 3.23	$ 2.66
Second Quarter	$ 2.73	$ 1.94
Third Quarter	$ 2.39	$ 1.92
Fourth Quarter	$ 2.58	$ 1.94
FY 2023		
First Quarter	$ 2.51	$ 1.95
Second Quarter	$ 3.02	$ 2.33
Third Quarter	$ 3.10	$ 2.70
Fourth Quarter	$ 3.04	$ 2.78

As of August 8, 2024, there were approximately 1,400 stockholders of record of our common stock. The number of stockholders of record does not include beneficial owners of our securities whose shares are held in the name of various security brokers, dealers and registered clearing agencies.

Dividend Policy

We have not paid and do not plan to pay cash dividends in the foreseeable future. In addition, the terms of the certificate of designations governing our Preferred Shares presently restricts our ability to pay dividends. Our Board will decide any future payment of dividends, depending on the results of operations, financial condition, capital requirements and other relevant factors.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Report regarding information about securities authorized for issuance under our equity compensation plans.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The table below summarizes information about the Company's purchases of its equity securities during the year ended April 30, 2024.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under the Plans or Programs
May 1, 2023 – May 31, 2023	–	–	–	$ 6,439,377
June 1, 2023 – June 30, 2023	–	–	–	$ 6,439,377
July 1, 2023 – July 31, 2023	–	–	–	$ 6,439,377
August 1, 2023 – August 31, 2023	–	–	–	$ 6,439,377
September 1, 2023 – September 30, 2023	–	–	–	$ 6,439,377
October 1, 2023 – October 31, 2023	78,109	$ 2.1118	78,109	$ 6.272.775
November 1, 2023 – November 30, 2023	60,695	$ 2.1863	60,695	$ 6.138.751
December 1, 2023 – December 31, 2023	60,072	$ 2.2901	60,072	$ 5.999.807
January 1, 2024 – January 31, 2024	58,066	$ 2.2465	58,066	$ 5.868.058
February 1, 2024 – February 29, 2024	36,482	$ 2.1610	36,482	$ 5,788,433
March 1, 2024 – March 31, 2024	353,480	$ 2.4701	353,480	$ 4,906,583
April 1, 2024 – April 30, 2024	93,573	$ 2.3797	93,573	$ 4,681,682
Total	740,477	$ 2.3502	740,477	$ 4,681,682

On June 2, 2022, the Company announced that the Board had authorized a share repurchase program to acquire up to $10 million of the Company's outstanding common stock (the "First Repurchase Program"). The number of shares of common stock repurchased on any given trading day was determined by a formula, which was based on the market price of the common stock and average daily volumes. The First Repurchase Program expired on May 30, 2024. On January 31, 2023, the Board authorized a share repurchase program to repurchase up to an additional $10 million of the Company's outstanding common stock (the "Second Repurchase Program" and together with the First Repurchase Program, the "Repurchase Programs"). Under the Second Repurchase Program, the shares may be repurchased from time to time in open market transactions, privately negotiated block transactions or other means in accordance with applicable securities laws. For more information on the Repurchase Programs, see "Note 13 – Treasury Stock."

ITEM 6. [RESERVED]

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

The following discussion may contain forward-looking statements that involve risks and uncertainties. As described under the caption "Cautionary Note Regarding Forward-Looking Statements," our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, any factors discussed in this section as well as factors described in Part II, Item 1A. "Risk Factors" and under the caption "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer based upon our proprietary cellulose-based live cell encapsulation technology we refer to as Cell-in-a-Box®. We are working to advance clinical research and development of new cellular-based therapies in oncology.

We are engaged preparing for a clinical trial in LAPC using encapsulated live cells.

On September 1, 2020, we submitted an IND to the FDA for our planned clinical trial in LAPC. On October 1, 2020, we received notice from the FDA that it had placed our IND on clinical hold. On October 30, 2020, the FDA sent a letter to us setting forth the reasons for the clinical hold and specific guidance on what we must do to have the clinical hold lifted.

To address our clinical hold, we assembled a team of regulatory and scientific experts to respond to the items requested by the FDA. That team has been working to complete the list of items requested by the FDA. For a complete discussion of what the FDA requires of us and the efforts we have undertaken to lift the clinical hold, see Item 1. Business under the Section entitled, "Clinical Hold" of this Report.

Private Placement

On May 9, 2023, we entered into a securities purchase agreement with certain accredited investors, pursuant to which we issued and sold, in a private placement (the "PIPE"), an aggregate of (i) 35,000 Series B Preferred Shares, initially convertible into up to 8,750,000 shares of common stock at a conversion price of $4.00 per share, and (ii) warrants (the "PIPE Warrants") to acquire up to 8,750,000 shares of common stock at an exercise price of $4.00 per share. Each Series B Preferred Share and accompanying PIPE Warrants were sold together at a combined offering price of $1,000. The terms of the Preferred Shares are as set forth in the Certificate of Designations of Series B Convertible Preferred Stock of PharmaCyte Biotech, Inc. (the "Certificate of Designations"), which was filed and became effective with the Secretary of State of the State of Nevada on May 10, 2023. The PIPE Warrants are immediately exercisable and expire 5 years from issuance.

In connection with the PIPE, we entered into a registration rights agreement, pursuant to which we filed a Registration Statement on Form S-3 (File No. 333-272569) to register the resale of the shares underlying the Series B Preferred Shares and the PIPE Warrants. Such Registration Statement was declared effective by the Commission on September 29, 2023.

For descriptions of the Series B Preferred Shares and the PIPE Warrants, see "Note 12 – Preferred Stock" and Note 6 – Stock Options and Warrants," respectively.

Femasys Transaction

On November 14, 2023, we entered into a securities purchase agreement (the "Femasys Purchase Agreement") with Femasys Inc. ("Femasys"), pursuant to which we purchased from Femasys (i) senior unsecured convertible notes (the "Notes") in an aggregate principal amount of $5,000,000, convertible into shares of Femasys common stock, par value $0.001 per share (the "Femasys Shares") at a conversion price of $1.18 per share, (ii) Series A Warrants (the "Series A Warrants") to purchase up to an aggregate of 4,237,288 Femasys Shares at an exercise price of $1.18 per share, and (iii) Series B Warrants (the "Series B Warrants" and, together with the Series A Warrants, the "Femasys Warrants") to purchase up to an aggregate of 4,237,288 Femasys Shares at an exercise price of $1.475 per share (collectively, the "Femasys Transaction").

The Femasys Purchase Agreement contains certain representations and warranties, covenants and indemnities customary for similar transactions. Pursuant to the Femasys Purchase Agreement, we have the right to nominate one individual to serve on Femasys' board of directors (the "Femasys Board") until the earlier of (a) when the Company beneficially owns less than 4.99% of the number of Femasys Shares outstanding and (b) the repayment of the Notes in full (such time, the "Investor Board Seat Fall-Away"). In addition, we agreed to a standstill until the later of (a) our nominee remaining on the Femasys Board and (b) 12 months after the Investor Board Seat Fall-Away, during which period we may not, among other things, acquire additional securities of Femasys other than pursuant to the Notes or Femasys Warrants.

The Notes are senior unsecured obligations of Femasys and accrue interest at a rate of 6.00% per annum, payable annually, in cash or Femasys Shares at Femasys' option, and mature two years after the date of issuance. The Notes are convertible into Femasys Shares at our election at any time at an initial conversion price of $1.18. The conversion price is subject to customary adjustments for stock dividends, stock splits, reclassifications and similar corporate events. Femasys agreed in the Femasys Purchase Agreement and the Notes not to issue or sell any of its equity securities at a price below the then-current conversion price for a period of 18 months after closing, subject to certain exceptions.

Beginning six months after issuance, Femasys may require us to convert our Notes into Femasys Shares if the closing price of the Femasys Shares exceeds $2.36 per share (subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations or other similar events) for 10 consecutive trading days and the daily dollar trading volume of the Femasys Shares exceeds one million dollars ($1,000,000) per day during the same period and certain equity conditions described in the Notes are satisfied.

The Notes provide for certain events of default, including, among other things, Femasys' failure to file and maintain an effective registration statement covering the sale of the securities registrable pursuant to a registration rights agreement and Femasys' failure to pay any amounts due to us when due. In connection with an event of default, we will be able to require Femasys to redeem in cash any or all of our Notes at a premium of 115%.

Under the terms of the Notes, Femasys is subject to certain affirmative and negative covenants regarding the incurrence of indebtedness, acquisition and investment transactions, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends, distributions or redemptions, and the transfer of assets, among other matters.

The Series A Warrants are exercisable for Femasys Shares immediately at an exercise price of $1.18 per share and expire five years from the date of issuance. Femasys has the right to call the exercise of the Series A Warrants if the closing price of the Femasys Shares exceeds 200% of the exercise price for 10 consecutive trading days and the daily dollar trading volume of the Femasys Shares exceeds one million dollars ($1,000,000) per day during the same period and certain equity conditions are satisfied. The Series B Warrants are exercisable for Femasys Shares immediately at an exercise price of $1.475 per share and expire one year from the date of issuance. Femasys has the right to call the exercise of the Series B Warrants if the closing price of the Femasys Shares exceeds 200% of the exercise price for 10 consecutive trading days and the daily dollar trading volume of the Femasys Shares exceeds one million dollars ($1,000,000) per day during the same period and certain equity conditions are satisfied.

In connection with the Femasys Transaction, we entered into a registration rights agreement with Femasys, pursuant to which Femasys was required to file a resale registration statement with the Commission, registering 100% of the shares issuable pursuant to the Notes and the Femasys Warrants.

In connection with the Femasys Transaction, we entered into a collaboration agreement with Femasys, dated November 14, 2023, whereby, if the Company and Femasys agree to conduct research activities or enter into a research plan in connection with discussing, evaluating and seeking technology that may be available to in-license or acquire with a view to enhancing the existing products of Femasys or adding new complementary products, we will establish a joint research committee with two representatives of Femasys and one representative of the Company to oversee the execution of the research plan and coordinate research activities.

TNF Transaction

On May 20, 2024, we entered into a securities purchase agreement (the "TNF Purchase Agreement") with TNF Pharmaceuticals, Inc. (f/k/a MyMD Pharmaceuticals, Inc.) ("TNF"), pursuant to which we purchased from TNF (i) shares of TNF's Series G Convertible Preferred Stock (the "TNF Preferred Shares"), convertible into 3,854,626 shares of TNF's common stock, par value $0.001 per share (the "TNF Common Shares"), (ii) warrants to purchase up to 3,854,626 TNF Common Shares with a five-year term (the "Long-Term Warrants") and (iii) warrants to purchase up to 3,854,626 TNF Common Shares with an 18-month term (the "Short-Term Warrants" and, together with the Long-Term Warrants, the "TNF Warrants") for an aggregate purchase price of $7,000,000 (the purchase of the TNF Preferred Shares, the Long-Term Warrants and the Short-Term Warrants, the "TNF Transaction").

Pursuant to the TNF Purchase Agreement, we have the right to participate in future sales of TNF's equity and equity-linked securities until the second anniversary of the closing or the date on which no TNF Preferred Shares remain outstanding, whichever is earlier. Additionally, we have the right to nominate one individual to serve on TNF's board of directors until the Company no longer beneficially owns 20% of the TNF Common Shares on an as-converted basis.

The terms of the TNF Preferred Shares are as set forth a certificate of designations (the "TNF Certificate of Designations"), which TNF filed with the Secretary of State for the State of Delaware on May 21, 2024. The TNF Preferred Shares are convertible into TNF Common Shares at our election at any time at an initial conversion price of $1.816. The conversion price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of TNF Common Shares, or securities convertible, exercisable or exchangeable for TNF Common Shares, at a price below the then-applicable conversion price (subject to certain exceptions). At any time after the issuance date of the TNF Preferred Shares, TNF has the option to redeem in cash all or any portion of the outstanding TNF Preferred Shares then outstanding at a premium upon notice to the Company.

Pursuant to the TNF Certificate of Designations, we will be entitled to dividends of 10% per annum, compounded monthly, which will be payable in cash or in TNF Common Shares at our option. Upon the occurrence and during the continuance of a Triggering Event (as defined in the TNF Certificate of Designations), the TNF Preferred Shares will accrue dividends at the rate of 15% per annum. Upon conversion or redemption, we are entitled to receive a dividend make-whole payment. We will be entitled to vote with holders of the TNF Common Shares on as as-converted basis, with the number of votes to which we are entitled to be calculated assuming a conversion price of $2.253 per share. TNF's ability to settle conversions and make dividend make-whole payments by issuing TNF Common Shares is subject to certain limitations set forth in the TNF Certificate of Designations.

The TNF Certificate of Designations includes certain triggering events, including, among other things, the failure by TNF to file and maintain an effective registration statement covering the sale of the securities registrable pursuant to a registration rights agreement and the failure by TNF to pay any amounts to us when due. In connection with a triggering event, we will be able to require TNF to redeem in cash any or all of its TNF Preferred Shares at a premium set forth in the TNF Certificate of Designations.

TNF is subject to certain affirmative and negative covenants regarding the incurrence of indebtedness, the existence of liens, the repayment of indebtedness, the payment of cash in respect of dividends (other than dividends pursuant to the TNF Certificate of Designations), distributions or redemptions, and the transfer of assets, among other matters.

The Long-Term Warrants are exercisable for TNF Common Shares immediately, at an exercise price of $1.816 per share and expire five years from the date of issuance. The Short-Term Warrants are exercisable for TNF Common Shares immediately, at an exercise price of $1.816 per share and expire 18 months from the date of issuance. The exercise price of each TNF Warrant is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment, on a "full ratchet" basis, in the event of any issuances of TNF Common Shares or securities convertible, exercisable or exchangeable for TNF Common Shares at a price below the then-applicable exercise price (subject to certain exceptions).

In connection with the TNF Transaction, we entered into a registration rights agreement with TNF, pursuant to which TNF was required to file a resale registration statement with the Commission, registering 200% of the shares issuable pursuant to the TNF Preferred Shares and the TNF Warrants.

Increase in Authorized Shares

On September 6, 2023, pursuant to stockholder approval received at a special meeting of stockholders, we filed with the Secretary of State of the State of Nevada a Certificate of Change to our Articles of Incorporation, as amended, to increase the number of authorized shares of common stock from 133,333,334 to 200,000,000. The Certificate of Change had no impact on the number of authorized shares of preferred stock, which remains at 10,000,000.

Performance Indicators

Non-financial performance indicators used by management to manage and assess how the business is progressing will include, but are not limited to, the ability to: (i) acquire appropriate funding for all aspects of our operations; (ii) acquire and complete necessary contracts; (iii) complete activities for producing genetically modified human cells and having them encapsulated for our preclinical studies and the planned clinical trial in LAPC; (iv) have regulatory work completed to enable studies and trials to be submitted to regulatory agencies; (v) complete all required tests and studies on the cells and capsules we plan to use in our clinical trial in patients with LAPC; (vi) ensure completion of the production of encapsulated cells according to cGMP regulations to use in our planned clinical trial; (vii) complete all of the tasked the FDA requires of us in order to have the clinical hold lifted; and (viii) obtain approval from the FDA to lift the clinical hold on our IND that we may commence our planned clinical trial in LAPC.

There are numerous items required to be completed successfully to ensure our final product candidate is ready for use in our planned clinical trial in LAPC. The effects of material transactions with related parties, and certain other parties to the extent necessary for such an undertaking, may have substantial effects on both the timeliness and success of our current and prospective financial position and operating results. Nonetheless, we are actively working to ensure strong ties and interactions to minimize the inherent risks regarding success. We do not believe there are factors which will cause materially different amounts to be reported than those presented in this Report. We aim to assess this regularly to provide accurate information to our shareholders.

Liquidity and Capital Resources

As of April 30, 2024, our cash and cash equivalents totaled approximately $50.2 million, compared to approximately $68 million as of April 30, 2023. Working capital was approximately $43 million as of April 30, 2024, and approximately $67.6 million as of April 30, 2023. The decrease in cash is attributable to the repurchase of our common stock pursuant to the Repurchase Programs, recorded as treasury stock and an increase in our operating expenses.

Repurchase Programs

Pursuant to the First Repurchase Program, we may acquire up to $10 million of our outstanding shares of common stock, as determined by a formula based on the market price of the common stock and average daily volumes. Pursuant to the Second Repurchase Program, we may acquire up to $10 million of our outstanding shares of common stock from time to time in open market transactions, privately negotiated block transactions or other means in accordance with applicable securities laws. For more information on the Second Repurchase Program, see "Note 13 – Treasury Stock."

Other Liquidity Matters

We have no other off-balance sheet arrangements that could have a material current effect or that are reasonably likely to have a material adverse effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

To meet our short and long-term liquidity needs, we expect to use existing cash balances and a variety of other means. Other sources of liquidity could include additional potential issuances of debt or equity securities in public or private financings, partnerships, collaborations and sale of assets. Our history of operating losses and liquidity challenges may make it difficult for us to raise capital on acceptable terms or at all. The demand for the equity and debt of pharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations. Our future capital requirements are difficult to forecast and will depend on many factors, but we believe that our cash on hand will enable us to fund operating expenses for at least the next 12 months following the issuance of our consolidated financial statements.

Year ended April 30, 2024, compared to year ended April 30, 2023

Revenue

We had no revenues in the fiscal years ended April 30, 2024, and 2023.

Operating Expenses

Our total operating expenses during the year ended April 30, 2024 were $8,520,008, representing an increase of $2,064,514 compared to the year ended April 30, 2023. The increase is mainly attributable to increases in compensation expenses, director fees and general and administrative expenses, net of decreases in R&D and legal and professional expenses.

Operating expenses:	Year ended April 30, 2024	Change - Increase (Decrease) and Percent	Year ended April 30, 2023
R&D	$ 407,431	$ (61,105) (13%)	$ 468,536
Compensation expense	$ 1,322,414	$ 87,458 7%	$ 1,234,956
Director fees	$ 1,141,215	$ 189,868 20%	$ 951,347
Impairment of asset	$ 2,000,000	$ 2,000,000 –	–
General and administrative, legal and professional	$ 3,648,948	$ (151,707) (4%)	$ 3,800,655

Loss from Operations

Loss from operations during the year ended April 30, 2024 was $8,520,008, an increase of $2,064,514 compared to the year ended April 30, 2023. The increase is mainly attributable to increases in compensation expenses, director fees and general and administrative expense, impairment of asset, net of decreases in R&D and legal and professional expenses. See the table under "*Operating Expenses*" above for more detail.

Other Income (Expenses), Net

Other income, net for the year ended April 30, 2024, was $8,853,771, as compared to other income, net of $2,139,501 in the year ended April 30, 2023. Other income, net for the year ended April 30, 2024 is attributable to interest income of $3,398,819, changes in fair values of warrant liability of $3,343,000, derivative liability of $586,000, convertible note receivable of $1,089,000 and warrant asset of $1,818,000, less loss on write-off of long term asset of $1,572,193 net of other income of $191,145. Other income is attributable to recovery of accrued expenses of $195,000 less income taxes and foreign exchange loss. Other income, net for the year ended April 30, 2023 is attributable to interest income of $1,937,499 net settlement of accounts payable of $152,976 and net of other income and expense of $49,026.

Loss on write-off of long-term asset

For the year ended April 30, 2024, the Company recorded an asset loss of $1,572,193, related to the Company's investment in SG Austria, reducing the carrying value of such investment to zero. See Note 2 of the Consolidated Financial Statements to this Report for more information.

Discussion of Operating, Investing and Financing Activities

The following table presents a summary of our sources and uses of cash for the years ended April 30, 2024 and 2023.

	Year Ended April 30, 2024	Year Ended April 30, 2023
Net cash used in operating activities:	$ (2,151,457)	$ (3,793,731)
Net cash used in investing activities:	$ (5,000,000)	$ –
Net cash used in financing activities:	$ (10,708,003)	$ (13,559,743)
Effect of currency rate exchange	$ (508)	$ (7,246)
Increase (decrease) in cash	$ (17,859,968)	$ (17,360,720)

Operating Activities:

The cash and cash equivalents used in operating activities for the years ended April 30, 2024 and 2023 is a result of our net losses from operations offset by securities issued, assets impaired, changes in fair values of warrant liability, derivative liability, note receivable, warrant asset, changes to prepaid expenses, accounts payable and accrued expenses.

Investing Activities:

On November 14, 2023, we entered into a securities purchase agreement, pursuant to which agreed to purchase a convertible note receivable in the amount of $5 million, convertible into common stock and warrants (Series A and B) to purchase additional common stock. See Note 3 – Investment in Debt and Equity Securities. We had no investing activities for the year ended April 30, 2023.

Financing Activities:

The cash and cash equivalents used in financing activities for the year ended April 30, 2024 was mainly attributable to the Repurchase Programs of approximately $28,198,000, redemption of preferred stock of approximately $16,161,000, and the cash provided by proceeds from the issuance of preferred stock of approximately $33,650,000, net of transaction costs. For the year ended April 30, 2023, the cash and cash equivalents used is mainly attributable to the Repurchase Programs of approximately $13,561,000.

Critical Accounting Estimates

Our Consolidated Financial Statements are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). We are required to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the related disclosures. We base our assumptions, estimates and judgments on historical experience, current trends and other factors that management believes to be relevant at the time our Consolidated Financial Statements are prepared. On a regular basis, management reviews the accounting policies, assumptions, estimates and judgments to ensure that our Consolidated Financial Statements are presented fairly and in accordance with U.S. GAAP. However, because future events and their effects cannot be determined with certainty, actual results could differ from our assumptions and estimates, and such differences could be material.

Our significant accounting policies are discussed in Note 2 of the Notes to our Consolidated Financial Statements included in Item 8, "Financial Statements and Supplementary Data" of this Report. Management believes that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results and require management's most difficult, subjective or complex judgments resulting from the need to make estimates about the effects of matters that are inherently uncertain. Management has reviewed these critical accounting estimates and related disclosures with our Board.

Fair Value of Financial Instruments

Fair value measurements are based upon certain market assumptions and pertinent information available as of and during the year ended April 30, 2024. The fair value of the bifurcated embedded derivative related to the convertible preferred stock was estimated using a Monte Carlo simulation model, which uses as inputs the fair value of our common stock and estimates for the equity volatility and traded volume volatility of our common stock, the time to maturity of the convertible preferred stock, the risk-free interest rate for a period that approximates the time to maturity, dividend rate, a penalty dividend rate, and our probability of default. The fair value of the warrant liability was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield, expected term in years; equity volatility; and risk-free interest rate.

In addition, the Company elects to account for its convertible note receivable, which meets the required criteria, at fair value at inception and at each subsequent reporting date. Subsequent changes in fair value, including interest, are recorded as a component of non-operating income (loss) in the consolidated statements of operations. The Company estimates the fair value of the convertible note receivable using the income approach, which uses as inputs the fair value of debtor's common stock and estimates for the equity volatility and volume volatility of debtor's common stock, the time to expiration of the convertible note, the discount rate, the stated interest rate compared to the current market rate, the risk-free interest rate for a period that approximates the time to expiration, and probability of default. Therefore, the estimate of expected future volatility is based on the actual volatility of debtor's common stock and historical volatility of debtor's common stock utilizing a lookback period consistent with the time to expiration. The time to expiration is based on the contractual maturity date. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of measurement for time periods approximately equal to the time to expiration. The probability of default is estimated using the S&P Global default rate for companies with a similar credit rating to debtors. The fair value in our warrant asset investment is estimated using a Monte Carlo simulation model, which uses as inputs the fair value of the underlying common stock, and estimates for the equity volatility and traded volume volatility of the investee's common stock, the risk-free interest rate for a period that approximates the expected life of the warrants, and the expected life of the warrants.

Impairment of Assets

We determined that the diabetes licensed asset technology would likely not prove to be a viable technique for the production of insulin producing cells and the treatment of diabetes. We believe that a buyer of this technology would ascribe a de minimis value to this asset. Therefore, we determined that there should be a full impairment of the $2 million carrying value. We determined that research in the treatment of diabetes would no longer be pursued until the Cell-in-a-Box® use in pancreatic cancer treatment can be substantiated in a clinical trial and a viable cell line is acquired.

We determined that due to the SG Austria financial position, negative book value and viability make for an inconclusive determination of a specific value range of our minority interest in SG Austria and the value as of the present time is likely minimal. Therefore, we determined that there should be a full impairment of the approximately $1.6 million carrying value.

New Accounting Pronouncements Effective in Future Periods

For a discussion of new accounting pronouncements effective in future periods, see "Recent Accounting Pronouncements" in Note 2 of our Notes to our Consolidated Financial Statements included in Item 8, "Financial Statements and Supplementary Data" of this Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company and are not required to include information called for by this Item 7A.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Balance Sheets, as of April 30, 2024 and 2023, and our Consolidated Statements of Operations, Comprehensive Loss, Stockholders Equity and Cash Flows for each of the years in the years ended April 30, 2024 and April 30, 2023, and associated Notes and Schedules, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report and are incorporated by reference herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Interim Chairman, Interim Chief Executive Officer and Interim President, as our principal executive officer ("Chief Executive Officer"), and our Chief Financial Officer, as our principal financial officer ("Chief Financial Officer"), evaluated the effectiveness of our "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act. Disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or submit to the Commission pursuant to the Exchange Act are recorded, processed, summarized and reported within the period specified by the Commission's rules and forms and are accumulated and communicated to our management, including our Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosures. Based upon this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of April 30, 2024, certain of our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting. This is described below in Management's Report on Internal Control over Financial Reporting.

Management's Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting as that term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected in a timely basis.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal controls over financial reporting as of April 30, 2024, based on the criteria outlined in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and identified the following material weaknesses in internal controls over financial reporting:

- Insufficient Segregation of Duties of the Chief Financial Officer. We have delegated some of the duties of our Chief Financial Officer to other personnel within the Company and have added review and approval processes performed by the Chief Executive Officer. However, we have determined that we still have insufficient segregation of the duties of our Chief Financial Officer. We plan to hire an additional person to work for our Chief Financial Officer to enable sufficient segregation of his duties.
- Insufficient management review controls. We have identified weaknesses in the design of our internal controls which have led us to conclude that we currently have insufficient management review controls. We intend to hire an additional person to work for our Chief Financial Officer to enable sufficient review in the future.

Because of this material weakness, our Interim Chief Executive Officer and our Chief Financial Officer concluded that, as of April 30, 2024, our internal controls over financial reporting were not effective based on the COSO criteria.

We plan to make changes to our procedures and controls that we believe are reasonably likely to strengthen and materially affect our internal controls over financial reporting.

Prior to the remediation of our material weakness, there remains risk that the processes and procedures on which we currently rely will fail to be sufficiently effective, which could result in material misstatement of our financial position or results of operations and require a restatement. Because of the inherent limitations in all control systems, no evaluation of controls - even where we conclude the controls are operating effectively - can provide absolute assurance that all control issues, including instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of a person, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events; accordingly, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, our control systems, as we develop them, may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected and could be material to our financial statements.

Changes in Internal Controls over Financial Reporting

There were no changes to our internal control over financial reporting during the fiscal year ended April 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

The Certifications of our Principal Executive and Principal Financial Officer required in accordance with Rule 13a-14(a) under the Exchange Act and Section 302 of the Sarbanes-Oxley Act of 2002 (“Certifications”) are attached to this Report. The disclosures set forth in this Item 9A contain information concerning: (i) the evaluation of our disclosure controls and procedures, and changes in internal control over financial reporting, referred to in paragraph 4 of the Certifications; and (ii) material weaknesses in the design or operation of our internal control over financial reporting, referred to in paragraph 5 of the Certifications. The Certifications should be read in conjunction with this Item 9A for a more complete understanding of the matters covered by the Certifications.

Limitations on the Effectiveness of Disclosure Controls and Procedures

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. 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. Also, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

ITEM 9B. OTHER INFORMATION

During the year ended April 30, 2024, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

As of July 15, 2024, our directors and executive officers are:

	Age	Position
Joshua N. Silverman	54	Interim Chairman of the Board, Interim Chief Executive Officer and Interim President
Carlos A. Trujillo	66	Chief Financial Officer
Jonathan L. Schechter	50	Director
Robert Weinstein	64	Director
Wayne R. Walker	64	Director
Michael M. Abecassis	66	Director

Joshua N. Silverman

Joshua Silverman has served as a director of the Company since August 2022 and as our Interim Chief Executive Officer, Interim President and Interim Chairman of the Board since October 2022. Mr. Silverman has served as the managing member of Parkfield Funding LLC since August 2016. Mr. Silverman co-founded Iroquois Capital Management, LLC ("Iroquois"), an investment advisory firm, in 2003 and served as its principal, managing partner and co-chief investment officer until July 2016. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as co-chief investment officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as assistant press secretary to the president of the U.S. Mr. Silverman currently serves as a director of AYRO, Inc. (Nasdaq: AYRO), TNF Pharmaceuticals, Inc. (Nasdaq: TNFA), Synaptogenix, Inc. (Nasdaq: SNPX) and Petros Pharmaceutical, Inc. (Nasdaq: PTPI). He previously served as a director of Marker Therapeutics, Inc. (Nasdaq: MRKR) from 2016 until 2018 and Protagenic Therapeutics, Inc. (Nasdaq: PTIX) from 2016 to 2022. Mr. Silverman received his B.A. from Lehigh University in 1992. Mr. Silverman was chosen as a director of the Company because of his experience as an investment banker, as a management consultant and as a director of numerous public companies.

Jonathan L. Schechter

Jonathan L. Schechter has served as a director of the Company since August 2022. Mr. Schechter has served as the Director of Investment Banking at Chardan Capital Markets, a full-service investment bank, since February 2008. He has served as a partner of The Special Equities Group, a division of Dawson James Securities, Inc., a full-service investment bank specializing in healthcare, biotechnology, technology, and clean-tech sectors, since April 2021. Mr. Schechter is one of the founding partners of The Special Equities Opportunity Fund, a long-only fund that makes direct investments in micro-cap companies and has served in this capacity since August 2019. He currently serves on the board of directors of Synaptogenix, Inc., (Nasdaq: SNPX), a clinical-stage biopharmaceutical company, and previously served as a director of DropCar, Inc. He has received formal education in finance and accounting and has extensive experience analyzing and evaluating the financial statements of public companies. Mr. Schechter earned his A.B. in Public Policy/Political Science from Duke University and his J.D. from Fordham University School of Law. Mr. Schechter was chosen as a director of the Company because of his lengthy public company, legal and investment banking experience.

Michael M. Abecassis

Michael M. Abecassis, MD has served as a director of the Company since July 2017. Since November 2019, Dr. Abecassis has been Dean of the University of Arizona College of Medicine – Tucson, and following postgraduate training at the University of Toronto, Dr. Abecassis began his professional career as Assistant Professor of Surgery and Director of Liver Transplantation and Hepatobiliary Surgery at the University of Iowa. In 1992, Dr. Abecassis became Northwestern University's Director of Liver Transplantation, where he initiated Northwestern's liver transplant program. In 2004, Dr. Abecassis was named Chief of the Division of Transplantation at the Feinberg School of Medicine, and the James Roscoe Miller Distinguished Professor with Tenure at Feinberg. He then became Founding Director of the Comprehensive Transplant Center at Northwestern in 2009. He was appointed Dean for Clinical Affairs at the Feinberg School of Medicine in 2008, serving until 2011. Dr. Abecassis received continuous funding from the National Institutes of Health ("NIH") for 20+ consecutive years as principal investigator in research studies that include both laboratory and clinical studies. Dr. Abecassis is a member in good standing of several important professional societies, including the Society of University Surgeons and the American Surgical Association, and was elected President of the American Society of Transplant Surgeons from 2010-2011. He has served on the Editorial Boards of major scientific journals related to the fields of Hepato-pancreatico-biliary (HPB) and transplant surgery. He has served as a member of NIH grant study sections and special emphasis panels relating to both transplantation and virology. He served as a permanent member of the National Institute of Allergy and Infectious Diseases study section for career development and training grants. Dr. Abecassis has been a course director for the American Society of Transplant Surgeons Leadership Development Program for the Advanced Leader Development Program in 2013 at Northwestern's Kellogg School of Management. He was a voting member of the Medicare Coverage Advisory Committee and served on the United HealthCare Group Physician Advisory Board on Healthcare Performance and Quality. Dr. Abecassis has been a member of various local, regional and national regulatory committees and has published seminal papers on both the regulatory and financial aspects of transplantation, including the Healthcare Reform and the Affordable Care Act. Dr. Abecassis received his Medical Degree from the University of Toronto in 1983 and was awarded a Master of Business Administration degree from the Kellogg School of Management at Northwestern University in 2000. Dr. Abecassis was also a co-founder of Transplant Genomics Inc., a company focused on developing, validating and commercializing molecular biomarkers for transplant rejection, and currently a subsidiary of Eurofins Diagnostics. Dr. Abecassis was chosen as a director of the Company because of the combination of his clinical training and experience in HPB diseases (e.g. liver and pancreatic cancer), his research background in related areas, and his experience with the regulatory and business aspects of translation and commercialization of research efforts.

Robert Weinstein

Robert Weinstein has served as a director of the Company since November 2022. Mr. Weinstein has served as chief financial officer of Synaptogenix, Inc. (Nasdaq: SNPX since October 2013. In addition, Mr. Weinstein performs work as a consultant for Petros Pharmaceuticals, Inc. (Nasdaq: PTPI). He has extensive accounting and finance experience, spanning more than 30 years, as a public accountant, investment banker, healthcare private equity fund principal and chief financial officer. From September 2011 to the present, Mr. Weinstein has also been an independent consultant for several healthcare companies in the pharmaceutical and biotechnology industries. Mr. Weinstein also serves as a member of the Board of Directors of XWELL, Inc. (formerly XpresSpa Group, Inc.) (Nasdaq: XWEL), a health and wellness company whose core assets, XpresSpa and XpresCheck®, is a leading airport retailer of spa services and related health and wellness products. Mr. Weinstein also serves on the Board of Directors of Oblong, Inc. (Nasdaq: OBLG), a company providing multi-stream collaboration technologies and managed services for video collaboration and network applications. Mr. Weinstein received his MBA degree in finance and international business from the University of Chicago Graduate School of Business, is a Certified Public Accountant (inactive), and received his BS degree in accounting from the State University of New York at Albany. Mr. Weinstein was chosen as a director of the Company because of his public company and financial expertise.

Wayne R. Walker

Wayne R. Walker has served as a director of the Company since December 2022. Mr. Walker has over 35 years of experience in corporate governance, turnaround management, corporate restructuring and bankruptcy matters. In 1998, Mr. Walker founded Walker Nell Partners, Inc., an international business consulting firm, and has served as its president from its founding to the present. Before founding Walker Nell Partners, Inc., Mr. Walker worked for 15 years at the DuPont Company in Wilmington, Delaware in the Securities and Bankruptcy group, where he worked in the Corporate Secretary's office and served as Senior Counsel. From 2022 to present, Mr. Walker has served as a director of AMMO, Inc. (Nasdaq: POWW), a designer, producer, and marketer of ammunition products. From December 2020 to the present, Mr. Walker has served as a director of AYRO, Inc. (Nasdaq: AYRO), a designer and manufacturer of compact, sustainable electric vehicles. From 2018 to the present, Mr. Walker has served as a director of Wrap Technologies, Inc. (Nasdaq: WRAP), an innovator of modern policing solutions, where he also serves as chairman of the board. From 2018 to the present, Mr. Walker has served as a director of Pitcairn Company and as the Chair of its Compensation Committee. From 2013 to 2014, Mr. Walker served as chairman of the board of directors of BridgeStreet Worldwide, Inc., a global provider of extended corporate housing. From 2016 to 2018, Mr. Walker served as chairman of the board of directors of Last Call Operating Companies, an owner of various national restaurants. From 2013 to 2020, Mr. Walker served as chairman of the board of trustees of National Philanthropic Trust, a public charity. From 2018 to 2020, Mr. Walker served as Vice President of the Board of Education of the City of Philadelphia. From 2020 to the present, Mr. Walker has served as a director of Petros Pharmaceuticals, Inc. (Nasdaq: PTPI), which focuses on men's health. Mr. Walker has also served on the board of directors for numerous other companies and foundations including Seaborne Airlines, Inc., Green Flash Brewery, Inc., and Eagleville Hospital and Foundation. Mr. Walker has a J.D. from Catholic University (Washington, DC) and a Bachelor of Arts from Loyola University (New Orleans). He is an attorney licensed by the State Bar of Georgia. He is a member of the State Bar Association of Georgia, American Bar Association, American Bankruptcy Institute and Turnaround Management Association. Mr. Walker was chosen as a director of the Company because of his extensive board experience.

Carlos A. Trujillo

Carlos A. Trujillo has been our Chief Financial Officer since March 2017. He began working for us as an independent contractor in September 2014. In January 2015, Mr. Trujillo became a full-time employee as the Vice President of Finance of both us and Viridis Biotech, and in March 2017, Mr. Trujillo was appointed as our Chief Financial Officer. Mr. Trujillo has over three decades of experience in management, business, operations, and financial accounting. Mr. Trujillo is a Certified Public Accountant with an active license from the State of California. He has more than three decades of experience in finance, accounting, and management. Mr. Trujillo started his career in public accounting and was the manager of an audit department for a regional public accounting firm. Mr. Trujillo then established a consulting and accounting practice which he operated for ten years and provided services as the Chief Financial Accountant to numerous organizations in several different industries. His experience has extended to companies in the biotechnology, telecommunications, manufacturing, construction, and real estate development sectors. For the last fifteen years, Mr. Trujillo has been the Chief Financial Officer for both privately held and publicly traded and multinational companies. From June 2008 through September 2014, Mr. Trujillo was the Chief Financial Officer of VelaTel Global Communications, Inc. As a result, he brings experience to us in preparing and filing periodic reports with the Commission, in mergers and acquisitions and in the filing of comprehensive financial statements. Mr. Trujillo received his Bachelor of Accounting degree from California State University, Fullerton in 1982.

Family Relationships

There are no family relationships among our executive officers, directors and significant employees.

Legal Proceedings

As of April 30, 2024, our personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the rules and regulations of the Commission.

Code of Ethics

Our Board has adopted a written Code of Business Conduct and Ethics, an Insider Trading Policy and Software Policies that apply to our directors, officers, employees and contractors. These documents can be viewed and downloaded from the "Governance" dropdown menu of our website under the "Company" tab. The content of these documents is not incorporated into this Report.

Corporate Governance and Committees

Board Leadership and Structure

The Chairman of the Board presides at all meetings of the Board. Mr. Silverman serves as the Interim Chairman of the Board and as our Interim Chief Executive Officer, and Interim President.

The Board does not have a policy on whether or not the roles of Chief Executive Officer and Chairman of the Board should be separate. The Board believes that it should be free to make a choice from time to time in any manner that is in the best interests of the Company and our stockholders.

Audit Committee

The Audit Committee is currently comprised of Robert Weinstein, Wayne R. Walker, and Jonathan L. Schechter. The Chairman of the Audit Committee is Mr. Weinstein. The primary purposes of our Audit Committee are to assist the Board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, auditing, financial reporting, internal control, legal compliance and risk management functions of the Company, including, assisting the Board's oversight of: (i) the integrity of our financial statements; (ii) the effectiveness of our internal control over financial reporting; (iii) our compliance with legal and regulatory requirements; (iv) the qualifications and independence of our independent registered public accounting firm; and (v) the performance of our internal audit function and independent registered public accounting firm.

Our Board has determined that each member of our Audit Committee is independent within the meaning of the rules of Nasdaq. Our Board has determined that the Chairman of the Audit Committee, Mr. Weinstein, is an "audit committee financial expert," as that term is defined in Item 407(d) of Regulation S-K under the Exchange Act.

A copy of the Audit Committee's written charter is publicly available on our website at *ir.pharmacyte.com/governance-docs*.

Compensation Committee

The Compensation Committee is currently comprised of Mr. Walker, Dr. Abecassis and Mr. Schechter. The Chairperson of the Compensation Committee is Mr. Schechter. The primary purposes of our Compensation Committee are: (i) to establish and maintain our executive compensation policies and compensation consistent with corporate objectives and stockholder interests; (ii) to oversee the competency and qualifications of our senior management personnel and the provisions of senior management succession planning; and (iii) to advise the Board with respect to director compensation issues.

The Compensation Committee, which is composed of independent directors, provides overall guidance for our executive compensation policies and determines the value and elements of compensation for our executive officers.

A copy of the Compensation Committee's written charter is publicly available on our website at *ir.pharmacyte.com/governance-docs*.

Nominating Committee

The Nominating Committee is currently comprised of Mr. Walker, Mr. Schechter, and Mr. Weinstein. The Chairperson of the Nominating Committee is Mr. Walker.

The primary purposes of the Nominating Committee are: (i) to recommend to the Board the nomination of individuals who are qualified to serve as our directors and on committees of the Board; (ii) to advise the Board with respect to the composition, size, structure and procedures of the Board; (iii) to advise the Board with respect to the composition, size and membership of the Board's committees; (iv) to advise the Board with respect to corporate governance principles applicable to the Company; and (v) to oversee the evaluation of the Board as a whole and the evaluation of its individual members standing for re-election. The Nominating Committee also has responsibility for reviewing and approving all transactions that are "related party" transactions under the Commission's rules.

The Nominating Committee does not set specific, minimum qualifications that nominees for director must meet in order for the Nominating Committee to recommend them to the Board, but rather believes that each nominee should be evaluated based on his or her individual merits, considering our needs and the composition of the Board. Members of the Nominating Committee discuss and evaluate possible candidates in detail and suggest individuals to explore in more depth. Once a candidate is identified whom the Nominating Committee wants to seriously consider and move toward nomination, the Chairman of the Nominating Committee enters into a discussion with that nominee candidate. Subsequently, the Chairperson will discuss the qualifications of the candidate with the other members of the Nominating Committee, and the Nominating Committee will then make a final recommendation with respect to that candidate to the Board.

If a stockholder wishes to propose a candidate for consideration as a nominee for election to our Board, it must follow the procedures described in "Stockholder Proposals and Nominations for Director" at the end of this proxy statement. In general, persons recommended by stockholders will be considered in accordance with our Nominating Committee's written charter. Any such recommendation should be made in writing to the Nominating Committee, care of our Interim President at our principal office and should be accompanied by the following information concerning each recommending stockholder and the beneficial owner, if any, on whose behalf the nomination is made:

- all information relating to such person that would be required to be disclosed in a proxy statement;
- certain biographical and share ownership information about the stockholder and any other proponent, including a description of any derivative transactions in the Company's securities;
- a description of certain arrangements and understandings between the proposing stockholder and any beneficial owner and any other person in connection with such stockholder nomination; and
- a statement whether or not either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of voting shares sufficient to carry the proposal.

The recommendation must also be accompanied by the following information concerning the proposed nominee:

- certain biographical information concerning the proposed nominee;
- all information concerning the proposed nominee required to be disclosed in solicitations of proxies for election of directors;
- certain information about any other security holder of the Company who supports the proposed nominee;
- a description of all relationships between the proposed nominee and the recommending stockholder or any beneficial owner, including any agreements or understandings regarding the nomination; and
- additional disclosures relating to stockholder nominees for directors, including completed questionnaires and disclosures required by our Bylaws.

The recommendation must also be accompanied by the following information concerning the proposed nominee:

- certain biographical information concerning the proposed nominee;
- all information concerning the proposed nominee required to be disclosed in solicitations of proxies for election of directors;
- certain information about any other security holder of the Company who supports the proposed nominee;
- a description of all relationships between the proposed nominee and the recommending stockholder or any beneficial owner, including any agreements or understandings regarding the nomination; and
- additional disclosures relating to stockholder nominees for directors, including completed questionnaires and disclosures required by our Bylaws.

A copy of the Nominating Committee's written charter is publicly available on our website at *ir.pharmacyte.com/governance-docs*.

Board Practices

Our business and affairs are managed under the direction of our Board. The primary responsibilities of our Board are to provide oversight, strategic guidance, counseling and direction to our senior management.

Policy Regarding Board Attendance

Our directors are expected to attend meetings of the Board as frequently as necessary to properly discharge their responsibilities and to spend the time needed to prepare for each such meeting. If an annual meeting of stockholders is held, our directors are expected to attend that meeting, but we do not have a formal policy requiring them to do so. One director attended our annual meeting of stockholders held in April 2024.

Shareholder Communications

We have a process for shareholders who wish to communicate with our Board. Shareholders who wish to communicate with our Board may write to the Board at 3960 Howard Hughes Parkway, Suite 500, Las Vegas, NV 89169. These communications will be reviewed by our Interim Chief Executive Officer and Chief Financial Officer. Communications will be then distributed to our board of directors, or to any individual director or directors as appropriate, depending on the facts and circumstances outlined in the communications. Items that are unrelated to the duties and responsibilities of the Board may be excluded, such as:

- junk mail and mass mailings;
- resumes and other forms of job inquiries;
- surveys; and
- solicitations or advertisements

In addition, any material that is unduly hostile, threatening, or illegal in nature may be excluded, in which case it will be made available to any outside director upon request.

ITEM 11. EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below (each a "Named Executive Officer"), as well as the director compensation program for our directors. As a smaller reporting company, we are not required to include a Compensation Discussion and Analysis and have elected to comply with the scaled disclosure requirements applicable to smaller reporting companies.

For our fiscal year ended April 30, 2024, our Named Executive Officers and their positions were as follows:

- Joshua N. Silverman, Interim Chief Executive Officer, Interim President and Interim Chairman of the Board;
- Carlos A. Trujillo, Chief Financial Officer.

We have the same number of Named Executive Officers as we do "executive officers" as defined by Rule 3b-7 promulgated under the Exchange Act. The following tables provide information about compensation earned by our Named Executive Officers during our fiscal years ended April 30, 2024, and 2023.

Summary Compensation Table

Name	Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Joshua N. Silverman (2)	Interim Chief Executive Officer and Interim President	2024	$ 375,000	$ 100,000	$ –	$ 312,923	$ 787,923
		2023(3)	$ 197,917	$ –	$ –	$ –	$ 197,917
Carlos A. Trujillo	Chief Financial Officer	2024	$ 380,000	$ 50,000	$ –	$ 156,562	$ 586,462
		2023	$ 380,000	$ –	$ 2,667	$ 2,592	$ 385,259

(1) The amounts in the columns titled "Stock Awards" and "Option Awards" reflect the grant date fair values of awards made during the identified fiscal year, as computed in accordance with FASB ASC Topic 718 and the assumptions stated in Note 4 and Note 5 of the Consolidated Financial Statements to this Report.

(2) Includes $10,417 of compensation for Mr. Silverman's service as a member of the board of directors. Mr. Silverman was appointed as Interim Chief Executive Officer and Interim President on October 6, 2022.

Narrative Disclosure to Summary Compensation Table

Employment Arrangements

Joshua N. Silverman

On November 14, 2022, the Board approved employment of Mr. Silverman as the Interim Chief Executive Officer, Interim President and Interim Chairman of the Board on a month-to-month basis, and it further approved paying Mr. Silverman is paid an annual base salary of $375,000. Mr. Silverman is eligible to participate in the 2022 Plan. On November 20, 2023, the Compensation Committee granted Mr. Silverman a stock option grant to purchase 170,000 shares of common stock exercisable over a ten-year term at an exercise price of $2.18 per share, vesting 50% immediately and 50% on the one-year anniversary of the date of grant.

Carlos A. Trujillo

On May 8, 2022 we entered into an Amended and Restated Executive Compensation Agreement with Mr. Trujillo ("Trujillo Compensation Agreement") effective as of January 1, 2022. The current term of the Trujillo Compensation Agreement extends until December 31, 2024, with annual extensions at the end of the term (or any extension of the term) unless we or Mr. Trujillo provide 90-days written notice of termination.

The Trujillo Compensation Agreement provided that Mr. Trujillo will serve as a member of our Board, from which he resigned on August 15, 2022, and as our Chief Financial Officer. Mr. Trujillo is paid an annual base salary of $380,000, subject to annual increases at the discretion of the Compensation Committee and shall be eligible to receive an annual Bonus. Mr. Trujillo is eligible to participate in the 2022 Plan. On November 20, 2023, the Compensation Committee granted Mr. Trujillo a stock option grant to purchase 85,000 shares of common stock exercisable over a ten-year term at an exercise price of $2.18 per share, vesting 50% immediately and 50% on the one-year anniversary of the date of grant.

If Mr. Trujillo's employment is terminated by us without "Cause" or by him for "Good Reason" (as such terms are defined in the Trujillo Compensation Agreement), then subject to his execution of a timely release, he is entitled to: (i) severance equal to two times the sum of his base salary at the time his employment terminates, (ii) payment of the annual bonus, if any, earned by Mr. Trujillo for the year preceding the year of termination, or, if greater, the target bonus, if any, for the year of termination, (iii) accelerated vesting of any unvested stock or option awards and (iv) continued health coverage for Mr. Trujillo and his family and life insurance coverage for Mr. Trujillo, if any, at the Company's expense until the earliest of: (A) the eighteen-month anniversary of termination; (B) the date Mr. Trujillo is no longer eligible to receive COBRA continuation coverage; and (C) the date on which Mr. Trujillo receives or becomes eligible to receive substantially similar coverage from another employer.

Notwithstanding the foregoing, if Mr. Trujillo's employment is terminated by us without Cause or by him for Good Reason within two years after a "Change in Control" (as such term is defined in the Trujillo Compensation Agreement) or within six months prior to a Change in Control, then the base salary and bonus, if any, component of severance would be paid in lump sum. Also, Mr. Trujillo would be entitled to receive a full Code Section 280G tax gross-up, with respect to any amounts that may be subject to the excise tax provisions under Code Section 280G.

If Mr. Trujillo's employment ceases due to his death, (i) any otherwise unvested equity awards held by him at the time of his death would become vested, (ii) his eligible dependents would be entitled to continued healthcare coverage at the Company's expense for up to 18 months, and (iii) his designated beneficiary or estate would receive the proceeds, if any, from any life insurance.

If Mr. Trujillo's employment is terminated due to "Disability" (as such term is defined in the Trujillo Compensation Agreement) he would receive continued health coverage and life insurance coverage, if any, for 18 months at our expense, as well as any disability benefits payable under any long-term disability plan or policy we maintain. In addition, any otherwise unvested equity awards would then become vested.

Additionally, Mr. Trujillo is bound by confidentiality and non-disparagement provisions as well as non-solicitation and non-competition covenants that apply during the term of his employment and for twenty-four months after termination of his employment.

Potential Payments upon Termination or Change-In-Control

Employment Agreements

Information regarding potential payments upon termination or change-in-control pursuant to employment agreements with officers of the Company is set forth above.

2021 Plan

Under our 2021 Plan, upon a Change in Control (as defined in the 2021 Plan), the Compensation Committee may, in its sole discretion, take one or more of the following actions:

- cause any or all outstanding awards to become vested and immediately exercisable (as applicable), in whole or in part;
- cause any outstanding option or stock appreciation right to become fully vested and immediately exercisable for a reasonable period in advance of the Change in Control and, to the extent not exercised prior to that Change in Control, cancel that option or stock appreciation right upon closing of the Change in Control;
- cancel any unvested award or unvested portion thereof, with or without consideration;
- cancel any award in exchange for a substitute award;
- redeem any restricted stock or restricted stock unit for cash and/or other substitute consideration with value equal to the fair market value of an unrestricted share on the date of the Change in Control;
- cancel any option or stock appreciation right in exchange for cash and/or other substitute consideration with a value equal to: (a) the number of shares subject to that option or stock appreciation right, multiplied by (b) the difference, if any, between the fair market value on the date of the Change in Control and the exercise price of that option or the base price of the stock appreciation right; provided, that if the fair market value on the date of the Change in Control does not exceed the exercise price of any such option or the base price of any such stock appreciation right, the committee may cancel that option or stock appreciation right without any payment of consideration therefor; and/or
- take such other action as the Compensation Committee determines to be appropriate under the circumstances.

Further, in the discretion of the Compensation Committee, any cash or substitute consideration payable upon cancellation of an award may be subjected to (i) vesting terms substantially identical to those that applied to the cancelled award immediately prior to the Change in Control, or (ii) earn-out, escrow, holdback or similar arrangements, to the extent such arrangements are applicable to any consideration paid to stockholders in connection with the Change in Control.

Under the 2021 Plan, upon termination of a participant's service with the Company and unless otherwise specified in an applicable award agreement, any portion of an option or stock appreciation right that is not exercisable upon termination will expire immediately, and any portion of an option or stock appreciation right that is exercisable upon termination will expire on the date it ceases to be exercisable, as determined by the reason for termination:

- Termination by reason of death: If a participant's service with the Company terminates by reason of death, any option or stock appreciation right held by such participant may thereafter be exercised, to the extent it was exercisable at the time of his or her death or on such accelerated basis as the Compensation Committee may determine at or after grant, by the legal representative of the estate or by the legatee of the participant, for a period expiring (i) at such time as may be specified by the Compensation Committee at or after grant, or (ii) if not specified by the Compensation Committee, then 12 months from the date of death, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such option or stock appreciation right.

- Termination by reason of disability: If a participant's service with the Company terminates by reason of disability, any option or stock appreciation right held by such participant may thereafter be exercised by the participant or his or her personal representative, to the extent it was exercisable at the time of termination, or on such accelerated basis as the Compensation Committee may determine at or after grant, for a period expiring (i) at such time as may be specified by the Compensation Committee at or after grant, or (ii) if not specified by the Compensation Committee, then 12 months from the date of termination of service, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such option or stock appreciation right.

- Termination for Cause: If a participant's service with the Company is terminated for Cause (as defined in the 2021 Plan) or if a participant resigns at a time that there was a Cause basis for such participant's termination: (i) any option or stock appreciation right, or portion thereof, not already exercised will be immediately and automatically forfeited as of the date of such termination, and (ii) any shares for which the Company has not yet delivered share certificates will be immediately and automatically forfeited and the Company will refund to the participant the option exercise price paid for such shares, if any.

- Other termination: If a participant's service with the Company terminates for any reason other than death, disability or Cause, any option or stock appreciation right held by such participant may thereafter be exercised by the participant, to the extent it was exercisable at the time of such termination, or on such accelerated basis as the Compensation Committee may determine at or after grant, for a period expiring (i) at such time as may be specified by the Compensation Committee at or after grant, or (ii) if not specified by the Compensation Committee, then 90 days from the date of termination of service, or (iii) if sooner than the applicable period specified under (i) or (ii) above, upon the expiration of the stated term of such option or stock appreciation right.

Outstanding Equity Awards at Fiscal Year End

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Joshua N. Silverman	85,000	85,000 (1)	$ 2.18	11/19/2033
Carlos A. Trujillo	2,000	–	$ 61.20	01/02/2025
	2,000	–	$ 10.05	12/31/2025
	2,000	–	$ 2.50	01/01/2027
	42,500	42,500 (1)	$ 2.18	11/19/2033

(1) These options vest in full on November 20, 2024.

Director Compensation

The following table sets forth information concerning compensation paid or to each of our directors, other than our Named Executive Officers who also serve as directors, who served during the year ended April 30, 2024.

Director Compensation Table

Name	Fees Earned ($)	Stock Awards ($)(1)	Option Awards ($)(1)(2)	Total ($)
Jonathan L. Schechter (2)	$ 180,000	$ –	$ 110,000	$ 290,000
Robert Weinstein (3)	$ 180,000	$ –	$ 110,000	$ 290,000
Wayne R. Walker (4)	$ 155,000	$ –	$ 110,000	$ 265,000
Michael M. Abecassis (5)	$ 186,000	$ –	$ 110,000	$ 296,000

(1) The amounts in the columns titled "Stock Awards" and "Option Awards" reflect the grant date fair values of awards made during the fiscal year ended April 30, 2024, as computed in accordance with FASB ASC Topic 718 and the assumptions stated in Note 4 and Note 5 of the Consolidated Financial Statements to this Report.
(2) Mr. Schechter was appointed to the Board effective August 15, 2022.
(3) Mr. Weinstein was appointed to the Board effective November 14, 2022.
(4) Mr. Walker was elected to the Board on December 28, 2022.
(5) Dr. Abecassis was appointed to the Strategic Scientific Committee on November 20, 2023, at which point he began receiving a monthly retainer fee of $3,500.

On November 17, 2023, we adopted a nonemployee director compensation policy (the "Director Compensation Policy"). The Director Compensation Policy provides for the annual automatic grant of nonqualified stock options to purchase shares of common stock having an aggregate grant date fair value of $60,000. Such grants shall occur annually on the first business day after our annual meeting of stockholders, and the options shall vest on the date of the subsequent annual meeting of stockholders, subject to the director's continued service on the vesting date. The Director Compensation Policy also provides for the automatic grant of nonqualified stock options to purchase shares of common stock having an aggregate grant date fair value of $50,000 to each newly appointed director. Such grants occur on the first business day following appointment, and the options vest in full immediately. Each nonemployee director will also receive an annual retainer in the amount of $60,000, plus an additional $10,000 annually per committee chairmanship. Dr. Abecassis, as chair of the Strategic Scientific Committee, receives a monthly retainer fee of $3,500.

Our employee directors do not receive additional compensation for their service on the Board. For information regarding the compensation of our Named Executive Officers who are also directors, please see above, under the heading "Executive Compensation."

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

The following table sets forth as of July 17, 2024, certain information with respect to the beneficial ownership of our common stock by each person known by us to be the beneficial owner of more than five percent (5%) of our common stock, by each of our directors, by each of our Named Executive Officers and by all executive officers and directors as a group.

We deem shares of common stock that may be acquired by an individual or group within 60 days of July 17, 2024 pursuant to the exercise of options or warrants or the vesting of restricted stock units to be outstanding for the purpose of computing the percentage ownership of such individual or group, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders.

Under the terms of certain of our outstanding warrants, holders may not exercise the warrants to the extent such exercise would cause such holder, together with its affiliates, to beneficially own a number of shares of our common stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding common stock following such exercise, excluding for purposes of such determination common stock issuable upon exercise of the warrants which have not been exercised. Similarly, under the terms of our Series B Preferred Shares, holders may not convert their Series B Preferred Shares to the extent such conversion would cause such holder, together with its affiliates, to beneficially own a number of shares of our common stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding common stock following such conversion. The number of shares of common stock beneficially owned reflects these limitations.

The address of all beneficial owners is 3960 Howard Hughes Parkway, Suite 500, Las Vegas, Nevada, 89169. Each person has sole voting and investment power with respect to the shares of common stock.

Name and Address	Amount and Nature of Beneficial Ownership	Percentage of Common Stock (1)
More than 5% stockholders:		
Richard Abbe (2)(3)	4,469,350	37.2%
Entities affiliated with Iroquois Capital Management, LLC (2)(4)	3,774,654	33.3%
Entities affiliated with Sabby Management, LLC (5)	934,456	12.1%
Entities affiliated with Intracoastal Capital LLC (6)(7)	903,412	11.1%
Daniel B. Asher (6)(8)	894,230	11.1%
Entities affiliated with Ayrton Capital LLC (9)	956,229	11.0%
Directors, Officers and Named Executive Officers:		
Joshua N. Silverman, Interim Chairman of the Board, Interim Chief Executive Officer and Interim President (10)	135,000	1.7%
Jonathan L. Schechter, Board Member (11)	111,248	1.4%
Michael M. Abecassis, Board Member (12)	65,051	*
Robert Weinstein, Board Member (13)	61,248	*
Wayne R. Walker, Board Member (14)	61,248	*
Carlos A. Trujillo, Chief Financial Officer (15)	58,900	*
All directors and executive officers as a group (6 persons)	492,695	6.3%

* Indicates percentage is less than 1.0%.

(1) Percentages based on 7,724,319 shares of common stock outstanding as of July 17, 2024.

(2) This information is based solely on the Schedule 13D/A filed with the Commission by Richard Abbe, Kimberly Page, Iroquois Master Fund Ltd. ("Iroquois Master Fund"), Iroquois Capital Management, LLC ("Iroquois Capital") and Iroquois Capital Investment Group LLC ("ICIG," and collectively, the "Iroquois Parties") on June 16, 2023. The Iroquois Parties made a single, joint filing to reflect the formation of a "group" within the meaning of Section 13(d)(3) of the Exchange Act. Ms. Page serves as a director of Iroquois Master Fund. Iroquois Capital serves as the investment manager for Iroquois Master Fund, and Mr. Abbe serves as the president of Iroquois Capital. Each Iroquois Party disclaims beneficial ownership of the shares that he, she or it does not directly own and except to the extent of his, her or its pecuniary interest therein. The address of the Iroquois Parties is 2 Overhill Road, Suite 400, Scarsdale, New York 10583.

(3) Includes (i) 10,696 shares owned by ICIG, (ii) 384,000 shares issuable upon the exercise of warrants owned by ICIG, (iii) 300,000 shares issuable upon conversion of convertible preferred shares owned by ICIG, (iv) 178,654 shares owned by Iroquois Master Fund, (v) 1,896,000 shares issuable upon exercise of warrants owned by Iroquois Master Fund and (vi) 1,700,000 shares issuable upon conversion of convertible preferred shares owned by Iroquois Master Fund.

(4) Includes (i) 178,654 shares, (ii) 1,896,000 shares issuable upon exercise of warrants and (iii) 1,700,000 shares issuable upon conversion of convertible preferred shares owned by Iroquois Master Fund.

(5) This information is based on the Schedule 13G/A filed with the Commission on January 10, 2023 by Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz (collectively, "Sabby"). Sabby reported sole and shared voting and sole and shared dispositive power of 934,456 shares of common stock. Sabby Management, LLC is the investment manager of Sabby Volatility Warrant Master Fund, Ltd. Hal Mintz is the Manager of Sabby Management, LLC and in such capacity has the right to vote and dispose of the securities held by Sabby Volatility Warrant Master Fund, Ltd. The address of Sabby is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands.

(6) This information is based on the Schedule 13G/A filed with the Commission on February 6, 2024 by Mitchell P. Kopin, Daniel B. Asher and Intracoastal Capital LLC ("Intracoastal"). The address of Mr. Kopin and Intracoastal is c/o Intracoastal Capital, LLC, 245 Palm Trail, Delray Beach, Florida 33483. The address of Mr. Asher is 111 W. Jackson Boulevard, Suite 2000, Chicago, Illinois 60604.

(7) Includes (i) 475,884 shares of common stock held by Intracoastal and (ii) 427,528 shares of common stock issuable upon exercise of warrants held by Intracoastal. Mr. Kopin is the manager of Intracoastal.

(8) Includes (i) 475,884 shares held by Intracoastal, (ii) 82,727 shares held by Mr. Asher and (iii) 335,619 shares of common stock issuable upon exercise of warrants held by Intracoastal.

(9) Represents shares underlying warrants and preferred stock held by Alto Opportunity Master Fund, SPC – Segregated Master Portfolio B ("Alto"). Alto is a private investment vehicle for which Ayrton Capital LLC ("Ayrton") serves as the investment manager. Waqas Khatri serves as the managing member of Ayrton. Alto's address is Suite #7, Grand Pavilion Commercial Centre, 802 West Bay Road, Grand Cayman, P.O. Box 10250, Cayman Islands. Ayrton's and Mr. Khatri's address is 55 Post Rd West, 2nd Floor, Westport, CT 06880. This information is based on the Schedule 13G filed with the Commission on February 14, 2024.

(10) Includes 85,000 shares issuable upon the exercise of options to purchase common stock.

(11) Includes 61,248 shares issuable upon the exercise of options to purchase common stock.

(12) Includes 62,249 shares issuable upon the exercise of options to purchase common stock.

(13) Includes 61,248 shares issuable upon the exercise of options to purchase common stock.

(14) Includes 61,248 shares issuable upon the exercise of options to purchase common stock.

(15) Includes 48,500 shares issuable upon the exercise of options to purchase common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain aggregated information with respect to compensation plans (including individual arrangements) under which our securities are authorized for issuance as of April 30, 2024:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	909,364	$ 2.39	1,840,636
Equity compensation plans not approved by security holders	15,800	$ 36.29	–
Total	925,296	$ 2.97	1,840,636

Please see Notes 5 and 6 of the Consolidated Financial Statements to this Report for more information regarding our equity compensation arrangements.

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

Our Audit Committee charter requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K, or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our Audit Committee. Any request for such a transaction must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider all available information deemed relevant by the Audit Committee, including, but not limited to, the extent of the related person's interest in the transaction, and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances.

We had the following related party transactions during the years ended April 30, 2024 and 2023, respectively.

We own 13.9% of the equity in SG Austria, and such investment is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova and (ii) Austrianova Thailand. We purchased products and services from these subsidiaries in the approximate amounts of $0 and $339,000 in the years ended April 30, 2024, and 2023, respectively.

In April 2014, we entered a consulting agreement with Vin-de-Bona pursuant to which it agreed to provide professional consulting services to us. Vin-de-Bona is owned by Prof. Günzburg and Dr. Salmons, both of whom are involved in numerous aspects of our scientific endeavors relating to cancer (Prof. Günzburg is the Chairman of Austrianova, and Dr. Salmons is the Chief Executive Officer and President of Austrianova). The term of the agreement is for 12 months, automatically renewable for successive 12-month terms. After the initial term, either party can terminate the agreement by giving the other party 30 days' written notice before the effective date of termination. The amounts we paid Vin-de-Bona for the years ended April 30, 2024, and 2023, were approximately $5,000 and $61,000, respectively.

Except for Mr. Schechter, Dr. Abecassis, Mr. Weinstein and Mr. Walker, the Board has determined that none of our directors satisfy the definition of Independent Director as established in the Nasdaq Marketplace Rules. Mr. Schechter, Dr. Abecassis, Mr. Weinstein and Mr. Walker have been determined by the Board to be Independent Directors.

On May 20, 2024, we entered into the TNF Purchase Agreement with TNF, pursuant to which we purchased from TNF (i) TNF Preferred Shares, convertible into 3,854,626 TNF Common Shares, (ii) Long-Term Warrants to purchase up to 3,854,626 TNF Common Shares and (iii) Short-Term Warrants to purchase up to 3,854,626 TNF Common Shares for an aggregate purchase price of $7,000,000. Joshua Silverman, our Interim Chief Executive Officer and Interim President, is chairman of TNF's board of directors. For more information regarding the TNF Transaction, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – TNF Transaction."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Company engaged Armanino LLP ("Armanino") as its independent auditors from October 30, 2015 to November 5, 2023. The Company engaged Marcum LLP ("Marcum") from November 5, 2023 to present.

A summary of the fees billed by our independent audit firm, Armanino, for professional services rendered for the years ended April 30, 2024 and 2023 is set forth below.

Service	2024	2023
Audit Fees	$ 224,175	$ 180,098
Audit-Related Fees	–	–
Tax Fees	–	12,000
All Other Fees	–	–
Total	$ 224,175	$ 192,098

During the years ended April 30, 2024 and 2023, we incurred from Armanino $95,025 and $140,958 in annual audit fees, respectively, and $129,150 and $31,500 in quarterly review fees, respectively, and $0 and $19,640 in income tax analysis, respectively.

A summary of the fees billed by our independent audit firm, Marcum, for professional services rendered for the years ended April 30, 2024 and 2023 is set forth below.

Service	2024	2023
Audit Fees	$ 301,650	$ –
Audit-Related Fees	–	–
Tax Fees	–	–
All Other Fees	–	–
Total	$ 301,650	$ –

During the year ended April 30, 2024, we incurred from Marcum $225,000 in audit fees and $76,650 in quarterly review fees.

Our Audit Committee pre-approves all services to be performed by our independent auditor. All the services listed above have been pre-approved by our Audit Committee.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

Audit services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

Audit-Related services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

Tax services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

Other Fees are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

ITEM 15. EXHIBITS

(a) Documents filed as part of this Report:

(1) Financial Statements.

Our Consolidated Financial Statements and associated Notes and Schedules, as of April 30, 2024, and 2023, and for each of the two years in the period ended April 30, 2024, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report.

(3) Exhibits.

Except as so indicated below and in Exhibit 32.1, the following exhibits are filed as part of, or incorporated by reference into, the Report. Certain of the agreements filed as exhibits contain representations and warranties made by the parties thereto. The assertions embodied in such representations and warranties are not necessarily assertions of fact, but a mechanism for the parties to allocate risk. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts or for any other purpose at the time they were made or otherwise.

(3) Exhibits.

Except as so indicated below and in Exhibit 32.1, the following exhibits are filed as part of, or incorporated by reference into, the Report. Certain of the agreements filed as exhibits contain representations and warranties made by the parties thereto. The assertions embodied in such representations and warranties are not necessarily assertions of fact, but a mechanism for the parties to allocate risk. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts or for any other purpose at the time they were made or otherwise.

Exhibit No.	Description	Location
3.1	Articles of Incorporation of the Company, as amended, dated October 31, 2019.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the Commission on March 13, 2020.
3.2	Certificate of Amendment to Articles of Incorporation of the Company, dated July 2, 2021.	Incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the Commission on July 6, 2021.
3.3	Certificate of Change to Articles of Incorporation of the Company, dated July 9, 2021.	Incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the Commission on July 13, 2021.
3.4	Certificate of Change to Articles of Incorporation of the Company, dated March 7, 2023.	Incorporated by reference from Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the Commission on March 16, 2023.

3.5	Certificate of Change to Articles of Incorporation of the Company, dated September 6, 2023.	Incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on September 7, 2023
3.6	Certificate of Designations of Preferences and Rights of Series B Convertible Preferred Stock.	Incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on May 11, 2023.
3.7	Corporate Bylaws.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the Commission on August 20, 2001.
3.8	Amendment No. One to the Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on September 25, 2014.
3.9	Amendment No. Two to the Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on October 3, 2014.
3.10	Amendment No. Three to Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on June 4, 2021.
3.11	Amendment No. Four to Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on July 6, 2021.
3.12	Amendment No. Five to Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on November 18, 2022.
3.13	Amendment No. Six to Bylaws of PharmaCyte Biotech, Inc.	Incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on July 19, 2023.
4.1	Form of Common Stock Certificate.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the Commission on August 20, 2001.
4.2	Description of Securities.	Filed herewith.
4.3	Form of Common Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 12, 2021.
4.4	Form of Pre-funded Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 12, 2021.
4.5	Form of Underwriter's Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 12, 2021.
4.6	Form of Pre-Funded Common Stock Purchase Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 23, 2021.
4.7	Form of Series A Warrant Common Stock Purchase Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 23, 2021.

4.8	Form of Placement Agent Common Stock Purchase Warrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 23, 2021.
4.9	Form of Warrant.	Incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Commission on May 11, 2023.
10.1	Asset Purchase Agreement, dated May 26, 2011, between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on June 28, 2012.
10.2	First Addendum, dated June 11, 2011, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on June 28, 2012.
10.3	Second Addendum, dated June 14, 2012, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on June 28, 2012.
10.4	Third Addendum, dated June 25, 2013, to Asset Purchase Agreement between SG Austria Private Limited and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on July 18, 2013.
10.5	Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on July 18, 2013.
10.6	Manufacturing Framework Agreement, dated March 20, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 4, 2014.
10.7	Master Services Agreement, dated April 7, 2014, between ViruSure GmbH and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 4, 2014.
10.8	Consulting Agreement, dated April 1, 2014, between Vin-de-Bona Trading Company Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 4, 2014.
10.9	License Agreement, dated October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia Pty Ltd (formerly, Nuvilex Australia Pty Ltd).	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the Commission on October 17, 2014.
10.10	Master Services Agreement, dated March 7, 2014, between ViruSure GmbH and the Company.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the Commission on October 17, 2014.
10.11	Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Commission on December 15, 2014.
10.12	First Amendment, dated June 30, 2015, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on July 29, 2016.
10.13	Second Amendment, dated October 19, 2015, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on July 29, 2016.

10.14	Variation, dated April 20, 2016, to License Agreement, October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia Pty Ltd (formerly, Nuvilex Australia Pty Ltd).	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on July 29, 2016.
10.15	First Amendment, dated June 24, 2016, to Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on July 29, 2016.
10.16	Binding Memorandum of Understanding, dated July 28, 2016, between Austrianova Singapore Pte Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on July 29, 2016.
10.17†	Letter agreement, dated June 29, 2017, between Michael Abecassis, M.D. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on July 10, 2017.
10.18	Binding Term Sheet, dated August 30, 2017, among Austrianova Singapore Pte. Ltd., SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on September 6, 2017.
10.19	Fourth Addendum, dated May 14, 2018, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 15, 2018.
10.20	Third Amendment, dated May 14, 2018, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 15, 2018.
10.21	Second Amendment, dated May 14, 2018, to the Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 15, 2018.
10.22†	Amendment No. 3, dated as of October 14, 2020, to Executive Compensation Agreement between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on October 16, 2020.
10.23	Securities Purchase Agreement, dated as of August 19, 2021.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on August 23, 2021.
10.24†	Amended and Restated Executive Compensation Agreement, dated May 8, 2022, between Kenneth L. Waggoner and the Company.	Incorporated by reference from Exhibit 10.40 to the Company's Annual Report on Form 10-K filed with the Commission on July 28, 2022.
10.25†	Amended and Restated Executive Compensation Agreement, dated May 8, 2022, between Carlos A. Trujillo and the Company.	Incorporated by reference from Exhibit 10.41 to the Company's Annual Report on Form 10-K filed with the Commission on July 28, 2022.
10.26†	PharmaCyte Biotech, Inc. 2021 Equity Incentive Plan.	Incorporated by reference from Exhibit 10.42 to the Company's Annual Report on Form 10-K filed with the Commission on July 28, 2022.
10.27	Cooperation Agreement dated August 15, 2022, by and between PharmaCyte Biotech, Inc. and Iroquois Master Fund Ltd. and its affiliates.	Incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 16, 2022.
10.28†	Separation, Consulting and Release Agreement, dated October 6, 2022, by and between PharmaCyte Biotech, Inc. and Kenneth L. Waggoner.	Incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on October 7, 2022.

10.29†	Release Agreement, dated October 12, 2022, by and between PharmaCyte Biotech, Inc. and Gerald W. Crabtree.	Incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on October 14, 2022.
10.30	Securities Purchase Agreement, dated May 9, 2023.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 11, 2023.
10.31	Registration Rights Agreement, dated May 9, 2023.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 11, 2023.
10.32	Engagement Letter, dated May 9, 2023, by and between the Company and Katalyst Securities LLC.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 11, 2023.
10.33	PharmaCyte Biotech, Inc. 2022 Equity Incentive Plan.	Incorporated by reference from Appendix A to the Company's Schedule 14A filed with the Commission on November 25, 2022.
10.34	Form of Series A Warrant of Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023.
10.35	Form of Series B Warrant of Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023
10.36	Securities Purchase Agreement, dated November 14, 2023, by and between PharmaCyte Biotech, Inc. and Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023.
10.37	Form of Convertible Note of Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023.
10.38	Registration Rights Agreement, dated November 14, 2023, by and between PharmaCyte Biotech, Inc. and Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023.
10.39	Collaboration Agreement, dated November 14, 2023, by and between PharmaCyte Biotech, Inc. and Femasys, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on November 16, 2023.
10.40	Securities Purchase Agreement, dated May 20, 2024 by and among PharmaCyte Biotech, Inc. and MyMD Pharmaceuticals, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2024.
10.41	Form of Certificate of Designations of Series G Convertible Preferred Stock of MyMD Pharmaceuticals, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2024.
10.42	Form of Long-Term Warrant of MyMD Pharmaceuticals, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2024.
10.43	Form of Short-Term Warrant of MyMD Pharmaceuticals, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2024.
14.1	PharmaCyte Biotech, Inc. Code of Business Conduct and Ethics.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on September 25, 2014.
19.1	PharmaCyte Biotech, Inc. Insider Trading Policy.	Filed herewith.

21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of Marcum LLP.	Filed herewith.
23.2	Consent of Armanino LLP.	Filed herewith.
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
31.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
32.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
97.1	PharmaCyte Biotech, Inc. Clawback Policy.	Filed herewith.
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.	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)	Filed herewith.

† A contract, compensatory plan or arrangement to which a director or executive officer is a party or in which one or more directors or executive officers are eligible to participate.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PharmaCyte Biotech, Inc.

August 13, 2024

By: /s/ Joshua N. Silverman
Joshua N. Silverman
Interim Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

August 13, 2024

By: /s/ Carlos A Trujillo
Carlos A. Trujillo
Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Pursuant to the requirements of the Exchange Act, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

August 13, 2024

By: /s/ Joshua N. Silverman
Joshua N. Silverman
Interim Chief Executive Officer, Interim Chairman of the Board and Director
(Principal Executive Officer)

August 13, 2024

By: /s/ Carlos A. Trujillo
Carlos A. Trujillo
Chief Financial Officer and Director
(Principal Financial and Accounting Officer)

August 13, 2024

By: /s/ Jonathan L. Schechter
Jonathan L. Schechter, Director

August 13, 2024

By: /s/ Robert Weinstein
Robert Weinstein, Director

August 13, 2024

By: /s/ Michael M. Abecassis
Michael M. Abecassis, Director

August 13, 2024

By: /s/ Wayne R. Walker
Wayne R. Walker, Director

SUPPLEMENTAL INFORMATION TO BE FURNISHED WITH REPORTS FILED PURSUANT TO SECTION 15(d) OF THE ACT BY REGISTRANTS WHICH HAVE NOT REGISTERED SECURITIES PURSUANT TO SECTION 12 OF THE ACT

The registrant has not sent to its security holders any annual report covering the registrant's fiscal year ended April 30, 2024.

PHARMACYTE BIOTECH, INC.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
PharmaCyte Biotech, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of PharmaCyte Biotech, Inc. (the "Company") as of April 30, 2024, the related consolidated statements of operations, comprehensive income (loss), changes in convertible preferred stock and stockholders' equity, and cash flows for the year ended April 30, 2024, 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 April 30, 2024, and the results of its operations and its cash flows for the year ended April 30, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments.

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Critical Audit Matter – Fair Value of Financial Instruments

As described in Note 3 and Note 12 to the financial statements, the Company records certain financial instruments at fair value on a recurring basis, including a derivative liability, a note receivable, and a warrant asset, which are classified as level 3 as they contain one or more inputs to valuation which are unobservable and significant to their fair value measurement.

The principal considerations for our determination that performing procedures relating to the fair value of certain level 3 financial instruments is a critical audit matter are (i) the significant judgment and estimation by management and their third party valuation experts in determining the inputs to estimate fair value, which in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and in evaluating audit evidence obtained related to the fair value of these financial instruments, and (ii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing this matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included reviewing the terms of the underlying agreements that gave rise to the financial instruments. These procedures also included, among others, the involvement of professionals with specialized skill and knowledge to assist in the testing and evaluation of the valuation models prepared by management's third-party valuation experts. This included assessing the appropriateness of the methodologies used in the valuation process and developing an independent estimate of fair value for these financial instruments and comparing management's estimate to the independently developed estimate of fair value. Developing the independent estimate involved testing the completeness, accuracy, and relevance of underlying data used in the models, and testing the reasonableness of significant assumptions, including equity volatility, trading volume volatility, market interest rate, probability of default, risk-free rate, calibration adjustment factor, and starting daily share volume, as applicable.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2023**.**

East Hanover, New Jersey
August 13, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
PharmaCyte Biotech, Inc.
Las Vegas, Nevada

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of PharmaCyte Biotech, Inc. and its subsidiaries (collectively the "Company") as of April 30, 2023, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year then ended April 30, 2023, and the related notes (collectively referred to as the "consolidated financial statements").

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of April 30, 2023, and the results of its operations and cash flows for the year ended April 30, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

/s/ Armanino LLP

Irvine, California
July 31, 2023

We have served as the Company's auditor since 2015. In 2023, we became the predecessor auditor.

PHARMACYTE BIOTECH, INC.
CONSOLIDATED BALANCE SHEETS

	April 30, 2024	April 30, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,179,968	$ 68,039,936
Prepaid expenses and other current assets	259,800	107,681
Total current assets	50,439,768	68,147,617
Other assets:		
Intangible assets	1,549,427	3,549,427
Investment in SG Austria	–	1,572,193
Convertible note receivable	2,755,000	–
Warrant asset	5,152,000	–
Other assets	7,688	7,688
Total other assets	9,464,115	5,129,308
Total Assets	$ 59,903,883	$ 73,276,925
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 389,369	$ 128,281
Accrued expenses	735,199	458,300
Accrued Series B convertible preferred stock redemption and dividends	6,296,696	–
Total current liabilities	7,421,264	586,581
Other liabilities:		
Warrant liability	10,784,000	–
Derivative liability	2,184,000	–
Total other liabilities	12,968,000	–
Total Liabilities	20,389,264	586,581
Commitments and Contingencies (Notes 7 and 9)		
Convertible Preferred Stock:		
Series B convertible preferred stock: authorized 35,000 shares, $0.0001 par value and $1,000 face value, 14,646 and 0 shares issued and outstanding excluding 5,833 and 0 shares subject to redemption as of April 30, 2024 and April 30, 2023, respectively. Liquidation preference of $15,060,421 and 0, as of April 30, 2024 and April 30, 2023, respectively	11,867,016	–
Stockholders' equity:		
Preferred stock, authorized 10,000,000		
Series A preferred stock: authorized 1 share, $0.0001 par value and 0 shares issued and outstanding as of April 30, 2024 and 2023		
Common stock, authorized: 200,000,000 shares, $0.0001 par value; shares issued 21,672,078, shares outstanding 8,037,624 as of April 30, 2024, and shares issued 21,602,078, shares outstanding 16,793,980 as of April 30, 2023	2,167	2,160
Additional paid-in capital	185,334,173	202,230,583
Accumulated deficit	(115,625,010)	(115,958,773)
Treasury stock, at cost, 13,634,454 and 4,808,098 shares as of April 30, 2024, and 2023, respectively	(42,040,216)	(13,560,623)
Accumulated other comprehensive loss	(23,511)	(23,003)
Total stockholders' equity	27,647,603	72,690,344
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity	$ 59,903,883	$ 73,276,925

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30, 2024	2023
Revenue	$ –	$ –
Operating expenses:		
Research and development costs	407,431	468,536
Compensation expense	1,322,414	1,234,956
Director fees	1,141,215	951,347
Legal and professional	1,531,626	2,687,978
Intangible asset impairment	2,000,000	–
General and administrative	2,117,322	1,112,677
Total operating expenses	8,520,008	6,455,494
Loss from operations	(8,520,008)	(6,455,494)
Other income (expense):		
Interest income	3,398,819	1,937,499
Change in fair value of warrant liability	3,343,000	–
Change in fair value of derivative liability	586,000	–
Change in fair value of convertible note receivable	1,089,000	–
Change in fair value of warrant asset	1,818,000	–
Loss on long term asset	(1,572,193)	–
Other income, net	191,145	202,002
Total other income, net	8,853,771	2,139,501
Net income (loss)	$ 333,763	$ (4,315,993)
Preferred stock dividends	(2,517,645)	–
Preferred stock accretion	(15,053,521)	–
Net loss attributable to common stockholders	$ (17,237,403)	$ (4,315,993)
Basic and diluted loss per share attributable to common stockholders	$ (1.80)	$ (0.22)
Weighted average shares outstanding basic and diluted	9,581,059	19,489,204

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Years Ended April 30,	
	2024	**2023**
Net income (loss)	$ 333,763	$ (4,315,993)
Other comprehensive loss:		
Foreign currency translation adjustments	(508)	(7,246)
Other comprehensive loss	(508)	(7,246)
Comprehensive income (loss)	$ 333,255	$ (4,323,239)

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
YEARS ENDED APRIL 30, 2024 AND 2023

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Treasury Stock		Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit	Loss	Equity
Balance, April 30, 2022	–	$ –	20,721,047	$ 2,072	$201,582,107	–	$ –	$(111,648,656)	$ (15,757)	$ 89,919,766
Stock issued for compensation	–	–	–	–	7,334	–	–	–	–	7,334
Stock issued for services	–	–	1,002	–	2,278	–	–	–	–	2,278
Stock issued for warrant exercise	–	–	880,000	88	792	–	–	–	–	880
Stock based compensation - options	–	–		–	638,072	–	–	–	–	638,072
Reverse stock split adjustment	–	–	29	–	–	–	–	–	–	–
Gain on de-consolidation of subsidiary	–	–	–	–	–	–	–	5,876	–	5,876
Foreign currency translation adjustment	–	–	–	–	–	–	–	–	(7,246)	(7,246)
Net loss	–	–	–	–	–	–	–	(4,315,993)	–	(4,315,993)
Repurchase of common stock	–	–	–	–	–	(4,808,098)	(13,560,623)	–	–	(13,560,623)
Balance, April 30, 2023	–	$ –	21,602,078	$ 2,160	$202,230,583	(4,808,098)	$(13,560,623)	$(115,958,773)	$ (23,003)	$ 72,690,344
Stock-based compensation options	–	–	–	–	674,693	–	–	–	–	674,693
Stock issued for warrant exercise	–	–	70,000	7	63	–	–	–	–	70
Series B preferred stock redeemed	(14,521)	(13,999,302)	–	–	–	–	–	–	–	–
Series B preferred stock subject to redemption	(5,833)	(5,940,278)								
Series B preferred stock dividends	–	–	–	–	(2,517,645)	–	–	–	–	(2,517,645)
Preferred stock accretion	–	15,053,521	–	–	(15,053,521)	–	–	–	–	(15,053,521)
Issuance of Series B Preferred Stock, net of discounts and issuance costs of $18,246,925	35,000	16,753,075	–	–	–	–	–	–	–	–
Repurchase of common stock	–	–	–	–	–	(8,826,356)	(28,479,593)	–	–	(28,479,593)
Foreign currency translation adjustment	–	–	–	–	–	–	–	–	(508)	(508)
Net income	–	–	–	–	–	–	–	333,763	–	333,763
Balance, April 30, 2024	14,646	$ 11,867,016	21,672,078	$ 2,167	$185,334,173	(13,634,454)	$(42,040,216)	$(115,625,010)	$ (23,511)	$ 27,647,603

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30, 2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 333,763	$ (4,315,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Asset impaired	2,000,000	–
Loss on long term asset	1,572,193	–
Other non-cash (income) expense	(195,000)	171,744
Stock issued for services	–	2,278
Stock issued for compensation	–	7,334
Stock-based compensation	674,693	638,072
Change in fair value of warrant liability	(3,343,000)	–
Change in fair value of derivative liability	(586,000)	–
Change in fair value of convertible note receivable	(1,089,000)	–
Change in fair value of warrant asset	(1,818,000)	–
Change in assets and liabilities:		
Increase in prepaid expenses and other current assets	(152,119)	(13,509)
Increase (decrease) in accounts payable	261,090	(242,948)
Increase (decrease) in accrued expenses	189,923	(40,709)
Net cash used in operating activities	(2,151,457)	(3,793,731)
Cash flows from investing activities:		
Investment - note receivable and warrants	(5,000,000)	–
Net cash used in investing activities	(5,000,000)	–
Cash flows from financing activities:		
Repurchase of common stock, net of excise tax	(28,197,617)	(13,560,623)
Proceeds from issuance of preferred stock, net of transaction costs	33,650,075	–
Redemption of preferred stock	(16,160,531)	–
Proceeds from warrant exercise	70	880
Net cash used in financing activities	(10,708,003)	(13,559,743)
Effect of currency rate exchange on cash and cash equivalents	(508)	(7,246)
Net decrease in cash and cash equivalents	(17,859,968)	(17,360,720)
Cash and cash equivalents at beginning of the year	68,039,936	85,400,656
Cash and cash equivalents at end of the year	$ 50,179,968	$ 68,039,936
Supplemental disclosure of cash flows information:		
Cash paid during the year for income taxes	$ 1,600	$ –
Supplemental schedule of non-cash investing and financing activities:		
Non-cash derivative liability at initial fair value	$ 2,770,000	$ –
Non-cash warrant liability at initial fair value	$ 14,127,000	$ –
Reclassification of Series B Convertible Preferred Stock and dividends to current liability	$ 22,457,227	$ –
Accretion of discounts to redemption value of Series B Preferred Stock	$ 15,053,521	$ –
Excise tax accrued on repurchase of common stock	$ 281,976	$ –

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

NOTE 1 – NATURE OF BUSINESS

PharmaCyte Biotech, Inc. ("Company") is a biotechnology company focused on developing cellular therapies for cancer based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." The Cell-in-a-Box® technology is intended to be used as a platform upon which therapies for several types of cancer, including locally advanced, inoperable pancreatic cancer ("LAPC") will be developed. The current generation of the Company's product candidate is referred to as "CypCaps™."

The Company is a Nevada corporation incorporated in 1996. In 2013, the Company restructured its operations to focus on biotechnology. The Company acquired licenses from SG Austria Pte. Ltd., a Singapore corporation ("SG Austria") to treat cancer and Austrianova Singapore Pte. Ltd., a Singapore corporation ("Austrianova Singapore") using the Cell-in-the-Box technology. The restructuring resulted in the Company focusing all its efforts upon the development of a novel, effective and safe way to treat cancer. In January 2015, the Company changed its name from Nuvilex, Inc. to PharmaCyte Biotech, Inc. to reflect the nature of its current business. In October 2021, the Company moved its headquarters from Laguna Hills, California to Las Vegas, Nevada.

On September 1, 2020, the Company submitted an Investigational New Drug Application ("IND") to the U.S. Food and Drug Administration ("FDA") for a planned clinical trial in LAPC. On October 1, 2020, the Company received notice from the FDA that it had placed the IND on clinical hold. On October 30, 2020, the FDA sent a letter to the Company setting forth the reasons for the clinical hold and specific guidance on what the Company must do to have the clinical hold lifted.

To lift the clinical hold, the FDA informed the Company that it needs to conduct several additional preclinical studies. The FDA also requested additional information regarding several topics, including DNA sequencing data, manufacturing information and product release specifications. The Company has been in the process of conducting these studies and gathering additional information to submit to the FDA. See "Investigational New Drug Application and Clinical Hold" below.

On August 15, 2022, the Company entered into a Cooperation Agreement ("Cooperation Agreement") with Iroquois Master Fund Ltd. and its affiliates, pursuant to which the Company elected a reconstituted Board of Directors ("Board"). The Board has formed a Business Review Committee to evaluate, investigate and review the Company's business, affairs, strategy, management and operations and in its sole discretion to make recommendations to the Company's management and Board with respect thereto. The Business Review Committee is also reviewing many of the risks relative to the Company's business. In addition, the Board is reviewing the Company's development programs and its relationship with SG Austria, including that all licensed patents have expired, that know-how relating to the Company's Cell-in-a-Box® technology solely resides with SG Austria, and that the incentives of SG Austria and its management may not be currently aligned with those of the Company. The Board has curtailed spending on the Company's programs, including pre-clinical and clinical activities, until the review by the Business Review Committee and the Board is complete and the Board has determined the actions and plans to be implemented. The Business Review Committee's recommendations will include potentially seeking a new framework for the Company's relationship with SG Austria and its subsidiaries. In the event the Company is unsuccessful in seeking an acceptable new framework, the Company will reevaluate whether it should continue those programs which are dependent on SG Austria, including its development programs for LAPC. The issues involving SG Austria have delayed the Company's timeline for addressing the FDA clinical hold for its planned clinical trial in LAPC and could result in other delays or termination of the development activities. In addition, the curtailment of spending on the Company's programs pending the review by the Business Review Committee and the Board may cause additional delays.

The Cell-in-a-Box® encapsulation technology potentially enables genetically engineered live human cells to be used as a means to produce various biologically active molecules. The technology is intended to result in the formation of pinhead sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In a laboratory setting, this proprietary live cell encapsulation technology has been shown to create a micro-environment in which encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors and passage through catheters and needles, which the Company believes enables greater cell growth and production of the active molecules. The capsules are largely composed of cellulose (cotton) and are bioinert.

The Company has been developing therapies for pancreatic and other solid cancerous tumors by using genetically engineered live human cells that it believes are capable of converting a cancer prodrug into its cancer-killing form. The Company encapsulates those cells using the Cell-in-a-Box® technology and places those capsules in the body as close as possible to the tumor. In this way, the Company believes that when a cancer prodrug is administered to a patient with a particular type of cancer that may be affected by the prodrug, the killing of the patient's cancerous tumor may be optimized.

Until the review by the Business Review Committee and the Board is complete and the Board has determined the actions and plans to be implemented, spending on the Company's programs has been curtailed.

Investigational New Drug Application and Clinical Hold

On September 1, 2020, the Company submitted an IND to the FDA for a planned clinical trial in LAPC. On October 1, 2020, the Company received notice from the FDA that it had placed the Company's IND on clinical hold. On October 30, 2020, the FDA sent the Company a letter setting forth the reasons for the clinical hold and providing specific guidance on what the Company must do to have the clinical hold lifted.

In order to address the clinical hold, the FDA requested that the Company:

- Provide additional sequencing data and genetic stability studies;
- Conduct a stability study on the Company's final formulated product candidate as well as the cells from the Company's Master Cell Bank;
- Evaluate the compatibility of the delivery devices (the prefilled syringe and the microcatheter used to implant the CypCaps™) with the Company's product candidate for pancreatic cancer;
- Provide additional detailed description of the manufacturing process of the Company's product candidate for pancreatic cancer;
- Provide additional product release specifications for the Company's encapsulated cells;
- Demonstrate comparability between the 1st and 2nd generation of the Company's product candidate for pancreatic cancer and ensure adequate and consistent product performance and safety between the two generations;
- Conduct a biocompatibility assessment using the Company's capsules material;
- Address specified insufficiencies in the Chemistry, Manufacturing and Controls information in the cross-referenced Drug Master File;
- Conduct an additional nonclinical study in a large animal (such as a pig) to assess the safety, activity, and distribution of the product candidate for pancreatic cancer; and
- Revise the Investigators Brochure to include any additional preclinical studies conducted in response to the clinical hold and remove any statements not supported by the data the Company generated.

The FDA also requested that the Company address the following issues as an amendment to the Company's IND:

- Provide a Certificate of Analysis for pc3/2B1 plasmid that includes tests for assessing purity, safety, and potency;
- Perform qualification studies for the drug filling step to ensure that the Company's product candidate for pancreatic cancer remains sterile and stable during the filling process;
- Submit an updated batch analysis for the Company's product candidate for the specific lot that will be used for manufacturing all future product candidates;
- Provide additional details for the methodology for the Resorufin (CYP2B1) potency and the PrestoBlue cell metabolic assays;
- Provide a few examples of common microcatheters that fit the specifications in the Company's Angiography Procedure Manual;
- Clarify the language in our Pharmacy Manual regarding proper use of the syringe fill with the Company's product candidate for pancreatic cancer; and
- Provide a discussion with data for trial of the potential for cellular and humoral immune reactivity against the heterologous rat CYP2B1 protein and potential for induction of autoimmune-mediated toxicities in our study population.

The Company assembled a scientific and regulatory team of experts to address the FDA requests. That team has been working diligently to complete the items requested by the FDA.

Nasdaq Listing

The Company's common stock began trading on Nasdaq on August 10, 2021, under the symbol "PMCB." Prior to that, the Company's common stock was quoted on the OTCQB Market under the symbol "PMCB."

Increase in Authorized Shares

On September 6, 2023, pursuant to stockholder approval received at a special meeting of stockholders, the Company filed with the Secretary of State of the State of Nevada a Certificate of Change to its Articles of Incorporation, as amended, to increase the number of authorized shares of common stock from 133,333,334 to 200,000,000. The Certificate of Change had no impact on the number of authorized shares of preferred stock, which remains at 10,000,000.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries. The Company operates independently and through three wholly owned subsidiaries: (i) PharmaCyte Biotech Europe Limited; (ii) PharmaCyte Biotech Australia Pty. Ltd.; and (iii) Viridis Biotech, Inc. and are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and the Rules and Regulations of the Commission. Upon consolidation, intercompany balances and transactions are eliminated. The Company's 13.9% investment in SG Austria is presented using the measurement alternative allowed under ASC *321 Investments – Equity Securities* for investments with no readily determinable fair values. In March 2023, Bio Blue Bird was liquidated and was de-consolidated in these consolidated financial statements.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in accordance with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities known to exist as of the date the financial statements are published and the reported amounts of revenues and expenses during the reporting period. Uncertainties with respect to such estimates and assumptions are inherent in the preparation of the Company's consolidated financial statements; accordingly, it is possible that the actual results could differ from these estimates and assumptions, which could have a material effect on the reported amounts of the Company's consolidated financial position and results of operations.

Cash and Cash Equivalents

Cash and cash equivalents include cash in banks and short-term liquid investments purchased with maturities of three months or less.

Intangible Assets

The Financial Accounting Standards Board ("FASB") standard on goodwill and other intangible assets prescribes a two-step process for impairment testing of goodwill and indefinite-lived intangibles, which is performed annually, as well as when an event triggering impairment may have occurred. The first step tests for impairment, while the second step, if necessary, measures the impairment. The Company has elected to perform its annual analysis at the end of its reporting year.

The Company's intangible assets are licensing agreements related to the Cell-in-a-Box® technology for $1,549,427 and diabetes license for $2,000,000

These intangible assets have an indefinite life; therefore, they are not amortizable.

The Company concluded that the diabetes licensed asset technology would likely not prove to be a viable technique for the production of insulin producing cells and the treatment of diabetes. The Company believes that a buyer of this technology would ascribe a de minimis value to this asset. Therefore, it was determined that as of April 30, 2024 there should be a full impairment of the $2,000,000 carrying value. Therefore, the Company included a non-cash asset impairment of $2,000,000 on the Consolidated Statements of Operations. The Company also concluded that there was no impairment of the Cell-in-a-Box® technology for $1,549,427 for the years ended April 30, 2024 and 2023.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be fully recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value.

Investment in SG Austria

The Company's 13.9% investment in SG Austria is presented using the measurement alternative allowed under *ASC 321 – Investments – Equity Securities* with no readily determinable values. The Company evaluates equity investments annually for changes in circumstances that indicate the value of the securities have been affected. The Company concluded that there was a write-down of the investment in SG Austria at April 30, 2024 due to their financial position, negative book value and viability that makes for an inconclusive determination of a specific value range of the Company's minority interest in SG Austria. The Company concluded that as of the present time, the value of SG Austria is likely minimal and therefore, included a non-cash asset write-down of $1,572,191 on the Consolidated Statements of Operations. No write-down was identified or recorded during the year ended April 30, 2023.

Convertible Note Receivable

As permitted under Financial Accounting Standards Board ("FASB") ASC 825, Financial Instruments ("ASC 825"), the Company elects to account for its convertible note receivable, which meets the required criteria, at fair value at inception and at each subsequent reporting date. Subsequent changes in fair value, including interest, are recorded as a component of non-operating income (loss) in the consolidated statements of operations. As a result of electing the fair value option, direct costs and fees related to the convertible note receivable were expensed as incurred.

The Company estimates the fair value of the convertible note receivable using the income approach, which uses as inputs the fair value of debtor's common stock and estimates for the equity volatility and volume volatility of debtor's common stock, the time to expiration of the convertible note, the discount rate, the stated interest rate compared to the current market rate, the risk-free interest rate for a period that approximates the time to expiration, and probability of default. Therefore, the estimate of expected future volatility is based on the actual volatility of debtor's common stock and historical volatility of debtor's common stock utilizing a lookback period consistent with the time to expiration. The time to expiration is based on the contractual maturity date. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of measurement for time periods approximately equal to the time to expiration. The probability of default is estimated using the S&P Global default rate for companies with a similar credit rating to debtor's.

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") Topic 820, "Fair Value Measurements and Disclosures," requires disclosure of the fair value of financial instruments held by the Company. ASC Topic 825, "Financial Instruments," defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the Consolidated Balance Sheets for current assets and liabilities qualify as financial instruments and are a reasonable estimate of their fair values because of the short period between the origination of such instruments and their expected realization and their current market rate of interest. 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. The three levels of valuation hierarchy are defined as follows:

- Level 1. Observable inputs such as quoted prices in active markets
- Level 2. Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

These unobservable inputs are significant to the fair value measurement.

Income Taxes

Deferred taxes are calculated using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

A valuation allowance is provided for deferred income tax assets when, in management's judgment, based upon currently available information and other factors, it is more likely than not that all or a portion of such deferred income tax assets will not be realized. The determination of the need for a valuation allowance is based on an on-going evaluation of current information including, among other things, historical operating results, estimates of future earnings in different taxing jurisdictions and the expected timing of the reversals of temporary differences. The Company believes the determination to record a valuation allowance to reduce a deferred income tax asset is a significant accounting estimate because it is based on, among other things, an estimate of future taxable income in the U.S. and certain other jurisdictions, which is susceptible to change and may or may not occur, and because the impact of adjusting a valuation allowance may be material. In determining when to release the valuation allowance established against the Company's net deferred income tax assets, the Company considers all available evidence, both positive and negative. Consistent with the Company's policy, and because of the Company's history of operating losses, the Company does not currently recognize the benefit of all its deferred tax assets, including tax loss carry forwards, which may be used to offset future taxable income. The Company continually assesses its ability to generate sufficient taxable income during future periods in which deferred tax assets may be realized. When the Company believes it is more likely than not that it will recover its deferred tax assets, the Company will reverse the valuation allowance as an income tax benefit in the statements of operations.

The U.S. GAAP method of accounting for uncertain tax positions utilizes a two-step approach to evaluate tax positions. Step one, recognition, requires evaluation of the tax position to determine if based solely on technical merits it is more likely than not to be sustained upon examination. Step two, measurement, is addressed only if a position is more likely than not to be sustained. In step two, the tax benefit is measured as the largest amount of benefit, determined on a cumulative probability basis, which is more likely than not to be realized upon ultimate settlement with tax authorities. If a position does not meet the more likely than not threshold for recognition in step one, no benefit is recorded until the first subsequent period in which the more likely than not standard is met, the issue is resolved with the taxing authorities, or the statute of limitations expires. Positions previously recognized are derecognized when the Company subsequently determines the position no longer is more likely than not to be sustained. Evaluation of tax positions, their technical merits and measurements using cumulative probability are highly subjective management estimates. Actual results could differ materially from these estimates.

Consideration of Inflation Reduction Act Excise Tax

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IR Act") was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly-traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its stockholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of the Treasury (the "Treasury") has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax.

The Company repurchased 8,826,356 shares of common stock with a total cost of $28,479,593 including accrued excise tax during the year ended April 30, 2024 and 4,808,098 shares of common stock with a total cost of $13,560,623 including accrued excise tax for the year ended April 30, 2023. The Company recorded $281,976 and $58,096 in excise tax related to the IR Act, which is included in Treasury stock and accrued expenses for the years ended April 30, 2024 and 2023, respectively.

Research and Development

Research and development ("R&D") expenses consist of costs incurred for direct and overhead-related research expenses and are expensed as incurred. Costs to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in the Company's product candidates is expensed as incurred until technological feasibility has been established.

R&D costs for the years ended April 30, 2024 and 2023 were $407,431 and $468,536, respectively.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for only those awards ultimately expected to vest on a straight-line basis over the requisite service period of the award. The Company estimates the fair value of stock options using a Black-Scholes-Merton valuation model. This model requires the input of highly subjective assumptions, including the option's expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. Thus, if factors change and the Company uses different assumptions, the stock-based compensation expense could be materially different in the future.

Concentration of Credit Risk

The Company has no significant off-balance-sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains most of its cash balance at financial institutions located in throughout the U.S. Accounts at these institutions are insured by the Federal Deposit Insurance Corporation up to $250,000. Uninsured balances aggregated approximately $6,910,000 and $279,000 at April 30, 2024 and 2023, respectively. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash.

Foreign Currency Translation

The Company translates the financial statements of its foreign subsidiaries from the local (functional) currencies to U.S. dollars in accordance with FASB ASC 830, *Foreign Currency Matters*. All assets and liabilities of the Company's foreign subsidiaries are translated at year-end exchange rates, while revenue and expenses are translated at average exchange rates prevailing during the year. Adjustments for foreign currency translation fluctuations are excluded from net loss and are included in other comprehensive income (loss). Gains and losses on short-term intercompany foreign currency transactions are recognized as incurred.

New Accounting Pronouncements Effective in Future Periods

In November 2023, FASB issued ASU 2023-07 - Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities with a single reportable segment to provide all the disclosures required by this standard and all existing segment disclosures in Topic 280 on an interim and annual basis, including new requirements to disclose significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within the reported measure(s) of a segment's profit or loss, the amount and composition of any other segment items, the title and position of the CODM, and how the CODM uses the reported measure(s) of a segment's profit or loss to assess performance and decide how to allocate resources. The guidance is effective for our annual period beginning May 1, 2025, and interim periods thereafter, applied retrospectively with early adoption permitted. The Company is evaluating the impact of adoption of this standard on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09 - Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities to provide greater disaggregation within their annual rate reconciliation, including new requirements to present reconciling items on a gross basis in specified categories, disclose both percentages and dollar amounts, and disaggregate individual reconciling items by jurisdiction and nature when the effect of the items meet a quantitative threshold. The guidance also requires disaggregating the annual disclosure of income taxes paid, net of refunds received, by federal (national), state, and foreign taxes, with separate presentation of individual jurisdictions that meet a quantitative threshold. The guidance is effective for the Company's annual periods beginning May 1, 2025 on a prospective basis, with a retrospective option, and early adoption is permitted. The Company is evaluating the impact of adoption of this standard on its financial statements and disclosures.

NOTE 3 – INVESTMENT IN DEBT AND EQUITY SECURITIES

On November 14, 2023, the Company entered into a Securities Purchase Agreement (the "Femasys Purchase Agreement") with Femasys Inc. ("Femasys"), pursuant to which it agreed to purchase from Femasys for a sum of $5,000,000 (i) senior unsecured convertible notes (the "Femasys Notes") in an aggregate principal amount of $5,000,000, convertible into shares of Femasys common stock, par value $0.001 per share (the "Femasys Shares") at a conversion price of $1.18 per share, (ii) Series A Warrants (the "Series A Warrants") to purchase up to an aggregate of 4,237,288 Femasys Shares at an exercise price of $1.18 per share, and (iii) Series B Warrants (the "Series B Warrants", together with the Series A Warrants, the "Femasys Warrants," and, together with the Notes, the "Femasys Securities") to purchase up to an aggregate of 4,237,288 Femasys Shares at an exercise price of $1.475 per share (collectively, the "Investment"). The Femasys Notes accrue interest at 6.0% per annum, payable annually, and mature two years after the date of issuance. The Femasys Warrants expire five years from the date of issuance.

Pursuant to the terms of the Femasys Purchase Agreement, the Company's Interim Chief Executive Officer was appointed to the Femasys board of directors.

The convertible note receivable is not traded in active markets and the fair value was determined using a Monte Carlo simulation. The convertible note receivable is accounted for as available-for-sale debt securities based on "Level 3" inputs, which consist of unobservable inputs and reflect management's estimates of assumptions that market participants would use in pricing the asset. The Company elected the fair value option for the Femasys Notes, therefore, holding gains and losses are included within change in fair value of the notes in the consolidated statement of operations. The Femasys Warrants are accounted for as an equity security and are valued using a Monte Carlo simulation based on "Level 3" inputs, which consist of unobservable inputs and reflect management's estimates of assumptions that market participants would use in pricing the asset, recorded at fair value with subsequent changes included within change in fair value of the warrants in the consolidated statement of operations.

The Company recognized the Femasys Note and Femasys Warrants based on their respective fair values on the issuance date of $1,666,000 and $3,334,000, respectively. Subsequent changes in the fair value of the Femasys Note and Femasys Warrants will be recognized in earnings, at each reporting date. During the year ended April 30, 2024, the Company recognized a change in fair value of the convertible note receivable and warrant asset of $1,089,000 and $1,818,000, respectively. See Note 14 – Fair value Measurements for further information.

Below is a summary of activity for the Note and Warrants as of April 30, 2024:

Balance of Notes as of May 1, 2023	$ –
Purchased	1,666,000
Change in fair value	1,089,000
Balance of Notes as of April 30, 2024	$ 2,755,000

Balance of Warrants as of May 1, 2023	$ –
Purchased	3,334,000
Change in fair value	1,818,000
Balance of Warrants as of April 30, 2024	$ 5,152,000

NOTE 4 – ACCRUED EXPENSES

Accrued expenses at April 30, 2024 and 2023 are summarized below:

	2024	2023
Payroll related costs	$ 167,817	$ 112,894
Director fees	135,000	–
R&D costs	92,310	287,310
Excise tax on stock repurchases	340,072	58,096
Total	$ 735,199	$ 458,300

NOTE 5 – COMMON STOCK TRANSACTIONS

A summary of the Company's compensatory stock activity and related weighted average grant date fair value information for the years ended April 30, 2024 and 2023, are as follows:

In January 2022, the Company awarded 4,400 shares of common stock to the executive officers of the Company as part of their compensation agreements for 2022. These shares vest monthly over a twelve-month period and are subject to the executive officers continuing to provide service under their compensation agreements. During the years ended April 30, 2024 and 2023, the Company recorded a non-cash compensation expense in the amounts of $0 and $7,334. There were zero unvested shares as of April 30, 2024 and 2023, respectively.

During the year ended April 30, 2023, three non-employee members of the Board were issued 1,002 shares of common stock pursuant to their Director Letter Agreements ("DLAs") in respect of their service during that year. The shares were fully vested upon issuance. The Company recorded a non-cash expense of $0 and $2,278 for the years ended April 30, 2024 and 2023, respectively. There were zero unvested shares remaining related to such DLAs as of April 30, 2024 and 2023, respectively.

All shares were issued without registration under the Securities Act in reliance upon the exemption afforded by Section 4(a)(2) of the Securities Act.

There were no shares granted, vested or expired during the year ended April 30, 2024.

NOTE 6 – STOCK OPTIONS AND WARRANTS

2022 Equity Incentive Plan

Effective December 28, 2022, the Company implemented the 2022 Equity Incentive Plan ("2022 Equity Plan") as approved by the Company's stockholders. The 2022 Equity Plan is administered by the Compensation Committee of the Board and has 2,750,000 shares available under this plan. The 2022 Equity Plan can issue various types of awards, as follows: stock options, stock appreciation rights, restricted stock, restricted stock units, and cash or other stock-based awards. The 2022 Equity Plan is available to be issued to employees, directors, consultants, and other individuals who provide services to the Company. An incentive stock options ("ISOs") can only be granted to employees and shall not exceed 10-years (5-years in the case of ISOs granted to any 10% shareholder).

Stock Options

As of April 30, 2024, the Company had 925,164 outstanding stock options to its directors and officers (collectively, "Employee Options") and consultants ("Non-Employee Options").

During the years ended April 30, 2024 and 2023, the Company granted 652,028 and 251,002 Employee Options, respectively.

The fair value of the Employee Options at the date of grant was estimated using the Black-Scholes-Merton option-pricing model, based on the following weighted average assumptions:

	Years Ended April 30,	
	2024	2023
Risk-free interest rate	4.5%	3.3%
Expected volatility	109%	133%
Expected term (years)	5.2	3.5
Expected dividend yield	0.00%	0.00%

The Company's computation of expected volatility for the year ended April 30, 2024 is based on selected guideline companies historical weekly basis volatility and the Company's historical daily basis volatility for the year ended April 30, 2023. For stock option grants issued during the years ended April 30, 2024 and 2023, the Company used a calculated volatility for each grant. The Company lacks adequate information about the exercise behavior now and has determined the expected term assumption under the simplified method provided for under ASC 718, which averages the contractual term of the Company's stock options of ten years with the average vesting term of six months. The dividend yield assumption of zero is based upon the fact the Company has never paid cash dividends and presently has no intention of paying cash dividends. The risk-free interest rate used for each grant is equal to the U.S. Treasury rates in effect at the time of the grant for instruments with a similar expected life.

During the years ended April 30, 2024 and 2023, the Company granted no Non-Employee Options.

A summary of the Company's stock option activity and related information for the two years ended April 30, 2024 is shown below:

	Options	Weighted Average Exercise Price Per Share
Outstanding, April 30, 2022	40,900	$ 53.05
Granted	251,002	2.97
Expired	(10,633)	90.65
Outstanding, April 30, 2023	281,269	6.94
Granted	652,028	2.17
Expired	(8,133)	75.81
Outstanding, April 30, 2024	925,164	$ 2.97
Exercisable, April 30, 2024	645,627	$ 3.32
Vested and expected to vest	925,164	$ 2.97

A summary of the activity for unvested stock options during the years ended April 30, 2024 and 2023 is as follows:

	Options	Weighted Average Grant Date Fair Value Per Share
Unvested, April 30, 2022	4,000	$ 1.84
Granted	251,002	2.51
Vested	(255,002)	2.50
Forfeited	–	–
Unvested, April 30, 2023	–	–
Granted	652,028	1.76
Vested	(372,492)	1.81
Forfeited	–	–
Unvested, April 30, 2024	279,536	$ 1.70

The Company recorded $674,693 and $638,072 of stock-based compensation related to the issuance of Employee Options to certain officers and directors in exchange for services during the years ended April 30, 2024 and 2023, respectively. At April 30, 2024, there remained $474,692 unrecognized compensation expense related to unvested Employee Options granted to officers.

The following table summarizes the outstanding stock options by exercise price at April 30, 2024:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (Years) of Outstanding Options	Weighted Average Exercisable Price Per Share	Number of Options Exercisable	Weighted Average Exercise Price Per Share of Exercisable Options
$ 57.00	800	0.40	$ 57.00	800	$ 57.00
$ 55.50	333	0.17	$ 55.50	333	$ 55.50
$ 51.00	333	0.44	$ 51.00	333	$ 51.00
$ 61.20	6,000	0.67	$ 61.20	6,000	$ 61.20
$ 36.00	667	1.00	$ 36.00	667	$ 36.00
$ 37.05	333	1.17	$ 37.05	333	$ 37.05
$ 15.75	333	1.44	$ 15.75	333	$ 15.75
$ 10.05	6,000	1.67	$ 10.05	6,000	$ 10.05
$ 26.55	667	2.00	$ 26.55	667	$ 26.55
$ 16.20	334	2.17	$ 16.20	334	$ 16.20
$ 3.19	334	2.44	$ 3.19	334	$ 3.19
$ 2.50	6,000	2.67	$ 2.50	6,000	$ 2.50
$ 2.29	668	3.00	$ 2.29	668	$ 2.29
$ 2.24	334	3.17	$ 2.24	334	$ 2.24
$ 2.97	250,000	8.55	$ 2.97	250,000	$ 2.97
$ 2.18	499,992	9.56	$ 2.18	372,491	$ 2.18
$ 2.12	152,036	10.00	$ 2.12	–	$ –
Total	925,164	9.16	$ 2.97	645,627	$ 3.32

The aggregate intrinsic value of outstanding options as of April 30, 2024 was $0. This represents options whose exercise price was less than the closing fair market value of the Company’s common stock on April 30, 2024 of approximately $2.12 per share.

Warrants

Pursuant to the Private Placement (as defined below), the Company issued investors Warrants (as defined below) to purchase 8,750,000 shares of Common Stock, with an exercise price of $4.00 per share (subject to adjustment), for a period of five years from the date of issuance. For more information on the Private Placement, see "Note 11 – Preferred Stock".

The Warrants were determined to be within the scope of ASC 480-10 as they are puttable to the Company at Holders' election upon the occurrence of a Fundamental Transaction (as defined in the agreements). As such, the Company recorded the Warrants as a liability at fair value with subsequent changes in fair value recognized in earnings. The Company utilized the Black-Scholes-Merton Model to calculate the value of the Warrants issued during the year ended April 30, 2024. The fair value of the Warrants of approximately $14,127,000 was estimated at the date of issuance using the fair value of our common stock of $2.74 on the issuance date and was based on the following weighted average assumptions: dividend yield 0%; expected term of 5.0 years; equity volatility of 80.0%; and a risk-free interest rate of 3.37%.

Transaction costs incurred attributable to the issuance of the Warrants of approximately $913,640 were immediately expensed in accordance with ASC 480 and is included in general and administrative expense in the accompanying Consolidated Statements of Operations.

During the year ended April 30, 2024, the Company recorded a gain of approximately $3,343,000 related to the change in fair value of the warrant liability which is recorded in other income (expense) on the Consolidated Statements of Operations. The fair value of the Warrants of $10,784,000 was estimated at April 30, 2024, utilizing the Black-Scholes-Merton Model using the fair value of our common stock of $2.12 and the following weighted average assumptions: dividend yield 0%; remaining term of 4.03 years; equity volatility of 95.0%; and a risk-free interest rate of 4.79%.

A summary of the Company's warrant activity and related information for the two years ended April 30, 2024, are shown below:

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, April 30, 2022	10,772,735	$ 4.59
Issued	–	–
Exercised	(880,000)	–
Expired	(1,888)	–
Outstanding, April 30, 2023	9,890,847	4.99
Issued	8,750,000	4.00
Exercised	(70,000)	–
Expired	–	–
Outstanding, April 30, 2024	18,570,847	4.54
Exercisable, April 30, 2024	18,570,847	$ 4.54

The following table summarizes additional information concerning warrants outstanding and exercisable at April 30, 2024:

Exercise Prices	Number of Warrant Shares Exercisable at April 30, 2023	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price Per Share
$4.25	1,506,141	2.28	
$5.3125	264,706	2.28	
$5.00	7,000,000	2.32	
$6.25	1,050,000	2.30	
$4.00	8,750,000	4.03	
	18,570,847	3.12	$ 4.54

NOTE 7 – LEGAL PROCEEDINGS

From time to time, the Company is subject to legal proceedings and claims, either asserted or unasserted, that arise in the ordinary course of business. While the outcome of pending claims cannot be predicted with certainty, the Company does not believe that the outcome of any pending claims will have a material adverse effect on our financial condition or operating results.

On December 4, 2023, H.C. Wainwright & Co., LLC ("Wainwright") filed a complaint against the Company in the Supreme Court of the State of New York, County of New York, asserting a single cause of action for breach of contract and alleging that the Company breached an April 2021 engagement agreement with Wainwright by failing to pay a purported "tail fee" allegedly due in connection with a private placement transaction that closed in 2023. Wainwright seeks damages of not less than $1,950,000, warrants to purchase an aggregate of 656,250 shares of our common stock at an exercise price of $5.00 per share, and attorney's fees. On February 28, 2024, the Company responded to the complaint with an answer and affirmative defenses. The Company intends to vigorously defend against Wainwright's complaint and does not believe that any potential loss is reasonably probable at this time.

To our knowledge there are no other legal proceedings pending to which any property of the Company is subject.

NOTE 8 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the years ended April 30, 2024 and 2023, respectively.

The Company owns 13.9% of the equity in SG Austria, and this investment is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand. The Company purchased products and services from these subsidiaries in the approximate amounts of $0 and $339,000 in the years ended April 30, 2024, and 2023, respectively.

In April 2014, the Company entered the Vin-de-Bona Consulting Agreement pursuant to which it agreed to provide professional consulting services to the Company. Vin-de-Bona is owned by Prof. Günzburg and Dr. Salmons, both of whom are involved in numerous aspects of the Company's scientific endeavors relating to cancer (Prof. Günzburg is the Chairman of Austrianova, and Dr. Salmons is the Chief Executive Officer and President of Austrianova). The term of the agreement is for 12 months, automatically renewable for successive 12-month terms. After the initial term, either party can terminate the agreement by giving the other party 30 days' written notice before the effective date of termination. The agreement has been automatically renewed annually. The amounts incurred for the years ended April 30, 2024 and 2023, were approximately $5,000 and $61,000, respectively.

The Company's Interim Chief Executive Officer was appointed to the Femasys board of directors, see Note 3.

The Company's Interim Chief Executive Officer is on the board directors of TNF, see Note 15 – Subsequent Events.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

The Company acquires assets still in development and enters R&D arrangements with third parties that often require milestone and royalty payments to the third-party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development lifecycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the license agreements, the Company may have to make royalty payments based upon a percentage of the sales of the pharmaceutical products if regulatory approval for marketing is obtained.

Office Lease

In January 2022, the Company entered into a six-month lease of the Las Vegas, Nevada office space, commencing on May 1, 2022, which expired on October 31, 2022.

In July 2022, the Company entered into an additional six-month lease of the Las Vegas, Nevada office space, commencing on November 1, 2022, which expired on April 30, 2023.

In January 2023, the Company entered into a month-to-month agreement of the Las Vegas office space, commencing on May 1, 2023. Additionally, the Company rents storage space pursuant to a month-to-month agreement in Laguna Hills, California.

Rent expenses for these offices for the years ended April 30, 2024 and 2023 were $29,546 and $23,420, respectively.

With the month-to-month office rental agreements there are no aggregate future minimum lease payments required to be made.

Compensation Agreements

On January 1, 2022, the Company entered into an amended and restated executive compensation agreement with Carlos A. Trujillo, the Company's Chief Financial Officer. The compensation agreement for Mr. Trujillo has a term of three years, with automatic renewals unless the Company or Mr. Trujillo provides written notice of termination at least ninety days prior to the end of the current term.

On August 15, 2022, the Company and the Board: (i) accepted the previously tendered irrevocable resignation of each of Dr. Matthias Löhr, Dr. Raymond C.F. Tong, Thomas Liquard, Dr. Gerald W. Crabtree, and Carlos A. Trujillo, as members of the Board, and (ii) appointed Jonathan L. Schechter, Joshua N. Silverman, Daniel Allen, Daniel S. Farb, and Jack E. Stover as independent members of the Board, effective immediately, each with a term expiring at the Company's 2022 annual meeting of shareholders or until such person's earlier death, resignation, disqualification or removal.

On November 1, 2022, Jack E. Stover notified the Company of his decision to resign from the Board effective immediately. On November 14, 2022, in accordance with the recommendation of the Company's Nominating Committee, Robert Weinstein was appointed to serve as a director of the Board and the Chairperson of the Audit Committee, with a term expiring at the Company's annual meeting of shareholders or until death, resignation, disqualification or removal.

On November 14, 2022, the Board approved the employment of Mr. Joshua Silverman as the Interim Chief Executive Officer, Interim President and Interim Chairman of the Board on a month-to-month basis. Upon Mr. Silverman accepting employment he was no longer an independent director.

On December 28, 2022, the Company held its annual meeting of stockholders. The stockholders voted to elect the following directors to serve one-year terms expiring at the annual meeting of stockholders to be held during the year ended April 30, 2024: Joshua N. Silverman, Jonathan L. Schechter, Michael M. Abecassis, Robert Weinstein and Wayne R. Walker.

Each non-employee director was entitled to receive $12,500 in cash for each calendar quarter of service on the Board.

Effective November 20, 2023, each non-employee director is entitled to receive $15,000 each quarter of service on the Board, plus an additional $2,500 quarterly for each non-employee director who serves as chair of the Board's audit committee, compensation committee or nominating and corporate governance committee. Additionally, three directors received a one-time cash grant of $50,000 and one director received a one-time cash grant of $25,000. Dr. Abecassis, chair of the Strategic Scientific Committee receives a monthly fee of $3,500. Each non-employee director received fully vested stock option grants of $110,000 with ten-year terms. Additionally, each non-employee director is entitled to receive annual stock option grants one day after the annual shareholder meeting in the amount of $60,000 vesting on the next annual shareholder meeting.

On April 29, 2024, the Company held its annual meeting of stockholders. The stockholders voted to elect the following directors to serve one-year terms expiring at the annual meeting of stockholders to be held during the year ended April 30, 2025: Joshua N. Silverman, Jonathan L. Schechter, Michael M. Abecassis, Robert Weinstein and Wayne R. Walker.

As of April 30, 2024, the Company had five directors of which four are non-employee directors.

Service Agreements

The Company has entered into several service agreements with independent and related parties pursuant to which services will be provided over a specified period-of-time related to the IND which the FDA has placed on clinical hold. The services include regulatory affairs strategy, advice and follow up work on the IND and services related to having the clinical hold lifted. The total cost is estimated to be approximately $242,000, of which the related party (SG Austria and its subsidiaries) portion will be approximately $157,000. These amounts take into account some of the cost associated with the work and preclinical studies required to lift the clinical hold.

NOTE 10 – INCOME TAXES

At April 30, 2024, the Company had federal and state net operating loss carryforwards of approximately $57,383,000 and $27,000,000, respectively, available to offset against future taxable income; these operating loss carryforwards expire in 2023 through 2038. Internal Revenue Code Section 382 imposes an annual limitation for the utilization of tax attributes if there is an "ownership change". Based upon the equity activity during the year ended April 30, 2022, the Company had an ownership change in August 2021. As a result of the change in-control that occurred in the Company's shareholder base in August 2021, approximately $37,060,000 and $15,890,000 federal and state net operating loss carryforwards, respectively, became limited in their availability. The remaining net operating loss carryforwards are approximately $20,323,000 and $11,119,000 for federal and state purposes, respectively. The remaining net operating loss deferred tax assets are approximately $4,268,000 and $983,000 for federal and state purposes, respectively.

Current tax laws limit the amount of loss available to be offset against future taxable income when a substantial change in ownership occurs. Therefore, the amount available to offset future taxable income may be limited. Based on the assessment of all available evidence including, but not limited to, the Company's limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulations and healthcare reform initiatives and other risks normally associated with biotechnology companies, the Company has concluded that is more likely than not that these operating loss carryforwards will not be realized. Accordingly, 100% of the deferred tax valuation allowance has been recorded against these assets.

Deferred income taxes reflect the net effect of temporary differences between the financial reporting carrying amounts of assets and liabilities and income tax carrying amounts of assets and liabilities. The components of the Company's deferred tax assets and liabilities are as follows:

	April 30,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 14,437,888	$ 15,732,671
Stock compensation	494,130	369,666
Research and development	160,452	93,316
Investment in SG Austria	469,139	–
Intangible asset (diabetes license)	596,800	–
Fair value of derivative liability	(174,862)	–
Fair value of convertible note receivable	(324,958)	–
Fair value of warrant asset	(542,491)	–
Other	77,622	33,688
Total deferred tax assets	15,193,720	16,229,341
Valuation allowance	(15,193,720)	(16,229,341)
Net deferred tax assets	$ –	$ –

For all years presented, the Company did not recognize any deferred tax assets or liabilities. The net change in valuation allowance for the years ended April 30, 2024 and 2023 was a decrease of $1,035,621 and an increase of and $470,940, respectively.

The provision for income taxes differs from the provision computed by applying the Federal statutory rate to net loss before income taxes as follows:

	Years Ended April 30,	
	2024	2023
Federal benefit at statutory rate	$ 70,090	$ (906,359)
State income taxes, net of Federal taxes	29,505	(369,017)
Permanent differences	(996,649)	(12,462)
Provision related to change in valuation allowance	(1,035,621)	470,940
Expired stock options	76,864	405,057
Net valuation allowance for state NOLs	1,797,207	420,300
Return to provision	(883)	–
Other, net	59,487	(8,459)
	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended April 30, 2024.

The Company files its income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2024, the tax returns for 2019 through 2023 remain open to examination by the Internal Revenue Service and state tax authorities.

The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of the years ended April 30, 2024 and 2023, the Company had accrued no interest or penalties related to uncertain tax positions.

NOTE 11 – EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing earnings available to common stockholders by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares and potentially dilutive shares of common stock outstanding during the period increased to include the number of additional shares of common stock that would be outstanding if the potentially dilutive securities had been issued. Potential shares of common stock outstanding principally include stock options, warrants and convertible preferred stock. During the years ended April 30, 2024 and 2023, the Company incurred losses attributable to common shareholders. Accordingly, the effect of any common stock equivalent would be anti-dilutive during those periods and are not included in the calculation of diluted weighted average number of shares outstanding.

The table below sets forth the basic loss per share calculations:

	Years Ended April 30,	
	2024	**2023**
Net loss attributable to common stockholders	$ (17,237,403)	$ (4,315,993)
Basic and diluted weighted average number of shares outstanding	9,581,059	19,489,204
Basic and diluted loss per share	$ (1.80)	$ (0.22)

The table below sets forth these potentially dilutive securities:

	Years Ended April 30,	
	2024	**2023**
Excluded options	925,164	281,269
Excluded warrants	18,570,847	9,890,847
Series B convertible preferred stock	3,765,105	–
Total preferred stock, options and warrants	23,261,116	10,172,116

NOTE 12 – PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, with a par value of $0.0001, of which 35,000 shares have been designated as "Series B Convertible Preferred Stock". As of April 30, 2024 and 2023, there were 14,646 and zero shares issued and outstanding, respectively, and 5,833 and zero, shares, respectively, subject to redemption which are classified as Accrued Series B convertible preferred redemptions and dividends on the consolidated balance sheet.

On May 10, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which it agreed to sell to the Investors (i) an aggregate of 35,000 shares of the Company's newly-designated Series B convertible preferred stock with a stated value of $1,000 per share, initially convertible into up to 8,750,000 shares of the Company's common stock, par value $0.0001 per share at a conversion price of $4.00 per share (the "Preferred Shares"), and (ii) warrants to acquire up to an aggregate of 8,750,000 shares of common stock (the "Warrants") (collectively, the "Private Placement").

The terms of the Preferred Shares are as set forth in a Certificate of Designations (the "Certificate of Designations"), which was filed with the Secretary of the State of Nevada on May 10, 2023. The Preferred Shares are convertible into common stock (the "Conversion Shares") at the election of the holder at any time at an initial conversion price of $4.00 (the "Conversion Price"). The Conversion Price is subject to customary adjustments for stock dividends, stock splits, reclassifications and the like, and subject to price-based adjustment in the event of any issuances of common stock, or securities convertible, exercisable or exchangeable for common stock, at a price below the then-applicable Conversion Price (subject to certain exceptions). The Company is required to settle the Preferred Shares in equal monthly installments, commencing on November 9, 2023. The amortization payments due upon such redemption are payable, at the Company's election, in cash, or subject to certain limitations, in shares of common stock valued at the lower of (i) the Conversion Price then in effect and (ii) the greater of (A) a 20% discount to the average of the three lowest closing prices of the Company's common stock during the thirty trading day period immediately prior to the date the amortization payment is due or (B) the lower of $0.556 and 20% of the Minimum Price (as defined in Rule 5635 of the Rule of the Nasdaq Stock Market) on the date of receipt of Nasdaq Stockholder Approval (as defined below); provided that if the amount set forth in clause B is the lowest effective price, the Company will be required to pay the amortization payment in cash. The Company may require holders to convert their Preferred Shares into Conversion Shares if the closing price of the common stock exceeds $6.00 per share for 20 consecutive trading days and the daily trading volume of the common stock exceeds 1,000,000 shares per day during the same period and certain equity conditions described in the Certificate of Designations are satisfied.

The holders of the Preferred Shares are entitled to dividends of 4% per annum, compounded monthly, which are payable in cash or shares of common stock at the Company's option, in accordance with the terms of the Certificate of Designations. Upon the occurrence and during the continuance of a Triggering Event (as defined in the Certificate of Designations), the Preferred Shares will accrue dividends at the rate of 15% per annum. The holders of Preferred Shares have no voting rights on account of the Preferred Shares, other than with respect to certain matters affecting the rights of the Preferred Shares.

Notwithstanding the foregoing, the Company's ability to settle conversions and make amortization payments using shares of common stock is subject to certain limitations set forth in the Certificate of Designations, including a limit on the number of shares that may be issued until the time, if any, that the Company's stockholders have approved the issuance of more than 19.9% of the Company's outstanding shares of common stock in accordance with Nasdaq listing standards (the "Nasdaq Stockholder Approval"). The Company received Nasdaq Stockholder Approval at its special meeting of stockholders held on August 31, 2023. Further, the Certificate of Designations contains a certain beneficial ownership limitation after giving effect to the issuance of shares of common stock issuable upon conversion of, or as part of any amortization payment under, the Certificate of Designations or Warrants.

The Certificate of Designations includes certain Triggering Events (as defined in the Certificate of Designations), including, among other things, the failure to file and maintain an effective registration statement covering the sale of the holder's securities registrable pursuant to a registration rights agreement entered into by the Company and the Investors simultaneously with the Purchase Agreement and the Company's failure to pay any amounts due to the holders of the Preferred Shares when due. In connection with a Triggering Event, each holder of Preferred Shares will be able to require the Company to redeem in cash any or all of the holder's Preferred Shares at a premium set forth in the Certificate of Designations.

The Preferred Shares were determined to be more akin to a debt-like host than an equity-like host. The Company identified the following embedded features that are not clearly and closely related to the debt host instrument: 1) an installment redemption upon an Equity Conditions Failure (as defined in the Certificate of Designation), and 2) variable share-settled installment conversion. These features were bundled together, assigned probabilities of being affected and measured at fair value. Subsequent changes in the fair value of these features are recognized in the Consolidated Statements of Operations. The Company estimated the $2,770,000 fair value of the bifurcated embedded derivative at issuance using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's common stock of $2.74 on the issuance date, estimated equity volatility of 55.0%, estimated traded volume volatility of 355.0%, the time to maturity of 1.50 years, a discounted market interest rate of 15.9%, a risk free rate of 4.3%, dividend rate of 4.0%, a penalty dividend rate of 15.0%, and probability of default of 27.0%. The fair value of the bifurcated derivative liability was estimated utilizing the with and without method which uses the probability weighted difference between the scenarios with the derivative and the plain vanilla maturity scenario without a derivative.

The discount to the fair value is included as a reduction to the carrying value of the Preferred Shares. During the year ended April 30, 2024, the Company recorded a total discount of approximately $18,246,925 upon issuance of the Preferred Shares, which was comprised of the issuance date fair value of the associated embedded derivative of approximately $2,770,000, stock issuance costs of approximately $1,349,925 and the fair value of the Warrants of approximately $14,127,000. It was deemed probable that the Preferred Shares will become redeemable, the Company accreted the Preferred Shares from inception to April 30, 2024, pursuant to ASC 480-10-S99-3A.

During the year ended April 30, 2024, the Company recorded a gain of approximately $586,000 related to the change in fair value of the derivative liability, which is recorded in other income, net on the Consolidated Statements of Operations. The Company estimated the $2,184,000 fair value of the bifurcated embedded derivative at April 30, 2024 using a Monte Carlo simulation model, with the following inputs: the fair value of the Company's common stock of $2.12 on the valuation date, estimated equity volatility of 55.0%, estimated traded volume volatility of 165.0%, the time to maturity of 0.53 years, a discounted market interest rate of 20.3%, a risk free rate of 5.43%, dividend rate of 4.0%, a penalty dividend rate of 15.0%, probability of default of 15.2%, and instrument term elapsed of 64.6%

During the year ended April 30, 2024, the Company made all installment payments in cash pursuant to installment redemptions. The first six installment redemptions were paid in cash in the amounts of $16,160,531, which includes $14,520,835 of the Preferred Shares, $724,950 of accrued dividends and $914,746 of additional 6% cash premium pursuant to the terms of the Series B Preferred stock. During the year ended April 30, 2024, the Company made all installment payments in cash pursuant to installment redemptions and accreted $15,053,521 of discount related to the Preferred Shares. During the year ended April 30, 2024, the Company recognized a deemed dividend of $1,271,164 related to the amounts owed in addition to dividends if amortization is paid in cash which is included in Preferred stock dividends on the consolidated statement of operations.

As of April 30, 2024, the Company has reclassified a portion of the Preferred Shares to an accrued liability for the seventh and eighth installment redemptions owed to investors in cash of $6,296,696 which includes $5,833,334 of the stated value of the Preferred Shares, $106,944 of dividends payable, and $356,418 of additional 6% cash premium pursuant to the terms of the Series B Preferred stock. The Company provided notice to the investors of their intent to redeem an additional two installments in cash prior to April 30, 2024. The Company calculated dividends on the installment redemptions that investors elected to defer and are scheduled to be fully settled on November 9, 2024 of $3,509,864 which includes principal of $2,979,167 and dividends of $530,698.

The Company has one share of preferred stock designated as "Series A Preferred Stock" as of April 30, 2024 and April 30, 2023, there were no shares of Series A Preferred Stock issued and outstanding.

The description of the Series A Preferred Stock below is qualified in its entirety by reference to the Company's Articles of Incorporation, as amended.

The Series A Preferred Stock has the following features:

- There is one share of preferred stock designated as Series A Preferred Stock;
- The Series A Preferred Stock has a number of votes at any time equal to the number of votes then held by all other shareholders of the Company having a right to vote on any matter plus one. The Certificate of Designations that designated the terms of the Series A Preferred Stock cannot be amended without the consent of the holder of the Series A Preferred Stock;
- The Company may redeem the Series A Preferred Stock at any time for a redemption price of $1.00 paid to the holder of the share of Series A Preferred Stock; and
- The Series A Preferred Stock has no rights of transfer, conversion, dividends, preferences upon liquidation or participation in any distributions to shareholders.

NOTE 13 – TREASURY STOCK

In May 2022, the Board authorized a share repurchase program to acquire its outstanding common stock for up to $10 million. In January 2023, the Board authorized an additional share repurchase program to acquire up to an additional $10 million of the Company's outstanding common stock. In conjunction with the share repurchase programs, the Company selected a broker to repurchase shares on behalf of the Company. The amount of common stock repurchased on any given trading day is determined by a formula, which is based on the market price of the common stock and average daily volumes. Shares repurchased are held in treasury for general corporate purposes. The shares are treated as Treasury Stock using the cost method. During the year ended April 30, 2024, the Company repurchased 740,477 additional shares under the repurchase program at a total cost, including commissions and excise taxes of $1,757,696. As of April 30, 2024, the total number of shares repurchased pursuant to the repurchase programs was 5,548,575 shares at a total cost, including commissions and excise taxes of $15,318,318. Repurchased shares are included in Treasury Stock in the accompanying Consolidated Balance Sheets. At April 30, 2024, $4,681,682 remains available to repurchase the Company's common stock pursuant to the share repurchase programs.

Tender Offer

On May 11, 2023, the Company commenced a tender offer, in accordance with Rule 13e-4 promulgated under the Securities Exchange Act of 1934, as amended, to purchase up to 7,750,000 shares of its common stock, par value $0.0001 per share, at a price of $3.25 per share. The tender offer expired one minute after 11:59 p.m. on June 9, 2023, and following such expiration the Company accepted for purchase a total of 8,085,879 shares at $3.25 per share, including 335,879 shares that the Company elected to purchase pursuant to its right to purchase up to an additional 2% of its outstanding shares. The resultant aggregate purchase price was $26,721,897, including excise tax, fees and expenses relating to the tender offer. These shares are treated as Treasury Stock using the cost method and are included as Treasury Stock in the accompanying Consolidated Balance Sheets, Statements of Convertible Preferred Stock and Stockholders' Equity.

As of April 30, 2024, the total number of shares held in Treasury Stock is 13,634,454 shares at a total cost of $42,040,216.

NOTE 14 – FAIR VALUE MEASUREMENTS

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the year ended April 30, 2024. The carrying amounts of cash equivalents, other current assets, accounts payable and accrued expenses approximate their fair values at April 30, 2024 due to their short-term nature. The fair value of the bifurcated embedded derivative related to the convertible preferred stock was estimated using a Monte Carlo simulation model, which uses as inputs the fair value of the Company's common stock and guideline companies estimates for the equity volatility and traded volume volatility of our common stock, the time maturity of the convertible preferred stock, the risk-free interest rate for a period of time that approximates the time to maturity, dividend rate, a penalty dividend rate and the probability of default. The fair value of the warrant liability was estimated using the Black Scholes Merton Model which uses as inputs the following weighted average assumptions, as noted above: dividend yield, expected terms in years, equity volatility and risk-free rate.

Fair Value on a Recurring Basis

The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported and reported at fair at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The estimated fair value of the warrant liability and bifurcated embedded derivative represent Level 3 measurements. The following table presents information about the Company's liabilities that are measured at fair value on a recurring basis at April 30, 2024, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	Level	April 30, 2024	April 30, 2023
Liabilities:			
Warrant liability	3	$ 10,784,000	$ –
Bifurcated embedded derivative	3	$ 2,184,000	$ –

The following table sets forth a summary of the change in the fair value of the warrant liability that is measured at fair value on a recurring basis.

	April 30, 2024
Balance on April 30, 2023	$ –
Issuance of warrants	14,127,000
Change in fair value of warrant liability	(3,343,000)
Balance on April 30, 2024	$ 10,784,000

The following table sets forth a summary of the change in the fair value of the bifurcated embedded derivative liability that is measured on a recurring basis:

	April 30, 2024
Balance on April 30, 2023	$ –
Issuance of convertible preferred stock with bifurcated embedded derivative liability	2,770,000
Change in fair value of bifurcated embedded derivative	(586,000)
Balance on April 30, 2024	$ 2,184,000

The fair value of the convertible note receivable using the income approach, which uses as inputs the fair value of debtor's common stock and estimates for the equity volatility and volume volatility of debtor's common stock, the time to expiration of the convertible note, the discount rate, the stated interest rate compared to the current market rate, the risk-free interest rate for a period that approximates the time to expiration, and probability of default. Therefore, the estimate of expected future volatility is based on the actual volatility of debtor's common stock and historical volatility of debtor's common stock utilizing a lookback period consistent with the time to expiration. The time to expiration is based on the contractual maturity date. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of measurement for time periods approximately equal to the time to expiration. Probability of default is estimated using the S&P Global default rate for companies with a similar credit rating to debtor's.

The fair values of financial instruments by class as of April 30, 2024 are as follows:

	Level	April 30, 2024	April 30, 2023
Financial Assets			
Convertible note receivable – investment in debt security	3	$ 2,755,000	$ –
Warrant asset	3	$ 5,152,000	$ –

Assumptions used in the valuation of the Level 3 assets include time to expiration, discount rate, risk-free rate, volatility and probability of default.

NOTE 15 – SUBSEQUENT EVENTS

Stock Repurchase

From May 1, 2024 to August 8, 2024, the Company repurchased 328,182 shares of common stock through the stock repurchase program for $757,408, including commissions and accrued excise taxes.

Securities Purchase Agreement

Effective on May 23, 2024, the Company entered into a Securities Purchase Agreement with a public company operating in the medical industry, TNF Pharmaceuticals, Inc. (f/k/a MyMD Pharmaceuticals, Inc.) ("TNF"), pursuant to which the Company purchased (i) 7,000 shares of TNF's Series G Convertible Preferred Stock at a price of $1.816 per Preferred Share, which are convertible into 3,854,626 shares of common stock at a price of $1.816 per share; (ii) warrants to purchase up to 3,854,626 shares of TNF's common stock at a price of $1.816 per share with a five-year term ; and warrants to purchase up to 3,854,626 shares of TNF's common stock at an exercise price of $1.816 per share with a 18-month term , for an aggregate purchase price of $7,000,000.