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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, 2025

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**	**(917) 595-2850**
(Address of principal executive offices)	(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

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, 2024: $12,527,115.

As of August 4, 2025, the registrant had 6,795,779 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 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 may be 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 or shrinking 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, we are 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 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.

We assembled a scientific and regulatory team of experts to address the FDA requests. During the year ended April 30, 2025, our scientific consultants have been in active dialog with the FDA seeking permission to forego the large animal study. The technology upon which the LAPC treatment will be based, intra-arterial chemotherapy, has been used in five clinical trials in humans. The data available from these human clinical trials supersedes large animal study data. The treatment may not be a treatment of pancreatic cancer, but a method of improving and possibly enabling complete surgical resection of the tumor. We are waiting for the FDA's responses and hope the FDA will accept that the LAPC treatment now meets manufacturing standard requirements, which have significantly improved since the clinical hold was first placed. The FDA may require additional preclinical studies when the meeting takes place. We are in ongoing dialogue with SG Austria to prepare for the next steps and add requested information to the drug master file upon which the Company still relies on.

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.

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

Fourth Addendum to the SG Austria APA

In May 2018, we and SG Austria entered the Fourth Addendum to the Asset Purchase Agreement. The Fourth Addendum required us to make the following payment the payment was timely made in full under the payment deadlines set forth in the Fourth Addendum:

- $900,000 to SG Austria.

The Fourth Addendum also requires us to make future royalty payments as follows:

- Four percent royalty on all gross sales received by us or our affiliates;
- Twenty 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;
- Fifty percent of any other financial and non-financial consideration received from sublicensees of the Cell-in-a-Box® technology; and
- The removal of all milestone payments.

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, 2025, 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 from 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 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.

In 2024, the FDA approved a record number of biosimilars, reflecting the agency's continued implementation of the Biosimilars Action Plan. This trend underscores the growing competitiveness of the biologics market and the importance of robust intellectual property and market exclusivity strategies. We anticipate that biosimilar competition may increase in therapeutic areas relevant to our pipeline.

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.

On February 10, 2025, President Trump issued Executive Order 14209, which mandates a 180-day pause on new FCPA investigations and enforcement actions by the Department of Justice (DOJ), with limited exceptions. The order also directs a comprehensive review of FCPA enforcement guidelines, potentially signaling a shift in enforcement priorities. While the Securities and Exchange Commission (SEC) retains independent enforcement authority under the FCPA, it may also scale back enforcement during this review period. We continue to monitor developments and assess potential impacts on our compliance obligations and risk exposure.

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.

The FDA continues to apply its long-standing interpretation of orphan drug exclusivity, which limits exclusivity to the approved indication rather than the broader disease or condition. However, recent court decisions have challenged this interpretation, creating potential uncertainty around the scope and duration of orphan exclusivity. We will continue monitoring these developments, to the extent they may affect the competitive landscape for our orphan-designated product candidates.

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 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.

In August 2022, the Inflation Reduction Act of 2022, was signed into law, 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, 2025, and 2024, including no revenues from foreign countries. We have long-lived assets, other than financial instruments, located in the following geographical areas:

	FY 2025	FY 2024
U.S.:	$ 1,549,427	$ 1,549,427
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.

- 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 income attributable to common stockholders for the year ended April 30, 2025 was approximately $23 million, mostly attributable to a gain on the related party investment of approximately $21 million and fair value fluctuations of approximately $14 million, and for 2024 our net loss attributable to common stockholders was approximately $17.2 million. As of April 30, 2025, we had an accumulated deficit of approximately $85 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. 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, 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.

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; and (ix) delays or disruptions in our supply chain.

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 granting our 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 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 material weaknesses 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.

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, 2025, shares of our common stock were quoted and traded at a high of $2.42 per share and a low of $1.03 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 TNF Preferred Shares, the Femasys common stock, the Femasys Warrants and the TNF Warrants. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Femasys Transaction" and "– TNF Transaction" for more information regarding these securities. Defined terms used in this risk factor are defined in such section.

The Femasys 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 TNF Preferred Shares are convertible at a conversion price of $0.1832 per share. To the extent we convert the TNF Preferred Shares when the market price of the TNF 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 Femasys Series A Warrants are exercisable at an exercise price of $1.18 per share. The Femasys Series B Warrants expired on November 21, 2024. There can be no assurance that the Femasys Warrants will be in the money when exercisable, and as such they may expire worthless.

The TNF Warrants are exercisable at an exercise price of $0.1832 per share. There can be no assurance that the TNF 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 TNF 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, 2025, 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, 2025, we had federal net operating loss carryforwards of approximately $61 million, and approximately $31 million for state net operating losses, which will begin to expire in varying amounts beginning in 2025. 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 $24 million and $15 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.

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, we are 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, we do not believe that the outcome of any potential claims will have a material adverse effect on our financial condition or operating results.

On May 16, 2025, we entered into a settlement and release agreement ("Settlement Agreement") with H.C. Wainwright & Co., LLC relating to a complaint filed on December 4, 2023, alleging a breach of contract. The Settlement Agreement resolved fully all differences, disputes or claims without admitting any liability, fault or wrongdoing on the part of all parties. The Settlement Agreement requires us to pay $1.55 million, comprised of an initial payment of $1.25 million and twelve equal payments of $25,000 beginning on the one-month anniversary of the initial payment. On May 16, 2025, we also issued warrants "(First Warrant Issuance") to purchase 343,183 shares of our common stock with an exercise price of $4.00 per share with a term of five years from the issuance date. We had the option to pay $226,254 or issue additional warrants ("Additional Warrants") to purchase 313,067 shares of our common stock with an exercise price of $4.00 per share with a term of five years prior to the issuance date of this Annual Report on Form 10-K. We elected to issue the additional warrants with an effective date of July 29, 2025

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.

Holders

As of July 30, 2025, 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 relating to our common stock. In addition, the terms of the certificate of designations governing our Preferred Shares presently restricts our ability to pay dividends on our common stock. Our Board will decide any future payment of dividends, depending on the results of operations, financial condition, capital requirements and other relevant factors. We paid dividends on the Convertible Preferred Stock at 4% per annum as required.

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, 2025.

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, 2024 – May 31, 2024	25,851	$ 2.1927	25,851	$ 4,624,999
June 1, 2024 – June 30, 2024	260,795	$ 2.3828	260,795	$ 4,003,590
July 1, 2024 – July 31, 2024	33,700	$ 2.1219	33,700	$ 3,932,081
August 1, 2024 – August 31, 2024	29,795	$ 1.8429	29,795	$ 3,877,171
September 1, 2024 – September 30, 2024	56,663	$ 1.9103	56,663	$ 3,768,928
October 1, 2024 – October 31, 2024	596,578	$ 2.1027	596,578	$ 2,514,516
November 1, 2024 – November 30, 2024	55,707	$ 1.8498	55,707	$ 2,411,467
December 1, 2024 – December 31, 2024	38,172	$ 1.6901	38,172	$ 2,346,951
January 1, 2025 – January 31, 2025	35,486	$ 1.6826	35,486	$ 2,287,242
February 1, 2025 – February 28, 2025	36,242	$ 1.7061	36,242	$ 2,225,412
March 1, 2025 – March 31, 2025	47,646	$ 1.6677	47,646	$ 2,145,950
April 1, 2025 – April 30, 2025	25,227	$ 1.2708	25,227	$ 2,113,892
Total	1,241,862	$ 2.0677	1,241,862	$ 2,113,892

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.

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). We are 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 our 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 our 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, we will be required to pay the amortization payment in cash. We 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 our 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, our 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 our stockholders have approved the issuance of more than 19.9% of the our outstanding shares of common stock in accordance with Nasdaq listing standards (the "Nasdaq Stockholder Approval"). We 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 us and the Investors simultaneously with the Purchase Agreement and our 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 us to redeem in cash any or all of the holder's Preferred Shares at a premium set forth in the Certificate of Designations.

As of April 30, 2025, all preferred shares were redeemed and no remaining obligations exist.

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 initial annual interest payment was paid in stock. 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. During the years ended April 30, 2025 and 2024, the Notes earned $300,000 and $137,500, respectively. On November 21, 2024, we received a settlement of twelve months of interest in the form of 315,790 shares of Femasys common stock. The fair value of the shares was measured at April 30, 2025, resulting in an unrealized gain of $66,316.

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 expired on November 21, 2024.

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). In April 2025, the conversion price was adjusted to $0.1832 per share as a result of stock option grants. 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 initial 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 initial 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 April 2025, the exercise price for both the Long-Term Warrants and Short-Term Warrants was adjusted to $0.1832 per share. As a result of the exercise price adjustment, the number of warrant shares attributable to both the Long-Term and Short-Term Warrants increased to 38,209,611 each.

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, 2025, our cash and cash equivalents totaled approximately $15.2 million, compared to approximately $50.2 million as of April 30, 2024. Working capital was approximately $19.5 million as of April 30, 2025, and approximately $43 million as of April 30, 2024. The decrease in cash is attributable to our investment in TNF, the redemption of preferred stock, the repurchase of our common stock pursuant to the Repurchase Programs, recorded as treasury stock and 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, 2025, compared to year ended April 30, 2024

Revenue

We had no revenues in the fiscal years ended April 30, 2025, and 2024.

Operating Expenses

Our total operating expenses during the year ended April 30, 2025 were $4,377,862, representing a decrease of $4,142,146 compared to the year ended April 30, 2024. The decrease is mainly attributable to decreases in compensation expenses, director fees, impairment of asset, legal and professional and general and administrative expenses, net of an increase in R&D.

Research and development expenses

R&D expense was $438,416 for the year ended April 30, 2025, as compared to $407,431 for the year ended April 30, 2024, an increase of $30,985. The increase in cost is primarily due to entering into an agreement with consultants to conduct additional research into the treatment of pancreatic cancer.

General and administrative expenses

The majority of our operating losses from operations are from general and administrative expenses. General and administrative expenses consist primarily of costs associated with our overall operations and with being a public company. These costs include personnel, legal and professional services, insurance, investor relations and compliance related fees. These expenses were $3,939,446 and $6,112,577, respectively, for the years ended April 30, 2025 and 2024, a decrease of $2,173,131, or 36%. Compensation expenses decreased by $37,210 to a reduction in accrued vacation. Director fees decreased by $585,271 due to a reduction in equity compensation and payments made to directors. Investor relations decreased by $198,364 due to having two stockholder meetings in 2024 and one meeting in 2025. Legal and professional fees decreased by $300,266 primarily due to a reduction in legal fees relating to non-recurring legal issues. Warrant issuance costs decrease of $913,640 incurred in 2024 were non-recurring in 2025.

Impairment asset impairment

For the year ended April 30, 2024, we impaired a license in the amount of $2,000,000.

Other Income (Expenses), Net

Other income, net for the year ended April 30, 2025, was $35,033,912, as compared to other income, net of $8,853,771 in the year ended April 30, 2024. Other income, net for the year ended April 30, 2025 is attributable to interest income of $1,415,561, changes in fair values of warrant liability of $10,446,000, derivative liability of $2,184,000, convertible note receivable of $941,000, preferred stock investment – TNF of $5,063,950, and gain on related party investment – TNF of $21,395,734 and unrealized gain on the fair value of marketable securities of $66,316, less decreases in the fair value of Femasys warrant asset of $2,091,000, TNF warrant asset of $2,367,684, settlement of legal complaint of $2,019,000 and other expenses of $965. Other income, net for the year ended April 30, 2024 of $8,853,771 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. For the years ended April 30, 2025 and 2024, we recorded an asset loss of $0 and $1,572,193, respectively, related to the Company's investment in SG Austria, reducing the carrying value of such investment to zero.

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, 2025 and 2024.

	Year Ended April 30, 2025	Year Ended April 30, 2024
Net cash used in operating activities:	$ (2,978,296)	$ (2,151,457)
Net cash used in investing activities:	$ (7,000,000)	$ (5,000,000)
Net cash used in financing activities:	$ (25,029,151)	$ (10,708,003)
Effect of currency rate exchange	$ (358)	$ (508)
Decrease in cash	$ (35,007,805)	$ (17,859,968)

Operating Activities:

The cash used in operating activities for the year ended April 30, 2025 is a result of our net income of $30,656,050, offset by non-cash transactions, change in fair value of warrant asset in Femasys of $2,091,000 and legal settlement of $1,550,000, stock based compensation of $478,637, legal settlement warrant liability of $469,000, change in fair value of TNF warrants of $2,367,684, offset by the gain on related party investment of $(21,395,734) the changes in fair value of warrant liability of $(10,446,000), investment – TNF of $(5,063,950), derivative liability of $(2,184,000), convertible note receivable of $(941,000), change in unrealized gain of marketable securities of $(66,316), non-cash interest income of $(300,000), and changes to prepaid expenses, accounts payable, accrued expenses, and accrued dividends totaling $(193,667).

The cash used in operating activities for the year ended April 30, 2024 is a result of our net income of $333,763, convertible note receivable of $(1,089,000), changes in fair value of warrant liability of $(3,343,000), derivative liability of $(586,000), warrant asset – Femasys of $(1,818,000), other non-cash adjustments of $(195,000) offset by stock based compensation of $674,693, asset impairment of $2,000,000, loss on long term asset of $1,572,193, and changes to prepaid expenses, accounts payable and accrued expenses of $298,894.

Investing Activities:

The cash used in investing activities for the year ended April 30, 2025 is mainly attributable to our entry into the TNF Purchase Agreement with a public company operating in the medical industry, Pursuant to the TNF Purchase Agreement, we purchased (i) 7,000 shares of TNF's Series G Convertible Preferred Stock (the "Preferred Shares" or "Series G Preferred Stock"), representing approximately 33% of TNF's issued and outstanding share capital on an as-converted basis (and approximately 78% of all shares of Series G Preferred Stock outstanding), at a price of $1.816 per Preferred Share, which are convertible into 3,854,626 shares of Common Stock (as defined below); (ii) warrants to purchase up to 3,854,626 shares of TNF's Common Stock with a five-year term; and (iii) warrants to purchase up to 3,854,626 shares of TNF's Common Stock with a 18-month, for an aggregate purchase price of $7,000,000.

The cash used in investing activities for the year ended April 30, 2024 is mainly attributable to our entry into a Securities Purchase Agreement (the "Femasys Purchase Agreement") with Femasys Inc. ("Femasys"), pursuant to which we purchased 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. The Series B Warrants expired on November 21, 2024.

Financing Activities:

The cash used in financing activities for the year ended April 30, 2025 is mainly attributable to the repurchase of common stock of approximately $2,542,000 and redemption of preferred stock of approximately $22,487,000.The cash 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, offset by the cash provided by proceeds from the issuance of preferred stock of approximately $33,650,000, net of transaction costs.

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, 2025. 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, we elect 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. We estimate 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.

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

Fair Value of Long-Lived 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

In August 2023, the FASB issued ASU 2023-05 – Business Combinations – Joint Venture Formations (Subtopic 805-60), which requires public entities that qualify as a joint venture or corporate joint venture to establish a new basis of accounting upon formation. The guidance is effective for our annual periods beginning May 1, 2025, and early adoption is permitted. We are evaluating the impact of adoption of this standard on its financial statements and disclosures but does not expect it to have a material effect on its consolidated financial statements.

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 our annual periods beginning May 1, 2025 on a prospective basis, with a retrospective option, and early adoption is permitted. We are evaluating the impact of adoption of this standard on its financial statements and disclosures but does not expect it to have a material effect on our consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03 (“ASU 2024-03”), Disaggregation of Income Statement Expenses. The guidance requires additional, disaggregated disclosure about certain income statement expense line items. The amendments in ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027, with early adoption permitted, and is required to be applied prospectively with the option of retrospective application. We are currently evaluating the impact on the consolidated financial statements and related disclosures.

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, 2025 and 2024, and our Consolidated Statements of Operations, Comprehensive Income, Changes in Convertible Preferred Stock and Stockholders Equity and Cash Flows for each of the years in the years ended April 30, 2025 and April 30, 2024, and associated Notes and Schedules, together with the reports thereon of our independent registered public accounting firm, are set forth on Item 15 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, 2025, 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, 2025, 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 these material weaknesses, our Interim Chief Executive Officer and our Chief Financial Officer concluded that, as of April 30, 2025, 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, 2025, 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, 2025, 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.

On August 8, 2025, we entered into an Executive Compensation Agreement (the "Silverman Compensation Agreement") with Joshua N. Silverman Silverman, effective as of January 1, 2025, pursuant to which Mr. Silverman will serve as our Chief Executive Officer, President, and Executive Chairman.

The Silverman Compensation Agreement provides for an initial three-year term, with automatic one-year renewal periods unless either party provides at least ninety (90) days' prior written notice of non-renewal. Under the Silverman Compensation Agreement, Mr. Silverman is entitled to an annual base salary of $375,000, subject to annual review and potential increase by the Compensation Committee. Mr. Silverman is eligible to receive an annual performance-based bonus. In addition, Mr. Silverman is entitled to receive annual long-term incentive awards under the Company's Long Term Incentive Plan with a target annual equity award grant date fair value to equal 300% of Mr. Silverman's base salary.

In the event of termination without "Cause" or by Mr. Silverman for "Good Reason" (as such terms are defined in the Silverman Compensation Agreement). Mr. Silverman is entitled to receive accrued compensation through the termination date, severance equal to two times the sum of his base salary and target bonus (prorated for the year of termination), payable over 24 months, and accelerated vesting of all unvested equity awards. If such termination occurs within two years following or six months preceding a "Change in Control" (as defined in the Silverman Compensation Agreement), Mr. Silverman is entitled to enhanced severance equal to three times the sum of his base salary and target bonus, payable in a lump sum, and full acceleration of all unvested equity awards.

In the event of Mr. Silverman's death during the term of the Silverman Compensation Agreement, his estate is entitled to receive accrued compensation, any unpaid bonus amounts, accelerated vesting of all unvested equity awards, and any other benefits due under the Company's benefit plans. In addition, the death benefit under the Company's life insurance program, if any, will be paid to his designated beneficiary or estate. If Mr. Silverman's employment terminates due to disability, he is entitled to accrued compensation, prorated target bonus, and continued salary payments for 24 months, along with accelerated vesting of all unvested equity awards and benefits under the Company's long-term disability insurance plan, if applicable.

All severance and equity acceleration benefits are subject to Mr. Silverman's execution and non-revocation of a general release of claims. The Agreement also includes provisions regarding confidentiality, non-disparagement, post-employment cooperation, and compliance with Section 409A of the Internal Revenue Code. Compensation under the Agreement is subject to the Company's clawback policies as may be required by applicable law or listing standards.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

As of July 18, 2025, our directors and executive officers are:

	Age	Position
Joshua N. Silverman	55	Interim Chairman of the Board, Interim Chief Executive Officer and Interim President
Carlos A. Trujillo	67	Chief Financial Officer
Jonathan L. Schechter	51	Director
Robert Weinstein	65	Director
Wayne R. Walker	65	Director
Michael M. Abecassis	67	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), Femasys Inc. (Nasdaq: FEMY, TNF Pharmaceuticals, Inc. (Nasdaq: TNFA), TAO Synergies Inc. (formerly Synaptogenix, Inc.) (Nasdaq: TAOX) 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 TAO Synergies Inc. (formerly Synaptogenix, Inc.), (Nasdaq: TAOX), 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 TAO Synergies Inc. (formerly Synaptogenix, Inc.) (Nasdaq: TAOX) 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 40 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, 2025, our personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the rules and regulations of the Commission.

Insider Trading Policy

We have adopted a formal Insider Trading Policy, governing the purchase, sale, and/or other disposition of our securities by our directors, officers, employees, and other covered persons. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company.

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 2025 and 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, 2025, 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, 2025, and 2024.

Summary Compensation Table

Name	Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation (2)	Total ($)
Joshua N. Silverman (2)	Interim Chief Executive Officer and Interim President	2025	$ 375,000	$ 100,000	$ –	$ –	$ 45,257	$ 520,257
		2024	$ 375,000	$ 100,000	$ –	$ 312,923	$ 41,662	$ 829,585
Carlos A. Trujillo	Chief Financial Officer	2025	$ 380,000	$ 50,000	$ –	$ –	$ 52,017	$ 482,017
		2024	$ 380,000	$ 50,000	$ –	$ 156,562	$ 49,556	$ 636,118

(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. Our computation of expected volatility for the year ended April 30, 2024 on selected guideline companies historical weekly basis volatility. For stock option grants issued during the year ended April 30, 2024, we used a calculated volatility for each grant. We lack 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 our stock options of ten years with the average vesting term of six months. The dividend yield assumption of zero is based upon the fact we have 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.

(2) Includes health insurance premium payments for Mr. Silverman and Mr. Trujillo.

Narrative Disclosure to Summary Compensation Table

Employment Arrangements

Joshua N. Silverman

On November 14, 2022, the Board approved employment of Joshua N. 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.

On August 8, 2025, we entered into an Executive Compensation Agreement (the "Silverman Compensation Agreement") with Mr. Silverman, effective as of January 1, 2025, pursuant to which Mr. Silverman will serve as our Chief Executive Officer, President, and Executive Chairman.

The Silverman Compensation Agreement provides for an initial three-year term, with automatic one-year renewal periods unless either party provides at least ninety (90) days' prior written notice of non-renewal. Under the Silverman Compensation Agreement, Mr. Silverman is entitled to an annual base salary of $375,000, subject to annual review and potential increase by the Compensation Committee. Mr. Silverman is eligible to receive an annual performance-based bonus. In addition, Mr. Silverman is entitled to receive annual long-term incentive awards under the Company's Long Term Incentive Plan with a target annual equity award grant date fair value to equal 300% of Mr. Silverman's base salary.

In the event of termination without "Cause" or by Mr. Silverman for "Good Reason" (as such terms are defined in the Silverman Compensation Agreement). Mr. Silverman is entitled to receive accrued compensation through the termination date, severance equal to two times the sum of his base salary and target bonus (prorated for the year of termination), payable over 24 months, and accelerated vesting of all unvested equity awards. If such termination occurs within two years following or six months preceding a "Change in Control" (as defined in the Silverman Compensation Agreement), Mr. Silverman is entitled to enhanced severance equal to three times the sum of his base salary and target bonus, payable in a lump sum, and full acceleration of all unvested equity awards.

In the event of Mr. Silverman's death during the term of the Silverman Compensation Agreement, his estate is entitled to receive accrued compensation, any unpaid bonus amounts, accelerated vesting of all unvested equity awards, and any other benefits due under the Company's benefit plans. In addition, the death benefit under the Company's life insurance program, if any, will be paid to his designated beneficiary or estate. If Mr. Silverman's employment terminates due to disability, he is entitled to accrued compensation, prorated target bonus, and continued salary payments for 24 months, along with accelerated vesting of all unvested equity awards and benefits under the Company's long-term disability insurance plan, if applicable.

All severance and equity acceleration benefits are subject to Mr. Silverman's execution and non-revocation of a general release of claims. The Agreement also includes provisions regarding confidentiality, non-disparagement, post-employment cooperation, and compliance with Section 409A of the Internal Revenue Code. Compensation under the Agreement is subject to the Company's clawback policies as may be required by applicable law or listing standards.

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, 2025, 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 and 2022 Plan

Under our 2021 and 2022 Plans, upon a Change in Control (as defined in the 2021 and 2022 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 and 2022 Plans, 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 as of April 30, 2025

	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	170,000	–	$ 2.18	11/19/2033
Carlos A. Trujillo	2,000	–	$ 10.05	12/31/2025
	2,000	–	$ 2.50	01/01/2027
	85,000	–	$ 2.18	11/19/2033

Granting of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not grant equity awards in anticipation of the release of material nonpublic information that is likely to result in changes to the price of our common stock, and do not time the public release of such information based on award grant dates. During the last completed fiscal year, we have not made awards to any named executive officer or director during the period beginning four business days before and ending one business day after the filing of a period report on Form 10-Q or Form 10-K or the filing or furnishing of a current report on Form 8-K, and we have not timed the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Clawback Policy

The Board of Directors adopted a Clawback policy to create and maintain a culture that emphasizes integrity and accountability that reinforces pay-for-performance compensation policy. The policy applies to current and former executive officers in accordance with applicable rules and standards adopted by the SEC. The policy covers incentive-based compensation, which includes any compensation that is granted, earned or vested based on wholly or in part upon attaining any financial reporting measures that are determined and presented in accordance with accounting principles ("GAAP") used in preparing our financial statements as well as non-GAAP. An accounting restatement of its financial statements due to material noncompliance with securities law, including correction of an error on the financial statements may cause a recovery of the incentive-based compensation from the executive officer.

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, 2025.

Director Compensation Table

Name	Fees Earned ($)	Stock Awards ($)(1)	Option Awards ($)(1)(2)	Total ($)
Jonathan L. Schechter	$ 70,000	$ –	$ 60,000	$ 130,000
Robert Weinstein	$ 70,000	$ –	$ 60,000	$ 130,000
Wayne R. Walker	$ 70,000	$ –	$ 60,000	$ 130,000
Michael M. Abecassis	$ 102,000	$ –	$ 60,000	$ 162,000

(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, 2025, as computed in accordance with FASB ASC Topic 718. Our computation of expected volatility for the year ended April 30, 2025 on our historical weekly basis volatility. For stock option grants issued during the year ended April 30, 2024, we used a calculated volatility for each grant. We lack 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 our stock options of ten years with the average vesting term of six months. The dividend yield assumption of zero is based upon the fact we have 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.
and the assumptions stated in Note 4 and Note 5 of the Consolidated Financial Statements to this Report.

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. 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 18, 2025, 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 18, 2025 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.

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:		
Entities affiliated with Ayrton Capital LLC (2)	774,100	10.24%
Entities affiliated with Intracoastal Capital LLC (3)	714,844	10.23%
Directors, Officers and Named Executive Officers:		
Joshua N. Silverman, Interim Chairman of the Board, Interim Chief Executive Officer and Interim President (4)	220,000	3.16%
Jonathan L. Schechter, Board Member (5)	149,257	2.16%
Michael M. Abecassis, Board Member (6)	103,059	1.49%
Robert Weinstein, Board Member (7)	99,257	1.44%
Wayne R. Walker, Board Member (8)	99,257	1.44%
Carlos A. Trujillo, Chief Financial Officer (9)	99,400	1.44%
All directors and executive officers as a group (6 persons)	770,230	10.33%

(1) Percentages based on 6,795,779 shares of common stock outstanding as of July 18, 2025.

(2) Includes 774,100 shares of common stock issuable on the exercise of warrants held by Alto Opportunity Master Fund, SPC – Segregated Master Portfolio B ("Alto"). This information is based solely on the Schedule 13G filed with the SEC by Alto, Ayrton Capital LLC ("Ayrton") and Waqas Khatri on February 13, 2025. Alto is a private investment vehicle for which Ayrton serves as the investment manager. Mr. Khatri serves as the managing member of Ayrton. A blocker provision exists, limiting the percentage to 9.99%. The address of Alto is Suite #7, Grand Pavilion Commercial Centre, 802 West Bay Road, Grand Cayman, P.O. Box 10250, Cayman Islands. The address of Ayrton is 55 Post Rd West, 2nd Floor, Westport, CT 06880. The address of Mr. Khatri is 55 Post Rd West, 2nd Floor, Westport, CT 06880.

(3) Includes (i) 527,376 shares of common stock and (ii) 187,468 shares of common stock issuable upon the exercise of warrants owned by Intracoastal LLC ("Intracoastal"). This information is based on the Schedule 13G/A filed with the SEC January 15, 2025 by Intracoastal, Mitchell P. Kopin and Daniel B. Asher. A blocker provision exists, limiting the percentage to 9.99%. 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.

(4) Includes 170,000 shares issuable upon the exercise of options to purchase common stock.

(5) Includes 99,257 shares issuable upon the exercise of options to purchase common stock.

(6) Includes 100,257 shares issuable upon the exercise of options to purchase common stock.

(7) Includes 99,257 shares issuable upon the exercise of options to purchase common stock.

(8) Includes 99,257 shares issuable upon the exercise of options to purchase common stock.

(9) Includes 89,000 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, 2025:

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	1,162,629	$ 2.14	1,747,634
Equity compensation plans not approved by security holders	7,332	$ 13.17	–
Total	1,169,961	$ 2.21	1,747,634

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, 2025 and 2024, 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 $0 in the years ended April 30, 2025, and 2024, 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, 2025, and 2024, were approximately $16,000 and $5,000, 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 November 14, 2023, we entered into a Securities Purchase Agreement with Femasys, Inc., pursuant to which we purchased for a sum of $5,000,000 (i) senior unsecured convertible notes (ii) Series A Warrants to purchase 4,237,288 common shares and (iii) Series B Warrants to purchase 4,237,288 common shares. Pursuant to the terms of the Femasys agreement, our Interim Executive Officer was appointed to the Femasys board of directors. For more information regarding the Femasys Transaction, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Femasys Transaction."

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

We engaged Marcum LLP ("Marcum") from November 5, 2023 to February 21, 2025. CBIZ CPAs P.C. ("CBIZ CPAs") acquired Marcum effective November 1, 2024.

A summary of the fees billed by our independent audit firm, CBIZ CPAs, for professional services rendered for the years ended April 30, 2025 and 2024 is set forth below.

Service	2025	2024
Audit Fees	$ 247,250	$ -
Audit-Related Fees	–	–
Tax Fees	–	–
All Other Fees	–	–
Total	$ 247,250	$ -

A summary of the fees billed by our independent audit firm, Marcum, for professional services rendered for the years ended April 30, 2025 and 2024 is set forth below.

Service	2025	2024
Audit Fees	$ 116,342	$ 316,650
Audit-Related Fees	–	–
Tax Fees	–	–
All Other Fees	–	–
Total	$ 116,342	$ 316,650

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. We generally do 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, 2025, and 2024, and for each of the two years in the period ended April 30, 2025, 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 Exhibits 32.1 and 32.2, 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.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 13, 2024.
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.
4.10	Form of First Tranche Warrant	Filed herewith.
4.11	Form of Second Tranche Warrant	Filed herewith.
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	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.
10.36	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.
10.37	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.
10.38	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.
10.39	Securities Purchase Agreement, dated May 20, 2024 by and among PharmaCyte Biotech, Inc. and TNF Pharmaceuticals, Inc. (f/k/a MyMD Pharmaceuticals, Inc.)	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on May 23, 2024.
10.40	Form of Certificate of Designations of Series G Convertible Preferred Stock of TNF Pharmaceuticals, Inc. (f/k/a 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 Long-Term Warrant of TNF Pharmaceuticals, Inc. (f/k/a 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 Short-Term Warrant of TNF Pharmaceuticals, Inc. (f/k/a 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 Silverman Executive Compensation Agreement	Filed herewith.
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.
16.1	Letter from Marcum LLP to the Securities and Exchange Commission regarding the Company's change in certifying accountant dated February 26, 2025.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Commission on February 26, 2025.
19.1	PharmaCyte Biotech, Inc. Insider Trading Policy.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 13, 2024.
21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of CBIZ CPAs P.C.	Filed herewith.
23.2	Consent of Marcum 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.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the Commission on August 13, 2024.
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 8, 2025 By: /s/ Joshua N. Silverman
Joshua N. Silverman
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

August 8, 2025 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 8, 2025 By: /s/ Joshua N. Silverman
Joshua N. Silverman
Chief Executive Officer, Chairman of the Board and Director
(Principal Executive Officer)

August 8, 2025 By: /s/ Carlos A. Trujillo
Carlos A. Trujillo
Chief Financial Officer and Director
(Principal Financial and Accounting Officer)

August 8, 2025 By: /s/ Jonathan L. Schechter
Jonathan L. Schechter, Director

August 8, 2025 By: /s/ Robert Weinstein
Robert Weinstein, Director

August 8, 2025 By: /s/ Michael M. Abecassis
Michael M. Abecassis, Director

August 8, 2025 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, 2025.

PHARMACYTE BIOTECH, INC.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders 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, 2025, the related consolidated statements of operations, comprehensive income, changes in convertible preferred stock and stockholders' equity, and cash flows for the year ended April 30, 2025, 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, 2025, and the results of its operations and its cash flows for the year ended April 30, 2025, 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
The critical audit matters communicated below 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 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.

Fair Value of Financial Instruments

Critical Audit Matter Description

As described in Notes 3, 4, 14 and 15 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.

How We Addressed the Matter in Our Audit

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/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2023 (such date takes into account the acquisition of certain assets of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Morristown, New Jersey
August 8, 2025

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**,** 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.

/s/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2023 to 2025.

Morristown, New Jersey
August 13, 2024

PHARMACYTE BIOTECH, INC.
CONSOLIDATED BALANCE SHEETS

	April 30, 2025	April 30, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,172,163	$ 50,179,968
Marketable equity securities	366,316	–
Warrant asset – TNF - current	2,917,000	–
Convertible Note receivable – Femasys - current	3,696,000	–
Prepaid expenses and other current assets	223,759	259,800
Total current assets	22,375,238	50,439,768
Other assets:		
Intangible assets	1,549,427	1,549,427
Investment in preferred stock – TNF	22,474,000	–
Warrant assets – TNF - non current	5,701,000	–
Convertible note receivable – Femasys - non current	–	2,755,000
Warrant assets - Femasys	3,061,000	5,152,000
Other assets	7,688	7,688
Total other assets	32,793,115	9,464,115
Total Assets	$ 55,168,353	$ 59,903,883
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 399,204	$ 389,369
Accrued expenses	2,515,080	735,199
Accrued Series B convertible preferred stock redemption and dividends payable	–	6,296,696
Total current liabilities	2,914,284	7,421,264
Other liabilities:		
Long-term portion of accrued expenses	25,000	–
Warrant liability	338,000	10,784,000
Derivative liability	–	2,184,000
Total other liabilities	363,000	12,968,000
Total Liabilities	3,277,284	20,389,264
Commitments and Contingencies (Note 9)		
Convertible Preferred Stock:		
Series B convertible preferred stock: authorized 35,000 shares, $0.0001 par value and $1,000 face value, 0 and 14,646 shares issued and outstanding excluding 0 and 5,833 shares subject to redemption as of April 30, 2025 and April 30, 2024, respectively. Liquidation preference of $0 and $15,060,421, as of April 30, 2025 and April 30, 2024, 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, 2025 and 2024	–	–
Common stock, authorized: 200,000,000 shares, $0.0001 par value; shares issued 21,672,095, shares outstanding 6,795,779 as of April 30, 2025, and shares issued 21,672,078, shares outstanding 8,037,624 as of April 30, 2024	2,167	2,167
Additional paid-in capital	181,489,647	185,334,173
Accumulated deficit	(84,968,960)	(115,625,010)
Treasury stock, at cost, 14,876,316 and 13,634,454 shares as of April 30, 2025, and 2024, respectively	(44,607,916)	(42,040,216)
Accumulated other comprehensive loss	(23,869)	(23,511)
Total stockholders' equity	51,891,069	27,647,603
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity	$ 55,168,353	$ 59,903,883

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30,	
	2025	**2024**
Revenue	$ –	$ –
Operating expenses:		
Research and development costs	438,416	407,431
Intangible asset impairment	–	2,000,000
General and administrative	3,939,446	6,112,577
Total operating expenses	4,377,862	8,520,008
Loss from operations	(4,377,862)	(8,520,008)
Other income (expense):		
Interest income	1,415,561	3,398,819
Change in fair value of warrant liability	10,446,000	3,343,000
Change in fair value of derivative liability	2,184,000	586,000
Change in fair value of convertible note receivable – Femasys	941,000	1,089,000
Change in fair value of warrant asset – Femasys	(2,091,000)	1,818,000
Change in fair value of investment – TNF	5,063,950	–
Change in fair value of warrant assets - TNF	(2,367,684)	–
Gain on investment in preferred stock – TNF	21,395,734	–
Unrealized gain on marketable securities	66,316	–
Loss on legal settlement	(2,019,000)	–
Loss on long term asset	–	(1,572,193)
Other income (expense), net	(965)	191,145
Total other income (expense), net	35,033,912	8,853,771
Income tax benefit (expense)	–	–
Net income	$ 30,656,050	$ 333,763
Preferred stock dividends	(1,129,759)	(2,517,645)
Undistributed income to Series B convertible preferred stock	(2,970,780)	–
Preferred stock accretion	(3,193,404)	(15,053,521)
Net income (loss) attributable to common stockholders	$ 23,362,107	$ (17,237,403)
Basic and diluted income (loss) per share attributable to common stockholders	$ 3.19	$ (1.80)
Weighted average shares outstanding basic and diluted	7,329,596	9,581,059

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Years Ended April 30,	
	2025	**2024**
Net income	$ 30,656,050	$ 333,763
Other comprehensive loss:		
Foreign currency translation adjustments	(358)	(508)
Other comprehensive loss	(358)	(508)
Comprehensive income	$ 30,655,692	$ 333,255

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, 2025 AND 2024

	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, 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
Fractional shares adjustment	–	–	17	–	–	–	–	–	–	–
Stock-based compensation options	–	–	–	–	478,637	–	–	–	–	478,637
Preferred stock accretion	–	3,193,404	–	–	(3,193,404)	–	–	–	–	(3,193,404)
Series B preferred stock redemption	(14,646)	(15,287,599)	–	–	–	–	–	–	–	–
Deemed dividends	–	–	–	–	(902,580)	–	–	–	–	(902,580)
Preferred stock dividends	–	227,179	–	–	(227,179)	–	–	–	–	(227,179)
Foreign currency translation adjustment	–	–	–		–	–	–	–	(358)	(358)
Net Income	–	–	–		–	–	–	30,656,050	–	30,656,050
Repurchase of common stock	–	–	–	–	–	(1,241,862)	(2,567,700)	–	–	(2,567,700)
Balance, April 30, 2025	–	$ –	21,672,095	$ 2,167	$ 181,489,647	(14,876,316)	$ (44,607,916)	$ (84,968,960)	$ (23,869)	$ 51,891,069

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30,	
	2025	**2024**
Cash flows from operating activities:		
Net income	$ 30,656,050	$ 333,763
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on related party investment - TNF	(21,395,734)	–
Non-cash interest income	(300,000)	–
Non-cash warrant liability	469,000	–
Asset impaired	–	2,000,000
Loss on long term asset	–	1,572,193
Other non-cash income	–	(195,000)
Stock-based compensation	478,637	674,693
Unrealized gain on marketable equity securities	(66,316)	–
Change in fair value of warrant liability	(10,446,000)	(3,343,000)
Change in fair value of derivative liability	(2,184,000)	(586,000)
Change in fair value of convertible note receivable - Femasys	(941,000)	(1,089,000)
Change in fair value of warrant assets - Femasys	2,091,000	(1,818,000)
Change in fair value of investment - TNF	(5,063,950)	–
Change in fair value of warrants - TNF	2,367,684	–
Change in assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	36,041	(152,119)
Increase in accounts payable	9,835	261,090
Increase in accrued expenses	1,310,457	189,923
Net cash used in operating activities	(2,978,296)	(2,151,457)
Cash flows from investing activities:		
Investment in preferred stock and warrants	(7,000,000)	–
Investment – convertible note receivable and warrants	–	(5,000,000)
Net cash used in investing activities	(7,000,000)	(5,000,000)
Cash flows from financing activities:		
Repurchase of common stock, net	(2,542,276)	(28,197,617)
Proceeds from issuance of preferred stock, net of transaction costs	–	33,650,075
Redemption of preferred stock	(22,486,875)	(16,160,531)
Proceeds from warrant exercise	–	70
Net cash used in financing activities	(25,029,151)	(10,708,003)
Effect of currency rate exchange on cash and cash equivalents	(358)	(508)
Net decrease in cash and cash equivalents	(35,007,805)	(17,859,968)
Cash and cash equivalents at beginning of the year	50,179,968	68,039,936
Cash and cash equivalents at end of the year	$ 15,172,163	$ 50,179,968
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
Accrued Series B Convertible Preferred Stock dividends	$ –	$ 22,457,227
Series B Convertible Preferred stock dividends	$ 1,129,759	$ –
Accretion of discounts to redemption value of Series B Preferred Stock	$ 3,193,404	$ 15,053,521
Excise tax accrued on repurchase of common stock	$ 25,424	$ 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 shear 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.

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. During the year ended April 30, 2025, the Company's scientific consultants have been in active dialog with the FDA seeking permission to forego the large animal study. The technology upon which the LAPC treatment will be based, intra-arterial chemotherapy, has been used in five clinical trials in humans. The data available from these human clinical trials supersedes large animal study data. The treatment may not be a treatment of pancreatic cancer, but a method of improving and possibly enabling complete surgical resection of the tumor. The Company is waiting for the FDA's responses and hopes the FDA will accept that the LAPC treatment now meets manufacturing standard requirements, which have significantly improved since the clinical hold was first placed. The FDA may require additional preclinical studies when the meeting takes place. The Company is in ongoing dialogue with SG Austria to prepare for the next steps and add requested information to the drug master file upon which the Company still relies on.

NOTE 2 – LIQUIDITY AND OTHER UNCERTAINTIES

As of April 30, 2025, the Company had approximately $15.2 million in cash and cash equivalents as compared to $50.2 million at April 30, 2024. The Company expects that its current cash and cash equivalents, as of the date of this Annual Report, will be sufficient to support its projected operating requirements and financial commitments for at least the next twelve months from this date. The operating requirements include the expected costs to submit and clear the FDA clinical hold on our pancreatic cancer treatment.

The Company expects to need additional capital in order to complete a clinical trial for the treatment of pancreatic cancer. If any additional equity financing, if available, may not be on favorable terms and would likely be significantly dilutive to the Company's current stockholders and debt financing, if available, may involve restrictive covenants. If the Company is able to access funds through collaborative or licensing arrangements, it may be required to relinquish rights to some of its product candidates that the Company would otherwise seek to develop or commercialize on its own, on terms that are not favorable to the Company. The Company's ability to access capital is not assured and, if not achieved on a timely basis, will likely have a material adverse effect on our business, financial condition and results of operations.

The Company operates in an industry that is subject to rapid technological change, competition and government regulation. The Company's operations are subject to significant risk and uncertainties including financial operational, technological, regulatory, and other risks. Such factors, include but not limited to, results of clinical testing and trial activities, the ability to obtain regulatory approval, the supply of needed materials, the ability to obtain manufacturing and the ability to raise capital to achieve strategic objectives.

NOTE 3 – 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.

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. The Company's most significant estimates and assumptions are the assessment of the fair value of long-lived assets, fair value measurements of investments, the valuation of warrants and derivative liabilities, accretion of preferred stock and the measurement of stock based compensation.

Reclassification

Certain balances in the consolidated financial statements for the year ended April 30, 2024 have been reclassified to conform to the presentation in the consolidated financial statements for the year ended April 30, 2025. In the prior year, the Company separately disclosed compensation expense, director fees and legal and professional expenses and in the current year the Company has reclassified these costs on the consolidated statements of operations with general and administrative expenses. These reclassifications had no effect on the Company's previously reported results of operations, changes in convertible preferred stock and stockholders' equity, or cash flows.

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. Additionally, the Company, as of April 30, 2025 and 2024 has approximately $76,000 and $3.2 million, respectively, in a money market fund that is not insured by the Federal Deposit Insurance Corporation ("FDIC") and is classified as a cash equivalent. 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 FDIC up to $250,000. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash.

Basic and Diluted Income (Loss) Per Share

Basic earnings per share excludes dilution for common stock equivalents and is computed by dividing net income or loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted EPS is calculated based on the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period. Potentially dilutive securities consist of common stock options, warrants, and convertible preferred securities. The dilutive effect of stock options and warrants is reflected in diluted EPS by application of the treasury stock method. The dilutive effect of convertible preferred securities is reflected in the diluted EPS by application of the "if-converted" method. The "if-converted" method is only assumed in periods where such application would be dilutive. Basic and diluted net income (loss) per share is determined by dividing income (loss) by the weighted average ordinary shares outstanding during the period. For periods presented with a net loss, the shares underlying the ordinary share options, warrants and preferred stock have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per share is the same for periods with a net loss.

Marketable Equity Securities

Marketable securities consist of equity security investments. Equity investments with readily determinable fair values are measured at fair value. Changes in value are recorded in other income (expenses), net in the accompanying consolidated statements of operations.

Investment in TNF Pharmaceuticals, Inc.

In accordance with ASC 810, *Consolidation*, the Company assessed whether it has a variable interest in legal entities in which it has a financial relationship and, if so, whether or not those entities are variable interest entities ("VIEs"). For those entities that qualify as VIEs, ASC 810 requires the Company to determine if it is the primary beneficiary of the VIE, and if so, to consolidate the VIE. The investment in TNF did not meet the primary beneficiary requirements for consolidation, therefore no consolidation of this VIE was required.

If an entity is determined to be a VIE, the Company evaluates whether it is the primary beneficiary. The primary beneficiary analysis is a qualitative analysis based on power and economics. PharmaCyte consolidates a VIE if it has both power and benefits that is, PharmaCyte (i) has the power to direct the activities of a VIE that most significantly influence the VIE's economic performance (power), and (ii) has the obligation to absorb losses of, or the right to receive benefits from, the VIE that could potentially be significant to the VIE (benefits). PharmaCyte consolidates VIEs whenever it is determined that PharmaCyte is the primary beneficiary. Any intercompany transactions are eliminated in consolidation.

The Company applies ASC 321 *Investments—Equity Securities* to investments in equity securities for which the Company has no significant influence or equity investments that are not in substance common stock. Under this guidance, equity securities with and without readily determinable fair values are accounted for at fair value based on quoted market prices or utilizing an appropriate valuation methodology to estimate the fair value. All gains and losses on investments in equity securities are recognized in the Condensed Consolidated Statements of Operations.

Intangible Assets

The Company's accounts for intangible assets at cost. The intangible asset has an indefinite life; therefore, is not amortizable. The Company performs annual impairment analysis for the intangible asset to ascertain the value at each year end and records a non-cash impairment expense should the value decrease. The asset is deemed to be an In-Process Research and Development ("IPR&D") as the asset is in the research stage.

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.

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.

Convertible Note Receivable

As permitted under Financial Accounting Standards Board ("FASB") ASC 825, Financial Instruments ("ASC 825"), the Company elected to account for its convertible note receivable, which met 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.

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. The Company accrues for costs incurred by external service providers, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

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.

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.

Derivative Financial Instruments

The Company evaluates all its financial instruments to determine if such instruments contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the statement of operations each period. Bifurcated embedded derivatives are classified with the related host contract in the Company's balance sheet. These particular derivatives are assessed under ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*, as applicable.

Warrants and Preferred Shares

The accounting treatment of warrants and preferred share series issued is determined pursuant to the guidance provided by ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, as applicable. Each feature of a freestanding financial instrument including, without limitation, any rights relating to subsequent dilutive issuances, dividend issuances, equity sales, rights offerings, forced conversions, optional redemptions, automatic monthly conversions, dividends, and exercise is assessed with determinations made regarding the proper classification in the Company's audited consolidated financial statements.

Redeemable Preferred Stock

Applicable accounting guidance requires an equity instrument that is redeemable for cash or other assets to be classified outside of permanent equity if it is redeemable (a) at a fixed or determinable price on a fixed or determinable date, (b) at the option of the holder, or (c) upon the occurrence of an event that is not solely within the control of the issuer.

Segment Reporting

The Company determines its reporting units in accordance with FASB ASC 280, "Segment Reporting" ("ASC 280"). The Company evaluates a reporting unit by first identifying its operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

The Company operates in one business segment, which includes the business of research and development activities related to developing cellular cancer therapies. The determination of a single business segment is consistent with the financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Interim President and Interim CEO, who reviews and evaluates consolidated net income as presented in the accompanying consolidated statements of operations for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

Refer to the accompanying consolidated statements of operations for the presentation of consolidated loss from operations for the years ended April 30, 2025 and 2024. The measure of segment assets is reported in the accompanying consolidated balance sheets as "Total assets." There are no significant segment expenses as the expenses that are included in consolidated loss from operations are general and administrative and research and development.

Recently Adopted Accounting Pronouncements

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, 2024, and interim periods thereafter. The Company adopted the guidance for the annual reporting period ended April 30, 2025. There was no impact on the Company's reportable segments and additional required disclosures have been included above in Segment Reporting.

New Accounting Pronouncements Effective in Future Periods

In August 2023, the FASB issued ASU 2023-05 – Business Combinations – Joint Venture Formations (Subtopic 805-60), which requires public entities that qualify as a joint venture or corporate joint venture to establish a new basis of accounting upon formation. The guidance is effective for the Company's annual periods beginning May 1, 2025, and early adoption is permitted. The Company is evaluating the impact of adoption of this standard on its financial statements and disclosures but does not expect it to have a material effect on its consolidated financial statements.

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 but does not expect it to have a material effect on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03 ("ASU 2024-03"), Disaggregation of Income Statement Expenses. The guidance requires additional, disaggregated disclosure about certain income statement expense line items. The amendments in ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027, with early adoption permitted, and is required to be applied prospectively with the option of retrospective application. The Company is currently evaluating the impact on the consolidated financial statements and related disclosures.

NOTE 4 – INVESTMENT IN DEBT AND EQUITY SECURITIES

INVESTMENT IN FEMASYS, INC.

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 years ended April 30, 2025 and 2024, the Company recognized a gain in the fair value of the convertible note receivable of $941,000 and $1,089,000, respectively, and change in fair value of the warrant assets decrease of $2,091,000 and an increase of $1,818,000, respectively. The current year decrease of $2,091,000 includes the expiration of the Series B Warrants in the amount of $1,376,000 and carries a zero value. Series A Warrants remain unexercised and there were no Series B Warrants exercised prior to expiration. See Note 14 – Fair value Measurements for further information.

During the years ended April 30, 2025 and 2024, the Company recognized interest income of $300,000 and $137,500, respectively, from the Femasys Note. During the year ended April 30, 2025, the interest income received of $300,000 was paid in Femasys common stock and is presented as marketable equity securities. As of April 30, 2025 and 2024, the Company has accrued interest receivable of $137,500 and $137,500, respectively.

The Femasys Note was determined to meet the definition of a derivative and were required to be recorded at fair value in accordance with ASC 815. Subsequent changes in the fair value of the Note is recognized in earnings at each reporting date. The approximate $1,666,000 issuance date fair value of the Note was determined using the Monte Carlo method with the following assumptions: Femasys stock price of $0.93, time to expiration of 2 years, interest rate of 6.0%, discount rate of 16.7%, risk free rate of 4.80%, equity volatility of 96.0% and probability of default of 27.0%. As of April 30, 2025 and 2024, the fair value of the Note was $3,696,000 and $2,755,000, respectively. For the year ended April 30, 2025, using the following assumptions: stock price of $1.16, time to expiration of 0.54 years, interest rate of 6.0%, discount rate of 16.0%, risk free rate of 4.16%, equity volatility of 72.0% and probability of default of 26.0%. For the year ended April 30, 2024, using the following assumptions: stock price of $1.27, time to expiration of 1.54 years, interest rate of 6.0%, discount rate of 19.7%, risk free rate of 5.14%, equity volatility of 99.0% and probability of default of 27.0%.

The Warrants were determined to meet the definition of a derivative and were required to be recorded at fair value in accordance with ASC 815. Subsequent changes in the fair value of the Warrants are recognized in earnings, at each reporting date. The approximately $3,334,000 issuance date fair value of the Series A and B Warrants was determined utilizing the Black Scholes Merton Method with the following assumptions: Femasys stock price of $0.93, exercise price of $1.18 - $1.48, risk free rate of 4.42%-5.24%, equity volatility of 87.0%-105.0% and remaining term of 1.0-5.0 years. As of April 30, 2025 Series A stock price was $1.16, exercise price of $1.18, risk free rate of 3.62%, equity volatility of 89.0% and the remaining term of 3.54 years. As of April 30, 2024, the Series A and B assumptions: stock price of $1.27, exercise price of $1.18 - $1.48, risk free rate of 4.75%-5.42%, equity volatility of 91.0%-103.0% and remaining term of 0.54-4.54 years.

Below is a summary of activity for the Note and Warrants as of April 30, 2025 and 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
Change in fair value	941,000
Balance of Notes as of April 30, 2025	$ 3,696,000

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
Change in fair value, includes expiration of Series B Warrants of $1,376,000	(2,091,000)
Balance of Warrants as of April 30, 2025	$ 3,061,000

MARKETABLE SECURITIES

On November 21, 2024, the Company received from the Femasys Notes a payment in Femasys common stock for interest income in the amount of $300,000. The interest income payment was based on the Femasys average stock price on that date of $0.95, therefore, the Company received 315,790 common stock shares. As of April 30, 2025, the current market value of the Femasys common stock shares was $1.16 that generated an unrealized gain of $66,316.

Cost and fair value of marketable equity securities at April 30, 2025 are as follows:

Marketable securities	Carrying Value At Fair Market Value	Value at Cost Basis	Unrealized Gains
Equity – stock	$ 366,316	$ 300,000	$ 66,316

The fair value of equity securities has been measured on a recurring basis using Level 1 inputs, which are based on unadjusted quoted market prices within active markets. There have been no changes in valuation approaches or techniques and related inputs.

INVESTMENT IN TNF PHARMACEUTICALS, INC.

On May 20, 2024, the Company entered into a Securities Purchase Agreement (the "SPA") with a public company operating in the medical industry, MyMD Pharmaceuticals, Inc. which subsequently changed its name to TNF Pharmaceuticals, Inc., ("TNF"). Pursuant to the SPA, the Company purchased (i) 7,000 shares of TNF's Series G Convertible Preferred Stock (the "Preferred Shares" or "Series G Preferred Stock"), representing approximately 33% of TNF's issued and outstanding share capital on an as-converted basis (and approximately 78% of all shares of Series G Preferred Stock outstanding), at a price of $1.816 per Preferred Share, which are convertible into 3,854,626 shares of Common Stock (as defined below); (ii) warrants to purchase up to 3,854,626 shares of TNF's Common Stock with a five-year term ("Long-Term Warrant"); and (iii) warrants to purchase up to 3,854,626 shares of TNF's Common Stock with a 18-month term ("Short-Term Warrant") (collectively, the "TNF warrants"), for an aggregate purchase price of $7,000,000.

Pursuant to the SPA, the Company has 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, the Company has the right to nominate one individual to serve on TNF's board of directors until PharmaCyte no longer beneficially owns at least 20% of TNF's common stock on an as-converted basis. The Company's Interim Chief Executive Officer serves on the board of directors of TNF.

The Company has determined that TNF is a VIE, since TNF does not have sufficient equity at risk to finance its own operations without additional subordinated financial support. However, the Company has determined that it is not the primary beneficiary of TNF. Furthermore, TNF's Series G Preferred Stock is not considered in substance common stock, and as such, equity method accounting does not apply. The Company recorded its investment in TNF Series G Preferred Stock at its fair value of approximately $17,410,000 on May 23, 2024 as the Company did not elect the measurement alternative to account for the investment at cost less impairment. Subsequent changes in fair value of the TNF Series G Preferred Stock are recognized in earnings at each reporting period. The initial fair value of the TNF Series G Preferred Stock was estimated utilizing a Monte Carlo simulation with the following assumptions: TNF stock price of $2.00, price floor of $0.40, expected time to settlement of 5.00 years, dividend rate of 10%, discounted market interest rate of 9.8%, risk free rate of 4.52%, equity volatility of 115.0% and probability of default of 18.3%.

The Warrants were determined to meet the definition of a derivative and were required to be recorded at fair value in accordance with ASC 815. Subsequent changes in the fair value of the Warrants are recognized in earnings, at each reporting date. The approximately $10,986,000 issuance date fair value of the Warrants was determined utilizing the Black Scholes Merton Method with the following assumptions: TNF stock price of $2.00, exercise price of $1.82, risk free rate of 4.52%-5.05%, equity volatility of 115.0%-125.0% and remaining term of 1.5-5.0 years. As the fair value of the TNF Series G Preferred Stock and Warrants exceeded the Company's total investment in TNF, the Company recognized an approximately $21,396,000 gain on investment on the condensed consolidated statements of operations for the excess of the fair value of the Warrants over the investment amount.

On April 11, 2025, TNF, in connection with an issuance of stock options to certain TNF officers, the Series G conversion price was adjusted to $0.1832 per share pursuant to the full ratchet anti-dilution provisions in the Certificate of Designations and the Series G exercise price was adjusted to $0.1832 per share and the number of shares of common stock issuable upon exercise of such warrants was adjusted proportionally pursuant to the full ratchet anti-dilution provisions contained in the applicable warrants. As of April 30, 2025, there were 38,209,611 short-warrants and 38,209,611 long-term warrants.

The Series G Preferred Stock shares include a 10% dividend, the Company has elected to receive the shares as Payment in Kind ("PIK"). As of April 30, 2025, the Company owns 7,831 Series G Preferred Stock shares of which 831 shares relate to accrued dividends.

During the year ending April 30, 2025, the Company recognized a gain for the change in fair value of the TNF Series G Preferred Stock of approximately $5,063,950. The approximately $22,474,000 fair value of the TNF Series G Preferred Stock was estimated utilizing a Monte Carlo simulation with the following assumptions on April 30, 2025: TNF stock price of $0.19, price floor of $0.36, expected time to settlement of 5.00 years, dividend rate of 10.0%, discount market interest rate of 17.6%, risk free rate of 3.72%, equity volatility of 105.0% and probability of default of 47%. The Company recognized a loss for the change in fair value of the TNF Warrants of approximately $2,367,684. The approximately $8,618,000 fair value of the Warrants was determined utilizing the Black Scholes Merton Method with the following assumptions on April 30, 2025: TNF stock price of $0.19, exercise price of $0.18, risk free rate of 3.65%-4.14%, equity volatility of 115.0%-130.0% and remaining term of 0.57-4.07 years.

Below is a summary of activity for the Series G Preferred Stock as of April 30, 2025:

Balance of Series G Preferred Stock as of April 30, 2024	$ –
Purchased	17,410,050
Change in fair value	5,063,950
Balance of Series G Preferred Stock as of April 30, 2025	$ 22,474,000

Below is a summary of activity for the Preferred Stock Warrants as of April 30, 2025:

Balance of Warrant assets as of April 30, 2024	$ –
Purchased	10,985,684
Change in fair value	(2,367,684)
Balance of Warrant assets as of April 30, 2025	$ 8,618,000

NOTE 5 – ACCRUED EXPENSES

Accrued expenses at April 30, 2025 and 2024 are summarized below:

	2025	2024
Payroll related costs	$ 335,846	$ 167,817
Director fees	67,500	135,000
R&D costs	92,310	92,310
Legal settlement	2,019,000	–
Excise tax on stock repurchases	25,424	340,072
Total accrued expenses	2,540,080	735,199
Less: Long-term portion of legal settlement	(25,000)	–
Total – current portion	$ 2,515,080	$ 735,199

See Note 9 – Commitments and Contingencies for additional information on the legal settlement.

NOTE 6 – STOCK OPTIONS AND WARRANTS

2021 Equity Incentive Plan

Effective June 30, 2021, the Company implemented the 2021 Equity Incentive Plan ("2021 Equity Plan") as approved by the Company's stockholders. The 2021 Equity Plan is administered by the Compensation Committee of the Board and has 166,667 shares authorized under this plan. The 2021 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 2021 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). As of April 30, 2025, there are 152,594 shares remaining available under this plan.

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 authorized 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). As of April 30, 2025, there are 1,595,040 shares remaining available under this plan.

Stock Options

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,	
	2025	**2024**
Risk-free interest rate	4.3%	4.5%
Expected volatility	98%	109%
Expected term (years)	5.5	5.2
Expected dividend yield	0.00%	0.00%

The Company's computation of expected volatility for the year ended April 30, 2025 is based on the Company's historical basis volatility and on selected guideline companies historical weekly basis volatility for the year ended April 30, 2024. For stock option grants issued during the years ended April 30, 2025 and 2024, 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.

A summary of the Company's stock option activity and related information for the years ended April 30, 2025 and 2024 is shown below:

	Options	**Weighted Average Exercise Price Per Share**	**Weighted Average Remaining Contractual Term in Years**
Outstanding, April 30, 2023	281,269	$ 6.94	3.08
Granted	652,028	2.17	–
Expired	(8,133)	75.81	–
Outstanding, April 30, 2024	925,164	2.97	9.16
Granted	252,932	1.22	–
Expired	(8,135)	50.39	–
Outstanding, April 30, 2025	1,169,961	$ 2.21	8.62
Exercisable, April 30, 2025	917,029	$ 2.48	8.24

The Company recorded $478,637 and $674,693 of stock-based compensation related to the issuance of options to certain officers and directors in exchange for services during the years ended April 30, 2025 and 2024, respectively. At April 30, 2025, there remained $236,055 unrecognized compensation expense related to unvested granted to director and are scheduled to vest in April 2026.

The aggregate intrinsic value of vested outstanding options as of April 30, 2025 was $0.

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 subject to liability classification as they are considered to be indexed to the Company's own stock but fail to meet the requirements for equity classification in accordance with ASC 815. 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 years ended April 30, 2025 and 2024. The fair value of the Warrants of approximately $14,127,000, respectively, 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 and were included in general and administrative expense in the accompanying Consolidated Statements of Operations during the year ended April 30, 2024.

During the years ended April 30, 2025 and 2024, the Company recorded gains of approximately $10,446,000 and $3,343,000, respectively, 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 $338,000 and $10,784,000 were estimated at April 30, 2025 and 2024, respectively, utilizing the Black-Scholes-Merton Model using the fair value of our common stock of $1.24 and $2.12, respectively, and the following weighted average assumptions: dividend yield 0%; remaining term of 3.03 and 4.03 years, respectively; equity volatility of 40.0% and 95.0%; and a risk-free interest rate of 3.52 % and 4.79%, respectively.

A summary of the Company's warrant activity and related information for the years ended April 30, 2025 and 2024, are shown below:

	Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term In Years
Outstanding, April 30, 2023	9,890,847	$ 4.99	3.31
Issued	8,750,000	4.00	–
Exercised	(70,000)	–	–
Expired	–	–	–
Outstanding, April 30, 2024	18,570,847	4.54	3.12
Issued	–	–	–
Exercised	–	–	–
Expired	–	–	–
Outstanding, April 30, 2025	18,570,847	4.54	2.12
Exercisable, April 30, 2025	18,570,847	$ 4.54	2.12

NOTE 7 – INTANGIBLE ASSETS

The Company performs an annual analysis of impairment of the indefinite-lived assets at its fiscal year end as well as when a triggering event may have occurred. As of April 30, 2025 and 2024, the intangible asset held by the Company relates to an IPR&D asset, the cells producing cytochrome P450, used in the treatment of pancreatic cancer with a carrying value in the amount of $1,549,427. As of April 30, 2025 and 2024, the Company determined there was no impairment of the intangible asset. As of April 30, 2024, 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.

Balance, April 30, 2023	$	3,549,427
Impairment		(2,000,000)
Balance, April 30, 2024		1,549,427
Impairment		–
Balance, April 30, 2025	$	1,549,427

NOTE 8 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the years ended April 30, 2025 and 2024, 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 did not purchase products and services from these subsidiaries in the years ended April 30, 2025, and 2024, 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, 2025 and 2024, were approximately $16,000 and $5,000, respectively.

The Company's Interim Chief Executive Officer was appointed to the Femasys board of directors, see Note 4 – Investments in Debt and Equity Securities.

The Company's Interim Chief Executive Officer is on the board directors of TNF, see Note 4 – Investment in Debt and Equity Securities.

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. For the years ended April 30, 2025 and 2024, the company expensed $438,416 and $407,431, respectively, in research and development expenses within the accompanying consolidated statements of operations. There have been no recognized costs related to royalty payments.

There are future royalty payments as follows:

- Four percent royalty on all gross sales received by us or our affiliates;
- Twenty 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;
- Fifty percent of any other financial and non-financial consideration received from sublicensees of the Cell-in-a-Box® technology; and
- The removal of all milestone payments.

Office Lease

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, 2025 and 2024 were $28,335 and $29,546, respectively.

With the month-to-month office rental agreements there are no aggregate future minimum lease payments required to be made.

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 remaining cost is estimated to be approximately $591,000, 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.

Settlement of Legal Complaint Agreement

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 potential claims cannot be predicted with certainty, the Company does not believe that the outcome of any potential claims will have a material adverse effect on our financial condition or operating results.

On May 16, 2025, the Company entered into a settlement and release agreement (“Settlement Agreement”) with H.C. Wainwright & Co., LLC relating to a complaint filed on December 4, 2023, alleging a breach of contract. The Settlement Agreement resolved fully all differences, disputes or claims without admitting any liability, fault or wrongdoing on the part of all parties. The Settlement Agreement required the Company to pay $1.55 million, comprised of an initial payment of $1.25 million and twelve equal payments of $25,000 beginning on the one-month anniversary of the initial payment. On May 16, 2025, the Company also issued warrants “(First Warrant Issuance”) to purchase 343,183 shares of the Company’s common stock with an exercise price of $4.00 per share with a term of five years from the issuance date. The Company has the option to pay $226,254 or issue additional warrants (“Additional Warrants”) to purchase 313,067 shares of the Company’s common stock with an exercise price of $4.00 per share with a term of five years prior to the issuance date of this Annual Report on Form 10-K. The Company elected to issue the additional warrants with an effective date of July 29, 2025.

The Company estimated the fair value of the First Warrant Issuance and the Additional Warrant Issuance as of April 30, 2025 pursuant to Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 820 Fair Value Measurement (“ASC 820”). The Company concluded the fair value of the First Warrant Issuance to be $245,000 and the Additional Warrant Issuance to be $224,000. The Company utilized the Black-Scholes-Merton Model to calculate the value of the Warrants issued subsequent to the year ended April 30, 2025. The fair value of the Warrants were estimated as of April 30, 2025, using the fair value of our common stock of $1.24 and was based on the following weighted average assumptions: dividend yield 0%; expected term of 5.0 years; equity volatility of 98%; and a risk-free interest rate of 3.7%.The Company recorded a legal settlement expense of $2,019,000, consisting of $1.55 million payment and the fair value of the two warrant issues totaling $469,000. The Company recorded the $2,019,000 liability as of April 30, 2025 and is included in accrued expenses, see Note 5 – Accrued Expenses.

To the Company’s knowledge there are no legal proceedings pending to which any property of the Company is subject.

NOTE 10 - INCOME TAXES

At April 30, 2025, the Company had federal and state net operating loss carryforwards of approximately $61,270,000 and $30,921,000, 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 $24,210,000 and $15,031,000 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,	
	2025	**2024**
Deferred tax assets:		
Net operating loss carryforwards	$ 15,026,112	$ 14,437,888
Stock compensation	523,822	494,130
Research and development	216,831	160,452
Investment in SG Austria	439,953	469,139
Intangible asset (diabetes license)	559,672	596,800
Other - deferred tax asset	147,798	77,622
Total deferred tax assets	16,914,188	16,236,031
Deferred tax liabilities:		
Fair value of derivative liability	–	(174,862)
Fair value of convertible note receivable	(568,067)	(324,958)
Fair value of warrant asset	(228,906)	(542,491)
Fair value of investment in TNF	(754,512)	–
Other - deferred tax liability	(140,985)	–
Total deferred tax liabilities	(1,692,470)	(1,042,311)
Total deferred tax assets	15,221,718	15,193,720
Valuation allowance	(15,221,718)	(15,193,720)
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, 2025 and 2024 was an increase of $27,998 and a decrease of $1,035,621, 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,	
	2025	2024
Federal benefit at statutory rate	$ 6,437,771	$ 70,090
State income taxes, net of Federal taxes	2,139,792	29,505
Fair value of warrant liability	(2,922,791)	(997,551)
Gain on related party investment	(5,986,526)	–
Fair value of derivative liability	(611,083)	–
Redemption of derivative liability	(174,862)	–
Expiration of warrant asset – Series B	(79,743)	–
State deferred tax adjustment	572,607	–
Legal settlement	131,226	–
Provision related to change in valuation allowance	27,998	(1,035,621)
Fair value of warrant asset – Series B	385,005	–
Expired stock options	78,384	76,864
Net valuation allowance for state NOLs	(6,748)	1,797,207
Other, net	8,970	59,506
	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the years ended April 30, 2025 and 2024, respectively.

The Company files its income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2025, the tax returns for 2020 through 2024 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. Management does not believe that there are significant uncertain tax positions in the tax years 2024 and 2023. As of the years ended April 30, 2025 and 2024, the Company had accrued no interest or penalties related to uncertain tax positions.

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 Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize research and developmental expenditures under Internal Revenue Code Section 174. Effective January 1, 2022, the Company adopted the amended provisions of Internal Revenue Code Section 174, which require capitalization and amortization of specified research or experimental ("SRE") expenditures. Domestic SRE expenditures are amortized over five years, while foreign expenditures are amortized over fifteen years, beginning with the midpoint of the taxable year in which the costs are incurred.

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 purchase. 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 1,241,862 shares of common stock with a total cost of $2,567,770 including accrued excise tax during the year ended April 30, 2025 and 8,826,356 shares of common stock with a total cost of $28,479,593 including accrued excise tax for the year ended April 30, 2024. The Company recorded $25,424 and $281,976 in excise tax related to the IR Act, which is included in Treasury stock and accrued expenses for the years ended April 30, 2025 and 2024, respectively.

As a result, deferred tax assets increased due to timing differences between book and tax treatment of R&D costs. In 2025, the One Big Beautiful Bill Act repealed the amortization requirement for domestic R&E expenditures, restoring immediate expensing. The Company continues to monitor IRS guidance and may revise its treatment of SRE expenditures in future periods.

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.

On July 4, 2025, the U.S. government enacted The One Big Beautiful Bill Act of 2025 which includes, among other provisions, changes to the U.S. corporate income tax system including the allowance of immediate expensing of qualifying research and development expenses and permanent extensions of certain provisions within the Tax Cuts and Jobs Act. Certain provisions are effective for the Company beginning fiscal 2026. The Company is evaluating the future impact of these tax law changes on its financial statements.

NOTE 11 – EARNINGS PER SHARE

The Company computes earnings per share using the two-class method. The two-class method of computing earnings per share is an earnings allocation formula that determines earnings per share for common stock and any participating securities according to dividends declared (whether paid or unpaid) and participation rights in undistributed earnings. The Series B Preferred Shares are considered participating securities as preferred shareholders are entitled to participate with common stockholders on an as-converted basis in any distributions of assets by the Company under the terms of the Certificate of Designations. Under the two-class method, there is no change in the weighted average shares outstanding used between the basic and diluted earnings per share calculations as the Series B Preferred Shares represent the only dilutive share equivalents during the years ended April 30, 2025 and 2024. During the years ended April 30, 2025 and 2024, the Company incurred income (losses) attributable to common shareholders. Accordingly, the effects of any common stock equivalent would be anti-dilutive during the period and thus are not included in the calculation of diluted weighted average number of shares outstanding.

The following table illustrates the computation of basic and diluted earnings (loss) per share:

	Years Ended April 30,	
	2025	2024
Earnings per share		
Net income	$ 30,656,050	$ 333,763
Less: Accretion of discounts to redemption of Series B convertible preferred stock	(3,193,404)	(15,053,521)
Less: Series B convertible preferred stock dividends	(1,129,759)	(2,517,645)
Less: Allocation of undistributed income to Series B convertible preferred stock	(2,970,780)	–
Undistributed income (loss) available to common stockholders	$ 23,362,107	$ (17,237,403)
Weighted average shares outstanding used in basic earnings per share	7,329,596	9,581,059
Net income (loss) per share basic and diluted	$ 3.19	$ (1.80)

The table below sets forth the potentially dilutive securities excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive:

	Years Ended April 30,	
	2025	2024
Excluded options	1,169,961	925,164
Excluded warrants	18,570,847	18,570,847
Series B convertible preferred stock	–	3,765,105
Total excluded options and warrants	19,740,808	23,261,116

Diluted earnings per share were calculated under both the if-converted and the two-class methods to determine the most dilutive amount for the common stock. The Company applied the treasury stock two-class method which assumes the securities remain in their current non-exercised or converted form and therefore, deemed anti-dilutive.

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, 2025 and 2024, there were zero and 14,646 shares issued and outstanding, respectively, and zero and 5,833, shares, respectively. As of April 30, 2025 and 2024, there were $0 and $11,867,016 amounts subject to redemption, respectively.

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. In accordance with ASC 480-10-S99-3A the Company is accreting the discount on the effective interest method and $3,193,404 and $15,053,521, respectively, was recorded as a deemed dividend during the years ended April 30, 2025 and 2024.

During the years ended April 30, 2025 and 2024, the Company recorded gains of approximately $2,184,000 and $586,000, respectively, 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 had $0 fair value of the bifurcated embedded derivative at April 30, 2025 as there were no outstanding Preferred Shares at April 30, 2025. See Note 14 – Fair Value Measurements.

During the years ended April 30, 2025 and 2024, the Company made all installment payments in cash pursuant to installment redemptions. The installment redemptions were paid in cash in the amounts of $22,486,875 and $16,160,531, respectively, which included $20,479,169 and $14,520,835, respectively, of the Preferred Shares, $734,864 and $724,950, respectively, of accrued dividends and $1,272,842 and $914,746, respectively, of additional 6% cash premium pursuant to the terms of the Series B Preferred stock. During the year ended April 30, 2025, the Company recognized a net dividend of $1,129,759 which is comprised of deemed dividend of $902,580 and $227,179 of preferred dividend, related to the amounts owed in addition to dividends as the installments were paid in cash which are included in Preferred stock dividends on the consolidated statement of operations. During the year ended April 30, 2024, the Company recognized $2,517,645 of net dividends which is comprised of deemed dividend of $1,271,164 and $1,246,481 of preferred dividends, related to the amounts owed in addition to dividends as the installments were paid in cash which are included in Preferred stock dividends on the consolidated statement of operations.

The Company has one share of preferred stock designated as “Series A Preferred Stock” as of April 30, 2025 and April 30, 2024, 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 years ended April 30, 2025 and 2024, the Company repurchased 1,241,862 and 740,477, respectively, additional shares under the repurchase program at a total cost, including commissions and excise taxes of $2,567,700 and $1,757,696, respectively. As of April 30, 2025 and 2024, the total number of shares repurchased pursuant to the repurchase programs was 6,790,437 and 5,548,575 shares, respectively, at a total cost, including commissions and excise taxes of $17,886,108 and $15,318,318, respectively. Repurchased shares are included in Treasury Stock in the accompanying Consolidated Balance Sheets. At April 30, 2025 and 2024, $2,113,891 and $4,681,682, respectively, remain 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 2025, the Company has paused the repurchase program.

As of April 30, 2025 and 2024, the total number of shares held in Treasury Stock is 14,876,316 and 13,634,454 shares respectively, at a total cost of $44,607,916 and $42,040,216, respectively.

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, 2025 and 2024. The carrying amounts of cash equivalents, other current assets, accounts payable and accrued expenses approximate their fair values at April 30, 2025 and 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, 2025 and 2024, and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

Description	Level	April 30, 2025	April 30, 2024
Liabilities:			
Warrant liability	3	$ 338,000	$ 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, 2025
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
Issuance of warrants	–
Change in fair value of warrant liability	(10,446,000)
Balance on April 30, 2025	$ 338,000

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, 2025
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
Issuance of convertible preferred stock with bifurcated embedded derivative liability	–
Change in fair value of bifurcated embedded derivative	(2,184,000)
Balance on April 30, 2025	$ –

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, 2025 and 2024 are as follows:

	Level	April 30, 2025	April 30, 2024
Financial Assets			
Marketable equity securities	1	$ 366,316	$ –
Money market account	1	$ 76,287	$ 3,183,173
Convertible note receivable – investment in debt security - Femasys	3	$ 3,696,000	$ 2,755,000
Warrant asset - Femasys	3	$ 3,061,000	$ 5,152,000
Investment in preferred stock - TNF	3	$ 22,474,000	$ –
Warrant asset - TNF	3	$ 8,618,000	$ –

Assumptions used in the valuation of the Level 3 assets include time to expiration, discount rate, risk-free rate, volatility and probability of default.

EXHIBIT 4.10

WARRANT

NEITHER THE ISSUANCE AND SALE OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE NOR THE SECURITIES INTO WHICH THESE SECURITIES ARE EXERCISABLE HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (B) AN OPINION OF COUNSEL TO THE HOLDER (IF REQUESTED BY THE COMPANY), IN A FORM REASONABLY ACCEPTABLE TO THE COMPANY, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR (II) UNLESS SOLD OR ELIGIBLE TO BE SOLD PURSUANT TO RULE 144 OR RULE 144A UNDER SAID ACT. NOTWITHSTANDING THE FOREGOING, THE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SECURITIES. THE NUMBER OF SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE OF THIS WARRANT MAY BE LESS THAN THE AMOUNTS SET FORTH ON THE FACE HEREOF PURSUANT TO SECTION 1(a) OF THIS WARRANT.

PHARMACYTE BIOTECH, INC.

Warrant To Purchase Common Stock

Warrant No.:

Date of Issuance: May 16, 2025 ("**Issuance Date**")

PharmaCyte Biotech, Inc., a Nevada corporation (the "**Company**"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, H.C. Wainwright & Co., LLC, the registered holder hereof or its permitted assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon exercise of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "**Warrant**"), at any time or times on or after the Issuance Date, but not after 11:59 p.m., New York time, on the Expiration Date (as defined below), 343,183 (subject to adjustment as provided herein) fully paid and non-assessable shares of Common Stock (as defined below) (the "**Warrant Shares**", and such number of Warrant Shares, the "**Warrant Number**"). Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 17 or in the Securities Purchase Agreement (as defined below). This Warrant is, except as to the Issuance Date, expiration date and the related impact on the calculation of Black Scholes Value (as defined below) as set forth hereunder, identical to one of the Warrants to Purchase Common Stock (the "**SPA Warrants**") issued pursuant to Section 1 of that certain Securities Purchase Agreement, dated as of May 9, 2023 (the "**Subscription Date**"), by and among the Company and the investors (the "**Buyers**") referred to therein, as amended from time to time (the "**Securities Purchase Agreement**").

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof (including, without limitation, the limitations set forth in Section 1(f)), this Warrant may be exercised by the Holder on any day on or after the Issuance Date (an "**Exercise Date**"), in whole or in part, by delivery (whether via electronic mail or otherwise) of a written notice, in the form attached hereto as **Exhibit A** (the "**Exercise Notice**"), of the Holder's election to exercise this Warrant. Within one (1) Trading Day following an exercise of this Warrant as aforesaid, the Holder shall deliver payment to the Company of an amount equal to the Exercise Price in effect on the date of such exercise multiplied by the number of Warrant Shares as to which this Warrant was so exercised (the "**Aggregate Exercise Price**") in cash or via wire transfer of immediately available funds if the Holder did not notify the Company in such Exercise Notice that such exercise was made pursuant to a Cashless Exercise (as defined in Section 1(d)). The Holder shall not be required to deliver the original of this Warrant in order to effect an exercise hereunder. Execution and delivery of an Exercise Notice with respect to less than all of the Warrant Shares shall have the same effect as cancellation of the original of this Warrant and issuance of a new Warrant evidencing the right to purchase the remaining number of Warrant Shares. Execution and delivery of an Exercise Notice for all of the then-remaining Warrant Shares shall have the same effect as cancellation of the original of this Warrant after delivery of the Warrant Shares in accordance with the terms hereof. On or before the first (1st) Trading Day following the date on which the Company has received an Exercise Notice, the Company shall transmit by electronic mail an acknowledgment of confirmation of receipt of such Exercise Notice, in the form attached hereto as **Exhibit B**, to the Holder and the Company's transfer agent (the "**Transfer Agent**"), which confirmation shall constitute an instruction to the Transfer Agent to process such Exercise Notice in accordance with the terms herein. On or before the second (2nd) Trading Day following the date on which the Company has received such Exercise Notice (or such earlier date as required pursuant to the 1934 Act or other applicable law, rule or regulation for the settlement of a trade of such Warrant Shares initiated on the applicable Exercise Date), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program ("**FAST**") and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal at Custodian system, or (Y) if the Transfer Agent is not participating in the DTC FAST, upon the request of the Holder, issue and deliver (via reputable overnight courier) to the address as specified in the Exercise Notice, a certificate, registered in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder shall be entitled pursuant to such exercise. Upon delivery of an Exercise Notice, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares (as the case may be). If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise and upon surrender of this Warrant to the Company by the Holder, then, at the request of the Holder, the Company shall as soon as practicable and in no event later than two (2) Business Days after any exercise and at its own expense, issue and deliver to the Holder (or its designee) a new Warrant (in accordance with Section 7(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded up to the nearest whole number. The Company shall pay any and all transfer, stamp, issuance and similar taxes, costs and expenses (including, without limitation, fees and expenses of the Transfer Agent) that may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant. Notwithstanding the foregoing, except in the case where an exercise of this Warrant is validly made pursuant to a Cashless Exercise, the Company's failure to deliver Warrant Shares to the Holder on or prior to the later of (i) two (2) Trading Days after receipt of the applicable Exercise Notice (or such earlier date as required pursuant to the 1934 Act or other applicable law, rule or regulation for the settlement of a trade of such Warrant Shares initiated on the applicable Exercise Date) and (ii) one (1) Trading Day after the Company's receipt of the Aggregate Exercise Price (or valid notice of a Cashless Exercise if permissible) (such later date, the "**Share Delivery Date**") shall not be deemed to be a breach of this Warrant. Notwithstanding anything to the contrary contained in this Warrant or the Registration Rights Agreement, after the effective date of the Registration Statement (as defined in the Registration Rights Agreement) and prior to the Holder's receipt of the notice of a Grace Period (as defined in the Registration Rights Agreement), the Company shall cause the Transfer Agent to deliver unlegended shares of Common Stock to the Holder (or its designee) in connection with any sale of Registrable Securities (as defined in the Registration Rights Agreement) with respect to which the Holder has entered into a contract for sale, and delivered a copy of the prospectus included as part of the particular Registration Statement to the extent applicable, and for which the Holder has not yet settled. From the Issuance Date through and including the Expiration Date, the Company shall maintain a transfer agent that participates in FAST.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means $4.00, subject to adjustment as provided herein.

(c) Company's Failure to Timely Deliver Securities. If the Company shall fail, for any reason or for no reason, on or prior to the Share Delivery Date, either (I) if the Transfer Agent is not participating in DTC FAST, to issue and deliver to the Holder (or its designee) a certificate for the number of Warrant Shares to which the Holder is entitled and register such Warrant Shares on the Company's share register or, if the Transfer Agent is participating in DTC FAST and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, to credit the balance account of the Holder or the Holder's designee with DTC for such number of Warrant Shares to which the Holder is entitled upon the Holder's exercise of this Warrant (as the case may be) or (II) if a Registration Statement covering the resale of the Warrant Shares that are the subject of the Exercise Notice (the "**Unavailable Warrant Shares**") is not available for the resale of such Unavailable Warrant Shares and the Company fails to promptly, but in no event later than as required pursuant to the Registration Rights Agreement (x) so notify the Holder and (y) deliver the Warrant Shares electronically without any restrictive legend by crediting such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal At Custodian system (the event described in the immediately foregoing clause (II) is hereinafter referred as a "**Notice Failure**" and together with the event described in clause (I) above, a "**Delivery Failure**"), then, in addition to all other remedies available to the Holder, (X) the Company shall pay in cash to the Holder on each day after the Share Delivery Date and during such Delivery Failure an amount equal to 2% of the product of (A) the sum of the number of shares of Common Stock not issued to the Holder on or prior to the Share Delivery Date and to which the Holder is entitled, multiplied by (B) any trading price of the Common Stock selected by the Holder in writing as in effect at any time during the period beginning on the applicable Exercise Date and ending on the applicable Share Delivery Date, and (Y) the Holder, upon written notice to the Company, may void its Exercise Notice with respect to, and retain or have returned, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the voiding of an Exercise Notice shall not affect the Company's obligations to make any payments which have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise. In addition to the foregoing, if on or prior to the Share Delivery Date either (I) the Transfer Agent is not participating in the DTC FAST, the Company shall fail to issue and deliver to the Holder (or its designee) a certificate and register such shares of Common Stock on the Company's share register or, if the Transfer Agent is participating in the DTC FAST and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, the Transfer Agent shall fail to credit the balance account of the Holder or the Holder's designee with DTC for the number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise hereunder or pursuant to the Company's obligation pursuant to clause (ii) below or (II) a Notice Failure occurs, and if on or after such Share Delivery Date the Holder acquires (in an open market transaction, stock loan or otherwise) shares of Common Stock corresponding to all or any portion of the number of shares of Common Stock issuable upon such exercise that the Holder is entitled to receive from the Company and has not received from the Company in connection with such Delivery Failure or Notice Failure, as applicable (a "**Buy-In**"), then, in addition to all other remedies available to the Holder, the Company shall, within two (2) Business Days after the Holder's request and in the Holder's discretion, either (i) pay cash to the Holder in an amount equal to the Holder's total purchase price (including brokerage commissions, stock loan costs and other out-of-pocket expenses, if any) for the shares of Common Stock so acquired (including, without limitation, by any other Person in respect, or on behalf, of the Holder) (the "**Buy-In Price**"), at which point the Company's obligation to so issue and deliver such certificate (and to issue such shares of Common Stock) or credit the balance account of such Holder or such Holder's designee, as applicable, with DTC for the number of Warrant Shares to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) (and to issue such Warrant Shares) shall terminate, or (ii) promptly honor its obligation to so issue and deliver to the Holder a certificate or certificates representing such Warrant Shares or credit the balance account of such Holder or such Holder's designee, as applicable, with DTC for the number of Warrant Shares to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of Warrant Shares multiplied by (B) the lowest Closing Sale Price of the Common Stock on any Trading Day during the period commencing on the date of the applicable Exercise Notice and ending on the date of such issuance and payment under this clause (ii) (the "**Buy-In Payment Amount**"). Nothing shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity, including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock (or to electronically deliver such shares of Common Stock) upon the exercise of this Warrant as required pursuant to the terms hereof. While this Warrant is outstanding, the Company shall cause its transfer agent to participate in FAST. In addition to the foregoing rights, (i) if the Company fails to deliver the applicable number of Warrant Shares upon an exercise pursuant to Section 1 by the applicable Share Delivery Date, then the Holder shall have the right to rescind such exercise in whole or in part and retain and/or have the Company return, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the rescission of an exercise shall not affect the Company's obligation to make any payments that have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise, and (ii) if a registration statement (which may be the Registration Statement) covering the issuance or resale of the Warrant Shares that are subject to an Exercise Notice is not available for the issuance or resale, as applicable, of such Warrant Shares, as required by and in accordance with the terms of the Registration Rights Agreement, and the Holder has submitted an Exercise Notice prior to receiving notice of the non-availability of such registration statement and the Company has not already delivered the Warrant Shares underlying such Exercise Notice electronically without any restrictive legend by crediting such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit / Withdrawal At Custodian system, the Holder shall have the option, by delivery of notice to the Company, to (x) rescind such Exercise Notice in whole or in part and retain or have returned, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the rescission of an Exercise Notice shall not affect the Company's obligation to make any payments that have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise, and/or (y) switch some or all of such Exercise Notice from a cash exercise to a Cashless Exercise.

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary (other than Section 1(f) below), if at the time of exercise hereof a Registration Statement (as defined in the Registration Rights Agreement) is not effective (or the prospectus contained therein is not available for use) for the resale by the Holder of all of the Warrant Shares, then the Holder may, in its sole discretion, exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of Warrant Shares determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A= the total number of shares with respect to which this Warrant is then being exercised.

B = as elected by the Holder: (i) the VWAP of the Common Stock on the Trading Day immediately preceding the date of the applicable Exercise Notice if such Exercise Notice is (1) both executed and delivered pursuant to Section 1(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 1(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Exercise Notice or (z) the Bid Price of the Common Stock as of the time of the Holder's execution of the applicable Exercise Notice if such Exercise Notice is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 1(a) hereof, or (iii) the Closing Sale Price of the Common Stock on the date of the applicable Exercise Notice if the date of such Exercise Notice is a Trading Day and such Exercise Notice is both executed and delivered pursuant to Section 1(a) hereof after the close of "regular trading hours" on such Trading Day.

C = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

If the Warrant Shares are issued in a Cashless Exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the 1933 Act, the Warrant Shares take on the registered characteristics of the Warrants being exercised. For purposes of Rule 144(d) promulgated under the 1933 Act, as in effect on the Subscription Date, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Securities Purchase Agreement.

(e) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the number of Warrant Shares to be issued pursuant to the terms hereof, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed and resolve such dispute in accordance with Section 15.

(f) Limitations on Exercises.

(i) Beneficial Ownership. The Company shall not effect the exercise of any portion of this Warrant, and the Holder shall not have the right to exercise any portion of this Warrant, pursuant to the terms and conditions of this Warrant and any such exercise shall be null and void and treated as if never made, to the extent that after giving effect to such exercise, the Holder together with the other Attribution Parties collectively would beneficially own in excess of 4.99% (the "**Maximum Percentage**") of the Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by the Holder and the other Attribution Parties shall include the number of shares of Common Stock held by the Holder and all other Attribution Parties plus the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (A) exercise of the remaining, unexercised portion of this Warrant beneficially owned by the Holder or any of the other Attribution Parties and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company (including, without limitation, any convertible notes or convertible preferred stock or warrants, including other SPA Warrants) beneficially owned by the Holder or any other Attribution Party subject to a limitation on conversion or exercise analogous to the limitation contained in this Section 1(f)(i). For purposes of this Section 1(f)(i), beneficial ownership shall be calculated in accordance with Section 13(d) of the 1934 Act. In addition, a determination as to any group status as contemplated above shall be determined inaccordance with Section 13(d) of the 1934 Act and the rules and regulations promulgated thereunder. For purposes of determining the number of outstanding shares of Common Stock the Holder may acquire upon the exercise of this Warrant without exceeding the Maximum Percentage, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public filing with the SEC, as the case may be, (y) a more recent public announcement by the Company or (z) any other written notice by the Company or the Transfer Agent, if any, setting forth the number of shares of Common Stock outstanding (the "**Reported Outstanding Share Number**"). If the Company receives an Exercise Notice from the Holder at a time when the actual number of outstanding shares of Common Stock is less than the Reported Outstanding Share Number, the Company shall (i) notify the Holder in writing of the number of shares of Common Stock then outstanding and, to the extent that such Exercise Notice would otherwise cause the Holder's beneficial ownership, as determined pursuant to this Section 1(f)(i), to exceed the Maximum Percentage, the Holder must notify the Company of a reduced number of Warrant Shares to be acquired pursuant to such Exercise Notice (the number of shares by which such purchase is reduced, the "**Reduction Shares**") and (ii) as soon as reasonably practicable, the Company shall return to the Holder any exercise price paid by the Holder for the Reduction Shares. For any reason at any time, upon the written or oral request of the Holder, the Company shall within one (1) Business Day confirm orally and in writing or by electronic mail to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder and any other Attribution Party since the date as of which the Reported Outstanding Share Number was reported. In the event that the issuance of shares of Common Stock to the Holder upon exercise of this Warrant results in the Holder and the other Attribution Parties being deemed to beneficially own, in the aggregate, more than the Maximum Percentage of the number of outstanding shares of Common Stock (as determined under Section 13(d) of the 1934 Act), the number of shares so issued by which the Holder's and the other Attribution Parties' aggregate beneficial ownership exceeds the Maximum Percentage (the "**Excess Shares**") shall be deemed null and void and shall be cancelled ab initio, and the Holder shall not have the power to vote or to transfer the Excess Shares. As soon as reasonably practicable after the issuance of the Excess Shares has been deemed null and void, the Company shall return to the Holder the exercise price paid by the Holder for the Excess Shares. Upon delivery of a written notice to the Company, the Holder may from time to time increase (with such increase not effective until the sixty-first (61st) day after delivery of such notice) or decrease the Maximum Percentage to any other percentage not in excess of 9.99% as specified in such notice; provided that (i) any such increase in the Maximum Percentage will not be effective until the sixty-first (61st) day after such notice is delivered to the Company and (ii) any such increase or decrease will apply only to the Holder and the other Attribution Parties and not to any other holder of SPA Warrants that is not an Attribution Party of the Holder. For purposes of clarity, the shares of Common Stock issuable pursuant to the terms of this Warrant in excess of the Maximum Percentage shall not be deemed to be beneficially owned by the Holder for any purpose including for purposes of Section 13(d) or Rule 16a-1(a)(1) of the 1934 Act. No prior inability to exercise this Warrant pursuant to this paragraph shall have any effect on the applicability of the provisions of this paragraph with respect to any subsequent determination of exercisability. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(f)(i) to the extent necessary to correct this paragraph or any portion of this paragraph which may be defective or inconsistent with the intended beneficial ownership limitation contained in this Section 1(f)(i) or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitation contained in this paragraph may not be waived and shall apply to a successor holder of this Warrant.

(ii) **[Reserved]**.

(g) Reservation of Shares.

(i) Required Reserve Amount. So long as this Warrant remains outstanding, the Company shall at all times keep reserved for issuance under this Warrant a number of shares of Common Stock at least equal to 200% of the maximum number of shares of Common Stock as shall be necessary to satisfy the Company's obligation to issue shares of Common Stock under the SPA Warrants then outstanding (without regard to any limitations on exercise) (the "**Required Reserve Amount**"); provided that at no time shall the number of shares of Common Stock reserved pursuant to this Section 1(g)(i) be reduced other than proportionally in connection with any exercise or redemption of SPA Warrants or such other event covered by Section 2(a) below. The Required Reserve Amount (including, without limitation, each increase in the number of shares so reserved) shall be allocated pro rata among the holders of the SPA Warrants based on the number of shares of Common Stock issuable upon exercise of SPA Warrants held by each holder on the Closing Date (as defined in the Securities Purchase Agreement) (without regard to any limitations on exercise) or increase in the number of reserved shares, as the case may be (the "**Authorized Share Allocation**"). In the event that a holder shall sell or otherwise transfer any of such holder's SPA Warrants, each transferee shall be allocated a pro rata portion of such holder's Authorized Share Allocation. Any shares of Common Stock reserved and allocated to any Person which ceases to hold any SPA Warrants shall be allocated to the remaining holders of SPA Warrants, pro rata based on the number of shares of Common Stock issuable upon exercise of the SPA Warrants then held by such holders (without regard to any limitations on exercise).

(ii) Insufficient Authorized Shares. If, notwithstanding Section 1(g)(i) above, and not in limitation thereof, at any time while any of the SPA Warrants remain outstanding, the Company does not have a sufficient number of authorized and unreserved shares of Common Stock to satisfy its obligation to reserve the Required Reserve Amount (an "**Authorized Share Failure**"), then the Company shall use its best efforts to take all action necessary to increase the Company's authorized shares of Common Stock to an amount sufficient to allow the Company to reserve the Required Reserve Amount for all the SPA Warrants then outstanding. Without limiting the generality of the foregoing sentence, as soon as practicable after the date of the occurrence of an Authorized Share Failure, but in no event later than sixty (60) days after the occurrence of such Authorized Share Failure, the Company shall hold a meeting of its stockholders for the approval of an increase in the number of authorized shares of Common Stock. In connection with such meeting, the Company shall provide each stockholder with a proxy statement and shall use its best efforts to solicit its stockholders' approval of such increase in authorized shares of Common Stock and to cause its board of directors to recommend to the stockholders that they approve such proposal. Notwithstanding the foregoing, if at any such time of an Authorized Share Failure, the Company is able to obtain the written consent of a majority of the shares of its issued and outstanding shares of Common Stock to approve the increase in the number of authorized shares of Common Stock, the Company may satisfy this obligation by obtaining such consent and submitting for filing with the SEC an Information Statement on Schedule 14C. In the event that the Company is prohibited from issuing shares of Common Stock upon an exercise of this Warrant due to the failure by the Company to have sufficient shares of Common Stock available out of the authorized but unissued shares of Common Stock (such unavailable number of shares of Common Stock, the "**Authorization Failure Shares**"), in lieu of delivering such Authorization Failure Shares to the Holder, the Company shall pay cash in exchange for the cancellation of such portion of this Warrant exercisable into such Authorization Failure Shares at a price equal to the sum of (i) the product of (x) such number of Authorization Failure Shares and (y) the greatest Closing Sale Price of the Common Stock on any Trading Day during the period commencing on the date the Holder delivers the applicable Exercise Notice with respect to such Authorization Failure Shares to the Company and ending on the date of such issuance and payment under this Section 1(g); and (ii) to the extent the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of Authorization Failure Shares, any Buy-In Payment Amount, brokerage commissions and other out-of-pocket expenses, if any, of the Holder incurred in connection therewith. Nothing contained in this Section 1(g) shall limit any obligations of the Company under any provision of the Securities Purchase Agreement.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 2.

(a) Stock Dividends and Splits. Without limiting any provision of Section 2(b), Section 3 or Section 4, if the Company, at any time on or after the Subscription Date, (i) pays a stock dividend on one or more classes of its then outstanding shares of Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, other than Excluded Securities (as defined in the Securities Purchase Agreement), (ii) subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its then outstanding shares of Common Stock into a larger number of shares or (iii) combines (by combination, reverse stock split or otherwise) one or more classes of its then outstanding shares of Common Stock into a smaller number of shares then in each such case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination. If any event requiring an adjustment under this paragraph occurs during the period that an Exercise Price is calculated hereunder, then the calculation of such Exercise Price shall be adjusted appropriately to reflect such event.

(b) Adjustment Upon Issuance of Shares of Common Stock. If and whenever on or after the Subscription Date, the Company grants, issues or sells (or enters into any agreement or publicly announces its intention to grant, issue or sell), or in accordance with this Section 2 is deemed to have granted, issued or sold, any shares of Common Stock (including the issuance or sale of shares of Common Stock owned or held by or for the account of the Company, but excluding any Excluded Securities granted issued or sold or deemed to have been granted issued or sold) for a consideration per share (the "**New Issuance Price**") less than a price equal to the Exercise Price in effect immediately prior to such granting, issuance or sale or deemed granting, issuance or sale (such Exercise Price then in effect is referred to herein as the "**Applicable Price**") (the foregoing a "**Dilutive Issuance**"), then immediately after such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the New Issuance Price. Simultaneously with any decrease in the Exercise Price pursuant to this Section 2(b), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment (without regard to any limitations on exercise contained herein). For all purposes of the foregoing (including, without limitation, determining the adjusted Exercise Price and the New Issuance Price under this Section 2(b)), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants, issues or sells (or enters into any agreement to grant, issue or sell) any Options and the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting, issuance or sale (or the time of execution of such agreement to grant, issue or sell, as applicable) of such Option for such price per share. For purposes of this Section 2(b)(i), the "lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting, issuance or sale (or pursuant to the agreement to grant, issue or sell, as applicable) of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof and (y) the lowest exercise price set forth in such Option for which one share of Common Stock is issuable (or may become issuable assuming all possible market conditions) upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Option (or any other Person) upon the granting, issuance or sale (or the agreement to grant, issue or sell, as applicable) of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Option (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock or of such Convertible Securities upon the exercise of such Options or otherwise pursuant to the terms of or upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities.

(ii) Issuance of Convertible Securities. If the Company in any manner issues or sells (or enters into any agreement to issue or sell) any Convertible Securities and the lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale (or the time of execution of such agreement to issue or sell, as applicable) of such Convertible Securities for such price per share. For the purposes of this Section 2(b)(ii), the "lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to one share of Common Stock upon the issuance or sale (or pursuant to the agreement to issue or sell, as applicable) of the Convertible Security and upon conversion, exercise or exchange of such Convertible Security or otherwise pursuant to the terms thereof and (y) the lowest conversion price set forth in such Convertible Security for which one share of Common Stock is issuable (or may become issuable assuming all possible market conditions) upon conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Convertible Security (or any other Person) upon the issuance or sale (or the agreement to issue or sell, as applicable) of such Convertible Security plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Convertible Security (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities or otherwise pursuant to the terms thereof, and if any such issuance or sale of such Convertible Securities is made upon exercise of any Options for which adjustment of this Warrant has been or is to be made pursuant to other provisions of this Section 2(b), except as contemplated below, no further adjustment of the Exercise Price shall be made by reason of such issuance or sale.

( ) Change in Option Price or Rate of Conversion. If the purchase or exercise price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or exercisable or exchangeable for shares of Common Stock increases or decreases at any time (other than proportional changes in conversion or exercise prices, as applicable, in connection with an event referred to in Section 2(a)), the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price which would have been in effect at such time had such Options or Convertible Securities provided for such increased or decreased purchase price, additional consideration or increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 2(b)(iii), if the terms of any Option or Convertible Security (including, without limitation, any Option or Convertible Security that was outstanding as of the Subscription Date) are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Convertible Security and the shares of Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 2(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(i) Calculation of Consideration Received. If any Option and/or Convertible Security and/or Adjustment Right is issued in connection with the issuance or sale or deemed issuance or sale of any other securities of the Company (as determined by the Holder, the "**Primary Security**", and such Option and/or Convertible Security and/or Adjustment Right, the "**Secondary Securities**" and together with the Primary Security, each a "**Unit**"), together comprising one integrated transaction, the aggregate consideration per share of Common Stock with respect to such Primary Security shall be deemed to be the lower of (x) the purchase price of such Unit, (y) if such Primary Security is an Option and/or Convertible Security, the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise or conversion of the Primary Security in accordance with Sections 2(b)(i) or 2(b)(ii) above and (z) the lowest VWAP of the shares of Common Stock on any Trading Day during the five (5) Trading Day period (the "**Adjustment Period**") immediately following the public announcement of such Dilutive Issuance (for the avoidance of doubt, if such public announcement is released prior to the opening of the Principal Market on a Trading Day, such Trading Day shall be the first Trading Day in such five Trading Day period and if this Warrant is exercised, on any given Exercise Date during any such Adjustment Period, solely with respect to such portion of this Warrant exercised on such applicable Exercise Date, such applicable Adjustment Period shall be deemed to have ended on, and included, the Trading Day immediately prior to such Exercise Date). If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount of consideration received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company for such securities will be the arithmetic average of the VWAPs of such security for each of the five (5) Trading Days immediately preceding the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities (as the case may be). The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Holder. If such parties are unable to reach agreement within ten (10) days after the occurrence of an event requiring valuation (the "**Valuation Event**"), the fair value of such consideration will be determined within five (5) Trading Days after the tenth (10^{th}) day following such Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Holder. The determination of such appraiser shall be final and binding upon all parties absent manifest error and the fees and expenses of such appraiser shall be borne by the Company.

(ii) Record Date. If the Company takes a record of the holders of shares of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in shares of Common Stock, Options or in Convertible Securities or (B) to subscribe for or purchase shares of Common Stock, Options or Convertible Securities, then such record date will be deemed to be the date of the issuance or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase (as the case may be).

(c) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to Section 2(a), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment (without regard to any limitations on exercise contained herein).

(d) Board Reconstitution Black Scholes Value. In addition, if there is a reconstitution of the board of directors of the Company whereby three or more members of such board of directors resign or are replaced (a "**Board Reconstitution**"), the Company shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the Board Reconstitution, purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Board Reconstitution Black Scholes Value (as defined herein) of the remaining unexercised portion of this Warrant on the date of the Board Reconstitution. For purposes hereof, "**Board Reconstitution Black Scholes Value**" means the value of the unexercised portion of this Warrant remaining on the date of the Holder's request pursuant to this Section 2(d), which value is calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the highest Closing Sale Price of the Common Stock during the period beginning on the Trading Day immediately preceding the announcement of the Board Reconstitution and ending on the Trading Day of the Holder's request pursuant to this Section 2(d), (ii) a strike price equal to the Exercise Price in effect on the date of the Holder's request pursuant to this Section 2(d), (iii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the greater of (1) the remaining term of this Warrant as of the date of the Holder's request pursuant to this Section 2(d) and (2) the remaining term of this Warrant as of the date of the Holder's request pursuant to this Section 2(d), provided that, for purposes of determining the remaining term and calculating such value, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in such calculation, (iv) a zero cost of borrow and (v) an expected volatility equal to the greater of 100% and the 60 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the earliest to occur of (A) the public disclosure of the applicable Board Reconstitution and (B) the date of the Holder's request pursuant to Section 4(d).

(e) Stock Combination Event Adjustment. If at any time and from time to time on or after the Issuance Date there occurs any stock split, stock dividend, stock combination, reverse stock split, recapitalization or other similar transaction involving the outstanding Common Stock (each, a "**Stock Combination Event**", and such date thereof, the "**Stock Combination Event Date**") and the Event Market Price is less than the Exercise Price then in effect (after giving effect to the adjustment in clause 2(a) above), then on the sixteenth (16th) Trading Day immediately following such Stock Combination Event, the Exercise Price then in effect on such sixteenth (16th) Trading Day (after giving effect to the adjustment in clause 2(a) above) shall be reduced (but in no event increased) to the Event Market Price. For the avoidance of doubt, if the adjustment in the immediately preceding sentence would otherwise result in an increase in the Exercise Price hereunder, no adjustment shall be made.

(f) Other Events. In the event that the Company (or any Subsidiary (as defined in the Securities Purchase Agreement)) shall take any action to which the provisions hereof are not strictly applicable, or, if applicable, would not operate to protect the Holder from dilution or if any event occurs of the type contemplated by the provisions of this Section 2 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features), then the Company's board of directors shall in good faith determine and implement an appropriate adjustment in the Exercise Price and the number of Warrant Shares (if applicable) so as to protect the rights of the Holder, provided that no such adjustment pursuant to this Section 2(f) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2, provided further that if the Holder does not accept such adjustments as appropriately protecting its interests hereunder against such dilution, then the Company's board of directors and the Holder shall agree, in good faith, upon an independent investment bank of nationally recognized standing to make such appropriate adjustments, whose determination shall be final and binding absent manifest error and whose fees and expenses shall be borne by the Company.

(g) Calculations. All calculations under this Section 2 shall be made by rounding to the nearest cent or the nearest 1/100th of a share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company, and the disposition of any such shares shall be considered an issuance or sale of shares of Common Stock.

(h) Voluntary Adjustment By Company. Subject to the rules and regulations of the Principal Market, the Company may at any time during the term of this Warrant, with the prior written consent of the Required Holders (as defined in the Securities Purchase Agreement), reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

3. RIGHTS UPON DISTRIBUTION OF ASSETS. In addition to any adjustments pursuant to Section 2 above or Section 4(a) below, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property, options, evidence of indebtedness or any other assets by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations or restrictions on exercise of this Warrant, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Distribution to the extent of the Maximum Percentage (and shall not be entitled to beneficial ownership of such shares of Common Stock as a result of such Distribution (and beneficial ownership) to the extent of any such excess) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time or times, if ever, as its right thereto would not result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, at which time or times the Holder shall be granted such Distribution (and any Distributions declared or made on such initial Distribution or on any subsequent Distribution held similarly in abeyance) to the same extent as if there had been no such limitation).

4. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS.

(a) Purchase Rights. In addition to any adjustments pursuant to Sections 2 or 3 above, if at any time the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations or restrictions on exercise of this Warrant, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issuance or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Purchase Right to the extent of the Maximum Percentage (and shall not be entitled to beneficial ownership of such shares of Common Stock as a result of such Purchase Right (and beneficial ownership) to the extent of any such excess) and such Purchase Right to such extent shall be held in abeyance for the benefit of the Holder until such time or times, if ever, as its right thereto would not result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, at which time or times the Holder shall be granted such right (and any Purchase Right granted, issued or sold on such initial Purchase Right or on any subsequent Purchase Right held similarly in abeyance) to the same extent as if there had been no such limitation).

(b) Fundamental Transactions. The Company shall not enter into or be party to a Fundamental Transaction unless (i) the Successor Entity assumes in writing all of the obligations of the Company under this Warrant and the other Transaction Documents (as defined in the Securities Purchase Agreement) in accordance with the provisions of this Section 4(b) pursuant to written agreements in form and substance satisfactory to the Holder and approved by the Holder prior to such Fundamental Transaction, including agreements to deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant, including, without limitation, which is exercisable for a corresponding number of shares of capital stock equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such adjustments to the number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction) and (ii) the Successor Entity (including its Parent Entity) is a publicly traded corporation whose common stock is quoted on or listed for trading on an Eligible Market. Upon the consummation of each Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of the applicable Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of each Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the applicable Fundamental Transaction, in lieu of the shares of Common Stock (or other securities, cash, assets or other property (except such items still issuable under Sections 3 and 4(a) above, which shall continue to be receivable thereafter)) issuable upon the exercise of this Warrant prior to the applicable Fundamental Transaction, such shares of publicly traded common stock (or its equivalent) of the Successor Entity (including its Parent Entity) which the Holder would have been entitled to receive upon the happening of the applicable Fundamental Transaction had this Warrant been exercised immediately prior to the applicable Fundamental Transaction (without regard to any limitations on the exercise of this Warrant), as adjusted in accordance with the provisions of this Warrant. Notwithstanding the foregoing, and without limiting Section 1(f) hereof, the Holder may elect, at its sole option, by delivery of written notice to the Company to waive this Section 4(b) to permit the Fundamental Transaction without the assumption of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of each Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the applicable Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property (except such items still issuable under Sections 3 and 4(a) above, which shall continue to be receivable thereafter)) issuable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of the applicable Fundamental Transaction had this Warrant been exercised immediately prior to the applicable Fundamental Transaction (without regard to any limitations on the exercise of this Warrant). Provision made pursuant to the preceding sentence shall be in a form and substance reasonably satisfactory to the Holder.

(c) Black Scholes Value. Notwithstanding the foregoing and the provisions of Section 4(b) above, at the request of the Holder delivered at any time commencing on the earliest to occur of (x) the public disclosure of any Fundamental Transaction, (y) the consummation of any Fundamental Transaction and (z) the Holder first becoming aware of any Fundamental Transaction through the date that is ninety (90) days after the public disclosure of the consummation of such Fundamental Transaction by the Company pursuant to a Current Report on Form 8-K filed with the SEC, the Company or the Successor Entity (as the case may be) shall purchase this Warrant from the Holder on the date of such request by paying to the Holder cash in an amount equal to the Black Scholes Value of the remaining unexercised portion of this Warrant (calculated as set forth in Section 2(d), including, without limitation, Section 2(d)(iii)(2)). Payment of such amounts shall be made by the Company (or at the Company's direction) to the Holder on or prior to the later of (x) the second (2nd) Trading Day after the date of such request and (y) the date of consummation of such Fundamental Transaction.

(d) Application. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied as if this Warrant (and any such subsequent warrants) were fully exercisable and without regard to any limitations on the exercise of this Warrant (provided that the Holder shall continue to be entitled to the benefit of the Maximum Percentage, applied however with respect to shares of capital stock registered under the 1934 Act and thereafter receivable upon exercise of this Warrant (or any such other warrant)).

5. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation (as defined in the Securities Purchase Agreement), Bylaws (as defined in the Securities Purchase Agreement) or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issuance or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (a) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, and (b) shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and non-assessable shares of Common Stock upon the exercise of this Warrant. Notwithstanding anything herein to the contrary, if after the sixty (60) calendar day anniversary of the Issuance Date, the Holder is not permitted to exercise this Warrant in full for any reason (other than pursuant to restrictions set forth in Section 1(f) hereof), the Company shall use its best efforts to promptly remedy such failure, including, without limitation, obtaining such consents or approvals as necessary to permit such exercise into shares of Common Stock.

6. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in its capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of capital stock of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in its capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company. Notwithstanding this Section 6, the Company shall provide the Holder with copies of the same notices and other information given to the stockholders of the Company generally, contemporaneously with the giving thereof to the stockholders; provided that the Company shall have no such obligation to the extent such information is filed with the SEC through EDGAR and are available to the public through the EDGAR system.

7. REISSUANCE OF WARRANTS.

(a) Transfer of Warrant. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 7(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 7(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant (as to which a written certification and the indemnification contemplated below shall suffice as such evidence), and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary and reasonable form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 7(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 7(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, no warrants for fractional shares of Common Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 7(a) or Section 7(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

(e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

8. NOTICES. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in accordance with Section 9(f) of the Securities Purchase Agreement. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant (other than the issuance of shares of Common Stock upon exercise in accordance with the terms hereof), including in reasonable detail a description of such action and the reason therefor. Without limiting the generality of the foregoing, the Company will give written notice to the Holder (i) immediately upon each adjustment of the Exercise Price and the number of Warrant Shares, setting forth in reasonable detail, and certifying, the calculation of such adjustment(s), (ii) at least fifteen (15) days prior to the date on which the Company closes its books or takes a record (A) with respect to any dividend or distribution upon the Common Stock, (B) with respect to any grants, issuances or sales of any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property to holders of Common Stock or (C) for determining rights to vote with respect to any Fundamental Transaction, dissolution or liquidation, provided in each case that such information shall be made known to the public prior to or in conjunction with such notice being provided to the Holder, and (iii) at least ten (10) Trading Days prior to the consummation of any Fundamental Transaction. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its Subsidiaries, the Company shall simultaneously file such notice with the SEC (as defined in the Securities Purchase Agreement) pursuant to a Current Report on Form 8-K. If the Company or any of its Subsidiaries provides material non-public information to the Holder that is not simultaneously filed in a Current Report on Form 8-K and the Holder has not agreed to receive such material non-public information, the Company hereby covenants and agrees that the Holder shall not have any duty of confidentiality to the Company, any of its Subsidiaries or any of their respective officers, directors, employees, affiliates or agents with respect to, or a duty to any of the foregoing not to trade on the basis of, such material non-public information. It is expressly understood and agreed that the time of execution specified by the Holder in each Exercise Notice shall be definitive and may not be disputed or challenged by the Company.

9. DISCLOSURE. Upon delivery by the Company to the Holder (or receipt by the Company from the Holder) of any notice in accordance with the terms of this Warrant, unless the Company has in good faith determined that the matters relating to such notice do not constitute material, non-public information relating to the Company or any of its Subsidiaries, the Company shall on or prior to 9:00 am, New York City time on the Business Day immediately following such notice delivery date, publicly disclose such material, non-public information on a Current Report on Form 8-K or otherwise. In the event that the Company believes that a notice contains material, non-public information relating to the Company or any of its Subsidiaries, the Company so shall indicate to the Holder explicitly in writing in such notice (or immediately upon receipt of notice from the Holder, as applicable), and in the absence of any such written indication in such notice (or notification from the Company immediately upon receipt of notice from the Holder), the Holder shall be entitled to presume that information contained in the notice does not constitute material, non-public information relating to the Company or any of its Subsidiaries. Nothing contained in this Section 9 shall limit any obligations of the Company, or any rights of the Holder, under Section 4(i) of the Securities Purchase Agreement.

10. ABSENCE OF TRADING AND DISCLOSURE RESTRICTIONS. The Company acknowledges and agrees that the Holder is not a fiduciary or agent of the Company and that the Holder shall have no obligation to (a) maintain the confidentiality of any information provided by the Company or (b) refrain from trading any securities while in possession of such information in the absence of a written non-disclosure agreement signed by an officer of the Holder that explicitly provides for such confidentiality and trading restrictions. In the absence of such an executed, written non-disclosure agreement, the Company acknowledges that the Holder may freely trade in any securities issued by the Company, may possess and use any information provided by the Company in connection with such trading activity, and may disclose any such information to any third party.

11. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant (other than Section 1(f)) may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Required Holders (as defined in the Securities Purchase Agreement). No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

12. SEVERABILITY. If any provision of this Warrant is prohibited by law or otherwise determined to be invalid or unenforceable by a court of competent jurisdiction, the provision that would otherwise be prohibited, invalid or unenforceable shall be deemed amended to apply to the broadest extent that it would be valid and enforceable, and the invalidity or unenforceability of such provision shall not affect the validity of the remaining provisions of this Warrant so long as this Warrant as so modified continues to express, without material change, the original intentions of the parties as to the subject matter hereof and the prohibited nature, invalidity or unenforceability of the provision(s) in question does not substantially impair the respective expectations or reciprocal obligations of the parties or the practical realization of the benefits that would otherwise be conferred upon the parties. The parties will endeavor in good faith negotiations to replace the prohibited, invalid or unenforceable provision(s) with a valid provision(s), the effect of which comes as close as possible to that of the prohibited, invalid or unenforceable provision(s).

13. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. The Company hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to the Company at the address set forth in Section 9(f) of the Securities Purchase Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. The Company hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Nothing contained herein shall be deemed or operate to preclude the Holder from bringing suit or taking other legal action against the Company in any other jurisdiction to collect on the Company's obligations to the Holder, to realize on any collateral or any other security for such obligations, or to enforce a judgment or other court ruling in favor of the Holder. **THE COMPANY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS WARRANT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

14. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any Person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant. Terms used in this Warrant but defined in the other Transaction Documents shall have the meanings ascribed to such terms on the Closing Date (as defined in the Securities Purchase Agreement) in such other Transaction Documents unless otherwise consented to in writing by the Holder.

15. DISPUTE RESOLUTION.

(a) Submission to Dispute Resolution.

(i) In the case of a dispute relating to the Exercise Price, the Closing Sale Price, the Bid Price, Black Scholes Consideration Value, Black Scholes Value or fair market value or the arithmetic calculation of the number of Warrant Shares (as the case may be) (including, without limitation, a dispute relating to the determination of any of the foregoing), the Company or the Holder (as the case may be) shall submit the dispute to the other party via electronic mail (A) if by the Company, within two (2) Business Days after the occurrence of the circumstances giving rise to such dispute or (B) if by the Holder, at any time after the Holder learned of the circumstances giving rise to such dispute. If the Holder and the Company are unable to promptly resolve such dispute relating to such Exercise Price, such Closing Sale Price, such Bid Price, such Black Scholes Consideration Value, Black Scholes Value or such fair market value or such arithmetic calculation of the number of Warrant Shares (as the case may be), at any time after the second (2nd) Business Day following such initial notice by the Company or the Holder (as the case may be) of such dispute to the Company or the Holder (as the case may be), then the Holder may, at its sole option, select an independent, reputable investment bank to resolve such dispute.

(ii) The Holder and the Company shall each deliver to such investment bank (A) a copy of the initial dispute submission so delivered in accordance with the first sentence of this Section 15 and (B) written documentation supporting its position with respect to such dispute, in each case, no later than 5:00 p.m. (New York time) by the fifth (5th) Business Day immediately following the date on which the Holder selected such investment bank (the "**Dispute Submission Deadline**") (the documents referred to in the immediately preceding clauses (A) and (B) are collectively referred to herein as the "**Required Dispute Documentation**") (it being understood and agreed that if either the Holder or the Company fails to so deliver all of the Required Dispute Documentation by the Dispute Submission Deadline, then the party who fails to so submit all of the Required Dispute Documentation shall no longer be entitled to (and hereby waives its right to) deliver or submit any written documentation or other support to such investment bank with respect to such dispute and such investment bank shall resolve such dispute based solely on the Required Dispute Documentation that was delivered to such investment bank prior to the Dispute Submission Deadline). Unless otherwise agreed to in writing by both the Company and the Holder or otherwise requested by such investment bank, neither the Company nor the Holder shall be entitled to deliver or submit any written documentation or other support to such investment bank in connection with such dispute (other than the Required Dispute Documentation).

(iii) The Company and the Holder shall cause such investment bank to determine the resolution of such dispute and notify the Company and the Holder of such resolution no later than ten (10) Business Days immediately following the Dispute Submission Deadline. The fees and expenses of such investment bank shall be borne solely by the Company, and such investment bank's resolution of such dispute shall be final and binding upon all parties absent manifest error.

(b) Miscellaneous. The Company expressly acknowledges and agrees that (i) this Section 15 constitutes an agreement to arbitrate between the Company and the Holder (and constitutes an arbitration agreement) under the rules then in effect under § 7501, et seq. of the New York Civil Practice Law and Rules ("**CPLR**") and that the Holder is authorized to apply for an order to compel arbitration pursuant to CPLR § 7503(a) in order to compel compliance with this Section 15, (ii) the terms of this Warrant and each other applicable Transaction Document shall serve as the basis for the selected investment bank's resolution of the applicable dispute, such investment bank shall be entitled (and is hereby expressly authorized) to make all findings, determinations and the like that such investment bank determines are required to be made by such investment bank in connection with its resolution of such dispute, (iii) the Holder (and only the Holder), in its sole discretion, shall have the right to submit any dispute described in this Section 15 to any state or federal court sitting in The City of New York, Borough of Manhattan in lieu of utilizing the procedures set forth in this Section 15 and

( ) nothing in this Section 15 shall limit the Holder from obtaining any injunctive relief or other equitable remedies (including, without limitation, with respect to any matters described in this Section 15).

16. REMEDIES, CHARACTERIZATION, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant and the other Transaction Documents, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Warrant. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, exercises and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holder of this Warrant shall be entitled, in addition to all other available remedies, to specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Warrant (including, without limitation, compliance with Section 2 hereof). The issuance of shares and certificates for shares as contemplated hereby upon the exercise of this Warrant shall be made without charge to the Holder or such shares for any issuance tax or other costs in respect thereof, provided that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than the Holder or its agent on its behalf.

17. PAYMENT OF COLLECTION, ENFORCEMENT AND OTHER COSTS. If (a) this Warrant is placed in the hands of an attorney for collection or enforcement or is collected or enforced through any legal proceeding or the holder otherwise takes action to collect amounts due under this Warrant or to enforce the provisions of this Warrant or (b) there occurs any bankruptcy, reorganization, receivership of the company or other proceedings affecting company creditors' rights and involving a claim under this Warrant, then the Company shall pay the costs incurred by the Holder for such collection, enforcement or action or in connection with such bankruptcy, reorganization, receivership or other proceeding, including, without limitation, attorneys' fees and disbursements.

18. TRANSFER. This Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company, except as may otherwise be required by Section 2(g) of the Securities Purchase Agreement and applicable securities laws.

19. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**1933 Act**" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

(b) "**1934 Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

(c) "**Adjustment Right**" means any right granted with respect to any securities issued in connection with, or with respect to, any issuance or sale (or deemed issuance or sale in accordance with Section 2) of Common Stock (other than rights of the type described in Section 3 and 4 hereof) that could result in a decrease in the net consideration received by the Company in connection with, or with respect to, such securities (including, without limitation, any cash settlement rights, cash adjustment or other similar rights).

(d) "**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such Person, it being understood for purposes of this definition that "control" of a Person means the power directly or indirectly either to vote 10% or more of the stock having ordinary voting power for the election of directors of such Person or direct or cause the direction of the management and policies of such Person whether by contract or otherwise.

(e) "**Attribution Parties**" means, collectively, the following Persons and entities: (i) any investment vehicle, including, any funds, feeder funds or managed accounts, currently, or from time to time after the Issuance Date, directly or indirectly managed or advised by the Holder's investment manager or any of its Affiliates or principals, (ii) any direct or indirect Affiliates of the Holder or any of the foregoing, (iii) any Person acting or who could be deemed to be acting as a Group together with the Holder or any of the foregoing and (iv) any other Persons whose beneficial ownership of the Company's Common Stock would or could be aggregated with the Holder's and the other Attribution Parties for purposes of Section 13(d) of the 1934 Act. For clarity, the purpose of the foregoing is to subject collectively the Holder and all other Attribution Parties to the Maximum Percentage.

(f) "**Bid Price**" means, for any security as of the particular time of determination, the bid price for such security on the Principal Market as reported by Bloomberg as of such time of determination, or, if the Principal Market is not the principal securities exchange or trading market for such security, the bid price of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg as of such time of determination, or if the foregoing does not apply, the bid price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg as of such time of determination, or, if no bid price is reported for such security by Bloomberg as of such time of determination, the average of the bid prices of any market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices) as of such time of determination. If the Bid Price cannot be calculated for a security as of the particular time of determination on any of the foregoing bases, the Bid Price of such security as of such time of determination shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during such period.

(g) "**Black Scholes Consideration Value**" means the value of the applicable Option, Convertible Security or Adjustment Right (as the case may be) as of the date of issuance thereof calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the Closing Sale Price of the Common Stock on the Trading Day immediately preceding the public announcement of the execution of definitive documents with respect to the issuance of such Option or Convertible Security (as the case may be), (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of such Option, Convertible Security or Adjustment Right (as the case may be) as of the date of issuance of such Option, Convertible Security or Adjustment Right (as the case may be), (iii) a zero cost of borrow and (iv) an expected volatility equal to the greater of 100% and the 30 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the date of issuance of such Option, Convertible Security or Adjustment Right (as the case may be), provided that, for purposes of this definition and any calculations hereunder, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in any such calculation.

(h) "**Black Scholes Value**" means the value of the unexercised portion of this Warrant remaining on the date of the Holder's request pursuant to Section 4(c)(i), which value is calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the greater of (1) the highest Closing Sale Price of the Common Stock during the period beginning on the Trading Day immediately preceding the announcement of the applicable Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to Section 4(c)(i) and (2) the sum of the price per share being offered in cash in the applicable Fundamental Transaction (if any) plus the value of the non-cash consideration being offered in the applicable Fundamental Transaction (if any), (ii) a strike price equal to the Exercise Price in effect on the date of the Holder's request pursuant to Section 4(c)(i), (iii) a risk- free interest rate corresponding to the U.S. Treasury rate for a period equal to the greater of (1) the remaining term of this Warrant as of the date of the Holder's request pursuant to Section 4(c)(i) and (2) the remaining term of this Warrant as of the date of consummation of the applicable Fundamental Transaction or as of the date of the Holder's request pursuant to Section 4(c)(i) if such request is prior to the date of the consummation of the applicable Fundamental Transaction, (iv) a zero cost of borrow and (v) an expected volatility equal to the greater of 100% and the 30 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the earliest to occur of (A) the public disclosure of the applicable Fundamental Transaction and (B) the date of the Holder's request pursuant to Section 4(c)(i), provided that for purposes of this definition and any calculations hereunder, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in any such calculation.

(i) "**Bloomberg**" means Bloomberg, L.P.

(j) "**Business Day**" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; p rovided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

(k) "**Closing Sale Price**" means, for any security as of any date, the last closing trade price for such security on the Principal Market, as reported by Bloomberg, or, if the Principal Market begins to operate on an extended hours basis and does not designate the closing trade price, then the last trade price of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Principal Market is not the principal securities exchange or trading market for such security, the last trade price of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing does not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no last trade price is reported for such security by Bloomberg, the average of the ask prices of any market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices). If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during such period.

(l) "**Common Stock**" means (i) the Company's shares of common stock, $0.0001 par value per share, and (ii) any capital stock into which such common stock shall have been changed or any capital stock resulting from a reclassification of such common stock.

(m) "**Convertible Securities**" means any stock or other security (other than Options) that is at any time and under any circumstances, directly or indirectly, convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any Common Stock.

(n) "**Eligible Market**" means The New York Stock Exchange, the NYSE American, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or the Principal Market.

(o) [Reserved]

(p) "**Event Market Price**" means, with respect to any Stock Combination Event Date, the quotient determined by dividing (x) the sum of the VWAP of the Common Stock for each of the five (5) lowest Trading Days during the twenty (20) consecutive Trading Day period ending and including the Trading Day immediately preceding the sixteenth (16th) Trading Day after such Stock Combination Event Date, divided by (y) five (5). All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination, recapitalization or other similar transaction during such period.

(o) "**Expiration Date**" means the date that is the fifth (5th) anniversary of the Issuance Date or, if such date falls on a day other than a Trading Day or on which trading does not take place on the Principal Market (a "**Holiday**"), the next date that is not a Holiday.

(q) "**Fundamental Transaction**" means (A) that the Company shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Subject Entity, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company or any of its "significant subsidiaries" (as defined in Rule 1-02 of Regulation S-X) to one or more Subject Entities, or (iii) make, or allow one or more Subject Entities to make, or allow the Company to be subject to or have its Common Stock be subject to or party to one or more Subject Entities making, a purchase, tender or exchange offer that is accepted by the holders of at least either (x) 50% of the outstanding shares of Common Stock, (y) 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all Subject Entities making or party to, or Affiliated with any Subject Entities making or party to, such purchase, tender or exchange offer were not outstanding; or (z) such number of shares of Common Stock such that all Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such purchase, tender or exchange offer, become collectively the beneficial owners (as defined in Rule 13d-3 under the 1934 Act) of at least 50% of the outstanding shares of Common Stock, or (iv) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with one or more Subject Entities whereby all such Subject Entities, individually or in the aggregate, acquire, either (x) at least 50% of the outstanding shares of Common Stock, (y) at least 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all the Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such stock purchase agreement or other business combination were not outstanding; or (z) such number of shares of Common Stock such that the Subject Entities become collectively the beneficial owners (as defined in Rule 13d-3 under the 1934 Act) of at least 50% of the outstanding shares of Common Stock, or (v) reorganize, recapitalize or reclassify its Common Stock, (B) that the Company shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, allow any Subject Entity individually or the Subject Entities in the aggregate to be or become the "beneficial owner" (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, whether through acquisition, purchase, assignment, conveyance, tender, tender offer, exchange, reduction in outstanding shares of Common Stock, merger, consolidation, business combination, reorganization, recapitalization, spin-off, scheme of arrangement, reorganization, recapitalization or reclassification or otherwise in any manner whatsoever, of either (x) at least 50% of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock, (y) at least 50% of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock not held by all such Subject Entities as of the date of this Warrant calculated as if any shares of Common Stock held by all such Subject Entities were not outstanding, or (z) a percentage of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock or other equity securities of the Company sufficient to allow such Subject Entities to effect a statutory short form merger or other transaction requiring other stockholders of the Company to surrender their shares of Common Stock without approval of the stockholders of the Company or (C) directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, the issuance of or the entering into any other instrument or transaction structured in a manner to circumvent, or that circumvents, the intent of this definition in which case this definition shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this definition to the extent necessary to correct this definition or any portion of this definition which may be defective or inconsistent with the intended treatment of such instrument or transaction.

(r) "**Group**" means a "group" as that term is used in Section 13(d) of the 1934 Act and as defined in Rule 13d-5 thereunder.

(s) [Reserved]

(t) [Reserved]

(u) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(v) "**Parent Entity**" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

( ) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity or a government or any department or agency thereof.

(w) "**Principal Market**" means the Nasdaq Capital Market.

(x) "**Registration Rights Agreement**" means that certain registration rights agreement, dated as of the Closing Date, by and among the Company and the Buyers of the Preferred Shares and SPA Warrants relating to, among other things, the registration of the resale of the shares of Common Stock issuable upon conversion of the Preferred Shares or otherwise pursuant to the terms of the Certificate of Designations and exercise of the SPA Warrants, as may be amended from time to time.

(y) "**SEC**" means the United States Securities and Exchange Commission or the successor thereto.

(aa) "**Subject Entity**" means any Person, Persons or Group or any Affiliate or associate of any such Person, Persons or Group.

(ab) "**Successor Entity**" means the Person (or, if so elected by the Holder, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Holder, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(ac) "**Trading Day**" means, as applicable, (x) with respect to all price or trading volume determinations relating to the Common Stock, any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded, provided that "Trading Day" shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock is suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time) unless such day is otherwise designated as a Trading Day in writing by the Holder or (y) with respect to all determinations other than price or trading volume determinations relating to the Common Stock, any day on which The New York Stock Exchange (or any successor thereto) is open for trading of securities.

(ad) **[Reserved]**

(ae) "**VWAP**" means, for any security as of any date, the dollar volume-weighted average price for such security on the Principal Market (or, if the Principal Market is not the principal trading market for such security, then on the principal securities exchange or securities market on which such security is then traded), during the period beginning at 9:30 a.m., New York time, and ending at 4:00 p.m., New York time, as reported by Bloomberg through its "VAP" function (set to 09:30 start time and 16:00 end time) or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30 a.m., New York time, and ending at 4:00 p.m., New York time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices). If the VWAP cannot be calculated for such security on such date on any of the foregoing bases, the VWAP of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination, recapitalization or other similar transaction during such period.

[*signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

PHARMACYTE BIOTECH, INC.

By: _____

Name: Carlos A. Trujillo
Title: Chief Financial Officer

EXHIBIT A

EXERCISE NOTICE
TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS
WARRANT TO PURCHASE COMMON STOCK
PHARMACYTE BIOTECH, INC.

The undersigned holder hereby elects to exercise the Warrant to Purchase Common Stock No._____(the "**Warrant**") of PHARMACYTE BIOTECH, INC., a Nevada corporation (the "**Company**"), as specified below. Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Form of Exercise Price. The Holder intends that payment of the Aggregate Exercise Price shall be made as:
☐ a "Cash Exercise" with respect to_____ Warrant Shares; and/or
☐ a "Cashless Exercise" with respect to_____ Warrant Shares.

In the event that the Holder has elected a Cashless Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the Holder hereby represents and warrants that (i) this Exercise Notice was executed by the Holder at_____ [a.m.][p.m.] on the date set forth below and (ii) if applicable, the Bid Price as of such time of execution of this Exercise Notice was
$_____

2. Payment of Exercise Price. In the event that the Holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the Holder shall pay the Aggregate Exercise Price in the sum of $_____
to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver to Holder, or its designee or agent as specified below,_____ shares of Common Stock in accordance with the terms of the Warrant. Delivery shall be made to Holder, or for its benefit, as follows:

☐ Check here if requesting delivery as a certificate to the following name and to the following address: Issue to:
_____
_____
_____

☐ Check here if requesting delivery by Deposit/Withdrawal at Custodian as follows:
DTC Participant: _____

DTC Number: _____

Account Number: _____

_____

Date:_____
Name of Registered Holder

By:_____
Name:
Title:

Tax ID: _____
E-mail:
Address: _____

EXHIBIT B

ACKNOWLEDGMENT

The Company hereby acknowledges this Exercise Notice and hereby directs_____to issue the above indicated number of shares of Common Stock in accordance with the Transfer Agent Instructions dated_____, 2023, from the Company and acknowledged and agreed to by_____.

PHARMACYTE BIOTECH, INC.

By:_____
Name:
Title:

EXHIBIT 4.11

WARRANT

NEITHER THE ISSUANCE AND SALE OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE NOR THE SECURITIES INTO WHICH THESE SECURITIES ARE EXERCISABLE HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (B) AN OPINION OF COUNSEL TO THE HOLDER (IF REQUESTED BY THE COMPANY), IN A FORM REASONABLY ACCEPTABLE TO THE COMPANY, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR (II) UNLESS SOLD OR ELIGIBLE TO BE SOLD PURSUANT TO RULE 144 OR RULE 144A UNDER SAID ACT. NOTWITHSTANDING THE FOREGOING, THE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SECURITIES. THE NUMBER OF SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE OF THIS WARRANT MAY BE LESS THAN THE AMOUNTS SET FORTH ON THE FACE HEREOF PURSUANT TO SECTION 1(a) OF THIS WARRANT.

PHARMACYTE BIOTECH, INC.

Warrant To Purchase Common Stock

Warrant No.:

Date of Issuance: July 29, 2025 ("**Issuance Date**")

PharmaCyte Biotech, Inc., a Nevada corporation (the "**Company**"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, _____, the registered holder hereof or its permitted assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon exercise of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "**Warrant**"), at any time or times on or after the Issuance Date, but not after 11:59 p.m., New York time, on the Expiration Date (as defined below), _____(subject to adjustment as provided herein) fully paid and non-assessable shares of Common Stock (as defined below) (the "**Warrant Shares**", and such number of Warrant Shares, the "**Warrant Number**"). Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 17 or in the Securities Purchase Agreement (as defined below). This Warrant is, except as to the Issuance Date, expiration date and the related impact on the calculation of Black Scholes Value (as defined below) as set forth hereunder, identical to one of the Warrants to Purchase Common Stock (the "**SPA Warrants**") issued pursuant to Section 1 of that certain Securities Purchase Agreement, dated as of May 9, 2023 (the "**Subscription Date**"), by and among the Company and the investors (the "**Buyers**") referred to therein, as amended from time to time (the "**Securities Purchase Agreement**").

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof (including, without limitation, the limitations set forth in Section 1(f)), this Warrant may be exercised by the Holder on any day on or after the Issuance Date (an "**Exercise Date**"), in whole or in part, by delivery (whether via electronic mail or otherwise) of a written notice, in the form attached hereto as **Exhibit A** (the "**Exercise Notice**"), of the Holder's election to exercise this Warrant. Within one (1) Trading Day following an exercise of this Warrant as aforesaid, the Holder shall deliver payment to the Company of an amount equal to the Exercise Price in effect on the date of such exercise multiplied by the number of Warrant Shares as to which this Warrant was so exercised (the "**Aggregate Exercise Price**") in cash or via wire transfer of immediately available funds if the Holder did not notify the Company in such Exercise Notice that such exercise was made pursuant to a Cashless Exercise (as defined in Section 1(d)). The Holder shall not be required to deliver the original of this Warrant in order to effect an exercise hereunder. Execution and delivery of an Exercise Notice with respect to less than all of the Warrant Shares shall have the same effect as cancellation of the original of this Warrant and issuance of a new Warrant evidencing the right to purchase the remaining number of Warrant Shares. Execution and delivery of an Exercise Notice for all of the then-remaining Warrant Shares shall have the same effect as cancellation of the original of this Warrant after delivery of the Warrant Shares in accordance with the terms hereof. On or before the first (1st) Trading Day following the date on which the Company has received an Exercise Notice, the Company shall transmit by electronic mail an acknowledgment of confirmation of receipt of such Exercise Notice, in the form attached hereto as **Exhibit B**, to the Holder and the Company's transfer agent (the "**Transfer Agent**"), which confirmation shall constitute an instruction to the Transfer Agent to process such Exercise Notice in accordance with the terms herein. On or before the second (2nd) Trading Day following the date on which the Company has received such Exercise Notice (or such earlier date as required pursuant to the 1934 Act or other applicable law, rule or regulation for the settlement of a trade of such Warrant Shares initiated on the applicable Exercise Date), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program ("**FAST**") and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal at Custodian system, or (Y) if the Transfer Agent is not participating in the DTC FAST, upon the request of the Holder, issue and deliver (via reputable overnight courier) to the address as specified in the Exercise Notice, a certificate, registered in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder shall be entitled pursuant to such exercise. Upon delivery of an Exercise Notice, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares (as the case may be). If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise and upon surrender of this Warrant to the Company by the Holder, then, at the request of the Holder, the Company shall as soon as practicable and in no event later than two (2) Business Days after any exercise and at its own expense, issue and deliver to the Holder (or its designee) a new Warrant (in accordance with Section 7(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded up to the nearest whole number. The Company shall pay any and all transfer, stamp, issuance and similar taxes, costs and expenses (including, without limitation, fees and expenses of the Transfer Agent) that may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant. Notwithstanding the foregoing, except in the case where an exercise of this Warrant is validly made pursuant to a Cashless Exercise, the Company's failure to deliver Warrant Shares to the Holder on or prior to the later of (i) two (2) Trading Days after receipt of the applicable Exercise Notice (or such earlier date as required pursuant to the 1934 Act or other applicable law, rule or regulation for the settlement of a trade of such Warrant Shares initiated on the applicable Exercise Date) and (ii) one (1) Trading Day after the Company's receipt of the Aggregate Exercise Price (or valid notice of a Cashless Exercise if permissible) (such later date, the "**Share Delivery Date**") shall not be deemed to be a breach of this Warrant. Notwithstanding anything to the contrary contained in this Warrant or the Registration Rights Agreement, after the effective date of the Registration Statement (as defined in the Registration Rights Agreement) and prior to the Holder's receipt of the notice of a Grace Period (as defined in the Registration Rights Agreement), the Company shall cause the Transfer Agent to deliver unlegended shares of Common Stock to the Holder (or its designee) in connection with any sale of Registrable Securities (as defined in the Registration Rights Agreement) with respect to which the Holder has entered into a contract for sale, and delivered a copy of the prospectus included as part of the particular Registration Statement to the extent applicable, and for which the Holder has not yet settled. From the Issuance Date through and including the Expiration Date, the Company shall maintain a transfer agent that participates in FAST.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means $4.00, subject to adjustment as provided herein.

(c) Company's Failure to Timely Deliver Securities. If the Company shall fail, for any reason or for no reason, on or prior to the Share Delivery Date, either (I) if the Transfer Agent is not participating in DTC FAST, to issue and deliver to the Holder (or its designee) a certificate for the number of Warrant Shares to which the Holder is entitled and register such Warrant Shares on the Company's share register or, if the Transfer Agent is participating in DTC FAST and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, to credit the balance account of the Holder or the Holder's designee with DTC for such number of Warrant Shares to which the Holder is entitled upon the Holder's exercise of this Warrant (as the case may be) or (II) if a Registration Statement covering the resale of the Warrant Shares that are the subject of the Exercise Notice (the "**Unavailable Warrant Shares**") is not available for the resale of such Unavailable Warrant Shares and the Company fails to promptly, but in no event later than as required pursuant to the Registration Rights Agreement (x) so notify the Holder and (y) deliver the Warrant Shares electronically without any restrictive legend by crediting such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal At Custodian system (the event described in the immediately foregoing clause (II) is hereinafter referred as a "**Notice Failure**" and together with the event described in clause (I) above, a "**Delivery Failure**"), then, in addition to all other remedies available to the Holder, (X) the Company shall pay in cash to the Holder on each day after the Share Delivery Date and during such Delivery Failure an amount equal to 2% of the product of (A) the sum of the number of shares of Common Stock not issued to the Holder on or prior to the Share Delivery Date and to which the Holder is entitled, multiplied by (B) any trading price of the Common Stock selected by the Holder in writing as in effect at any time during the period beginning on the applicable Exercise Date and ending on the applicable Share Delivery Date, and (Y) the Holder, upon written notice to the Company, may void its Exercise Notice with respect to, and retain or have returned, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the voiding of an Exercise Notice shall not affect the Company's obligations to make any payments which have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise. In addition to the foregoing, if on or prior to the Share Delivery Date either (I) the Transfer Agent is not participating in the DTC FAST, the Company shall fail to issue and deliver to the Holder (or its designee) a certificate and register such shares of Common Stock on the Company's share register or, if the Transfer Agent is participating in the DTC FAST and such Warrant Shares are eligible to be resold pursuant to Rule 144 or an effective registration statement, the Transfer Agent shall fail to credit the balance account of the Holder or the Holder's designee with DTC for the number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise hereunder or pursuant to the Company's obligation pursuant to clause (ii) below or (II) a Notice Failure occurs, and if on or after such Share Delivery Date the Holder acquires (in an open market transaction, stock loan or otherwise) shares of Common Stock corresponding to all or any portion of the number of shares of Common Stock issuable upon such exercise that the Holder is entitled to receive from the Company and has not received from the Company in connection with such Delivery Failure or Notice Failure, as applicable (a "**Buy-In**"), then, in addition to all other remedies available to the Holder, the Company shall, within two (2) Business Days after the Holder's request and in the Holder's discretion, either (i) pay cash to the Holder in an amount equal to the Holder's total purchase price (including brokerage commissions, stock loan costs and other out-of-pocket expenses, if any) for the shares of Common Stock so acquired (including, without limitation, by any other Person in respect, or on behalf, of the Holder) (the "**Buy-In Price**"), at which point the Company's obligation to so issue and deliver such certificate (and to issue such shares of Common Stock) or credit the balance account of such Holder or such Holder's designee, as applicable, with DTC for the number of Warrant Shares to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) (and to issue such Warrant Shares) shall terminate, or (ii) promptly honor its obligation to so issue and deliver to the Holder a certificate or certificates representing such Warrant Shares or credit the balance account of such Holder or such Holder's designee, as applicable, with DTC for the number of Warrant Shares to which the Holder is entitled upon the Holder's exercise hereunder (as the case may be) and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of Warrant Shares multiplied by (B) the lowest Closing Sale Price of the Common Stock on any Trading Day during the period commencing on the date of the applicable Exercise Notice and ending on the date of such issuance and payment under this clause (ii) (the "**Buy-In Payment Amount**"). Nothing shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity, including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock (or to electronically deliver such shares of Common Stock) upon the exercise of this Warrant as required pursuant to the terms hereof. While this Warrant is outstanding, the Company shall cause its transfer agent to participate in FAST. In addition to the foregoing rights, (i) if the Company fails to deliver the applicable number of Warrant Shares upon an exercise pursuant to Section 1 by the applicable Share Delivery Date, then the Holder shall have the right to rescind such exercise in whole or in part and retain and/or have the Company return, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the rescission of an exercise shall not affect the Company's obligation to make any payments that have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise, and (ii) if a registration statement (which may be the Registration Statement) covering the issuance or resale of the Warrant Shares that are subject to an Exercise Notice is not available for the issuance or resale, as applicable, of such Warrant Shares, as required by and in accordance with the terms of the Registration Rights Agreement, and the Holder has submitted an Exercise Notice prior to receiving notice of the non-availability of such registration statement and the Company has not already delivered the Warrant Shares underlying such Exercise Notice electronically without any restrictive legend by crediting such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit / Withdrawal At Custodian system, the Holder shall have the option, by delivery of notice to the Company, to (x) rescind such Exercise Notice in whole or in part and retain or have returned, as the case may be, any portion of this Warrant that has not been exercised pursuant to such Exercise Notice; provided that the rescission of an Exercise Notice shall not affect the Company's obligation to make any payments that have accrued prior to the date of such notice pursuant to this Section 1(c) or otherwise, and/or (y) switch some or all of such Exercise Notice from a cash exercise to a Cashless Exercise.

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary (other than Section 1(f) below), if at the time of exercise hereof a Registration Statement (as defined in the Registration Rights Agreement) is not effective (or the prospectus contained therein is not available for use) for the resale by the Holder of all of the Warrant Shares, then the Holder may, in its sole discretion, exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of Warrant Shares determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A= the total number of shares with respect to which this Warrant is then being exercised.

B = as elected by the Holder: (i) the VWAP of the Common Stock on the Trading Day immediately preceding the date of the applicable Exercise Notice if such Exercise Notice is (1) both executed and delivered pursuant to Section 1(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 1(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Exercise Notice or (z) the Bid Price of the Common Stock as of the time of the Holder's execution of the applicable Exercise Notice if such Exercise Notice is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter pursuant to Section 1(a) hereof, or (iii) the Closing Sale Price of the Common Stock on the date of the applicable Exercise Notice if the date of such Exercise Notice is a Trading Day and such Exercise Notice is both executed and delivered pursuant to Section 1(a) hereof after the close of "regular trading hours" on such Trading Day.

C = the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

If the Warrant Shares are issued in a Cashless Exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the 1933 Act, the Warrant Shares take on the registered characteristics of the Warrants being exercised. For purposes of Rule 144(d) promulgated under the 1933 Act, as in effect on the Subscription Date, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Securities Purchase Agreement.

(e) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the number of Warrant Shares to be issued pursuant to the terms hereof, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed and resolve such dispute in accordance with Section 15.

(f) Limitations on Exercises.

(i) Beneficial Ownership. The Company shall not effect the exercise of any portion of this Warrant, and the Holder shall not have the right to exercise any portion of this Warrant, pursuant to the terms and conditions of this Warrant and any such exercise shall be null and void and treated as if never made, to the extent that after giving effect to such exercise, the Holder together with the other Attribution Parties collectively would beneficially own in excess of 4.99% (the "**Maximum Percentage**") of the Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by the Holder and the other Attribution Parties shall include the number of shares of Common Stock held by the Holder and all other Attribution Parties plus the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (A) exercise of the remaining, unexercised portion of this Warrant beneficially owned by the Holder or any of the other Attribution Parties and (B) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company (including, without limitation, any convertible notes or convertible preferred stock or warrants, including other SPA Warrants) beneficially owned by the Holder or any other Attribution Party subject to a limitation on conversion or exercise analogous to the limitation contained in this Section 1(f)(i). For purposes of this Section 1(f)(i), beneficial ownership shall be calculated in accordance with Section 13(d) of the 1934 Act. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the 1934 Act and the rules and regulations promulgated thereunder. For purposes of determining the number of outstanding shares of Common Stock the Holder may acquire upon the exercise of this Warrant without exceeding the Maximum Percentage, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public filing with the SEC, as the case may be, (y) a more recent public announcement by the Company or (z) any other written notice by the Company or the Transfer Agent, if any, setting forth the number of shares of Common Stock outstanding (the "**Reported Outstanding Share Number**"). If the Company receives an Exercise Notice from the Holder at a time when the actual number of outstanding shares of Common Stock is less than the Reported Outstanding Share Number, the Company shall (i) notify the Holder in writing of the number of shares of Common Stock then outstanding and, to the extent that such Exercise Notice would otherwise cause the Holder's beneficial ownership, as determined pursuant to this Section 1(f)(i), to exceed the Maximum Percentage, the Holder must notify the Company of a reduced number of Warrant Shares to be acquired pursuant to such Exercise Notice (the number of shares by which such purchase is reduced, the "**Reduction Shares**") and (ii) as soon as reasonably practicable, the Company shall return to the Holder any exercise price paid by the Holder for the Reduction Shares. For any reason at any time, upon the written or oral request of the Holder, the Company shall within one (1) Business Day confirm orally and in writing or by electronic mail to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder and any other Attribution Party since the date as of which the Reported Outstanding Share Number was reported. In the event that the issuance of shares of Common Stock to the Holder upon exercise of this Warrant results in the Holder and the other Attribution Parties being deemed to beneficially own, in the aggregate, more than the Maximum Percentage of the number of outstanding shares of Common Stock (as determined under Section 13(d) of the 1934 Act), the number of shares so issued by which the Holder's and the other Attribution Parties' aggregate beneficial ownership exceeds the Maximum Percentage (the "**Excess Shares**") shall be deemed null and void and shall be cancelled ab initio, and the Holder shall not have the power to vote or to transfer the Excess Shares. As soon as reasonably practicable after the issuance of the Excess Shares has been deemed null and void, the Company shall return to the Holder the exercise price paid by the Holder for the Excess Shares. Upon delivery of a written notice to the Company, the Holder may from time to time increase (with such increase not effective until the sixty-first (61st) day after delivery of such notice) or decrease the Maximum Percentage to any other percentage not in excess of 9.99% as specified in such notice; provided that (i) any such increase in the Maximum Percentage will not be effective until the sixty-first (61st) day after such notice is delivered to the Company and (ii) any such increase or decrease will apply only to the Holder and the other Attribution Parties and not to any other holder of SPA Warrants that is not an Attribution Party of the Holder. For purposes of clarity, the shares of Common Stock issuable pursuant to the terms of this Warrant in excess of the Maximum Percentage shall not be deemed to be beneficially owned by the Holder for any purpose including for purposes of Section 13(d) or Rule 16a-1(a)(1) of the 1934 Act. No prior inability to exercise this Warrant pursuant to this paragraph shall have any effect on the applicability of the provisions of this paragraph with respect to any subsequent determination of exercisability. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(f)(i) to the extent necessary to correct this paragraph or any portion of this paragraph which may be defective or inconsistent with the intended beneficial ownership limitation contained in this Section 1(f)(i) or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitation contained in this paragraph may not be waived and shall apply to a successor holder of this Warrant.

(ii) **[Reserved]**.

(g) Reservation of Shares.

(i) Required Reserve Amount. So long as this Warrant remains outstanding, the Company shall at all times keep reserved for issuance under this Warrant a number of shares of Common Stock at least equal to 200% of the maximum number of shares of Common Stock as shall be necessary to satisfy the Company's obligation to issue shares of Common Stock under the SPA Warrants then outstanding (without regard to any limitations on exercise) (the "**Required Reserve Amount**"); provided that at no time shall the number of shares of Common Stock reserved pursuant to this Section 1(g)(i) be reduced other than proportionally in connection with any exercise or redemption of SPA Warrants or such other event covered by Section 2(a) below. The Required Reserve Amount (including, without limitation, each increase in the number of shares so reserved) shall be allocated pro rata among the holders of the SPA Warrants based on the number of shares of Common Stock issuable upon exercise of SPA Warrants held by each holder on the Closing Date (as defined in the Securities Purchase Agreement) (without regard to any limitations on exercise) or increase in the number of reserved shares, as the case may be (the "**Authorized Share Allocation**"). In the event that a holder shall sell or otherwise transfer any of such holder's SPA Warrants, each transferee shall be allocated a pro rata portion of such holder's Authorized Share Allocation. Any shares of Common Stock reserved and allocated to any Person which ceases to hold any SPA Warrants shall be allocated to the remaining holders of SPA Warrants, pro rata based on the number of shares of Common Stock issuable upon exercise of the SPA Warrants then held by such holders (without regard to any limitations on exercise).

(ii) Insufficient Authorized Shares. If, notwithstanding Section 1(g)(i) above, and not in limitation thereof, at any time while any of the SPA Warrants remain outstanding, the Company does not have a sufficient number of authorized and unreserved shares of Common Stock to satisfy its obligation to reserve the Required Reserve Amount (an "**Authorized Share Failure**"), then the Company shall use its best efforts to take all action necessary to increase the Company's authorized shares of Common Stock to an amount sufficient to allow the Company to reserve the Required Reserve Amount for all the SPA Warrants then outstanding. Without limiting the generality of the foregoing sentence, as soon as practicable after the date of the occurrence of an Authorized Share Failure, but in no event later than sixty (60) days after the occurrence of such Authorized Share Failure, the Company shall hold a meeting of its stockholders for the approval of an increase in the number of authorized shares of Common Stock. In connection with such meeting, the Company shall provide each stockholder with a proxy statement and shall use its best efforts to solicit its stockholders' approval of such increase in authorized shares of Common Stock and to cause its board of directors to recommend to the stockholders that they approve such proposal. Notwithstanding the foregoing, if at any such time of an Authorized Share Failure, the Company is able to obtain the written consent of a majority of the shares of its issued and outstanding shares of Common Stock to approve the increase in the number of authorized shares of Common Stock, the Company may satisfy this obligation by obtaining such consent and submitting for filing with the SEC an Information Statement on Schedule 14C. In the event that the Company is prohibited from issuing shares of Common Stock upon an exercise of this Warrant due to the failure by the Company to have sufficient shares of Common Stock available out of the authorized but unissued shares of Common Stock (such unavailable number of shares of Common Stock, the "**Authorization Failure Shares**"), in lieu of delivering such Authorization Failure Shares to the Holder, the Company shall pay cash in exchange for the cancellation of such portion of this Warrant exercisable into such Authorization Failure Shares at a price equal to the sum of (i) the product of (x) such number of Authorization Failure Shares and (y) the greatest Closing Sale Price of the Common Stock on any Trading Day during the period commencing on the date the Holder delivers the applicable Exercise Notice with respect to such Authorization Failure Shares to the Company and ending on the date of such issuance and payment under this Section 1(g); and (ii) to the extent the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of Authorization Failure Shares, any Buy-In Payment Amount, brokerage commissions and other out-of-pocket expenses, if any, of the Holder incurred in connection therewith. Nothing contained in this Section 1(g) shall limit any obligations of the Company under any provision of the Securities Purchase Agreement.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 2.

(a) Stock Dividends and Splits. Without limiting any provision of Section 2(b), Section 3 or Section 4, if the Company, at any time on or after the Subscription Date, (i) pays a stock dividend on one or more classes of its then outstanding shares of Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, other than Excluded Securities (as defined in the Securities Purchase Agreement), (ii) subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its then outstanding shares of Common Stock into a larger number of shares or (iii) combines (by combination, reverse stock split or otherwise) one or more classes of its then outstanding shares of Common Stock into a smaller number of shares then in each such case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination. If any event requiring an adjustment under this paragraph occurs during the period that an Exercise Price is calculated hereunder, then the calculation of such Exercise Price shall be adjusted appropriately to reflect such event.

(b) Adjustment Upon Issuance of Shares of Common Stock. If and whenever on or after the Subscription Date, the Company grants, issues or sells (or enters into any agreement or publicly announces its intention to grant, issue or sell), or in accordance with this Section 2 is deemed to have granted, issued or sold, any shares of Common Stock (including the issuance or sale of shares of Common Stock owned or held by or for the account of the Company, but excluding any Excluded Securities granted issued or sold or deemed to have been granted issued or sold) for a consideration per share (the "**New Issuance Price**") less than a price equal to the Exercise Price in effect immediately prior to such granting, issuance or sale or deemed granting, issuance or sale (such Exercise Price then in effect is referred to herein as the "**Applicable Price**") (the foregoing a "**Dilutive Issuance**"), then immediately after such Dilutive Issuance, the Exercise Price then in effect shall be reduced to an amount equal to the New Issuance Price. Simultaneously with any decrease in the Exercise Price pursuant to this Section 2(b), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment (without regard to any limitations on exercise contained herein). For all purposes of the foregoing (including, without limitation, determining the adjusted Exercise Price and the New Issuance Price under this Section 2(b)), the following shall be applicable:

(i) Issuance of Options. If the Company in any manner grants, issues or sells (or enters into any agreement to grant, issue or sell) any Options and the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Option or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the granting, issuance or sale (or the time of execution of such agreement to grant, issue or sell, as applicable) of such Option for such price per share. For purposes of this Section 2(b)(i), the "lowest price per share for which one share of Common Stock is at any time issuable upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to any one share of Common Stock upon the granting, issuance or sale (or pursuant to the agreement to grant, issue or sell, as applicable) of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof and (y) the lowest exercise price set forth in such Option for which one share of Common Stock is issuable (or may become issuable assuming all possible market conditions) upon the exercise of any such Options or upon conversion, exercise or exchange of any Convertible Securities issuable upon exercise of any such Option or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Option (or any other Person) upon the granting, issuance or sale (or the agreement to grant, issue or sell, as applicable) of such Option, upon exercise of such Option and upon conversion, exercise or exchange of any Convertible Security issuable upon exercise of such Option or otherwise pursuant to the terms thereof plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Option (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock or of such Convertible Securities upon the exercise of such Options or otherwise pursuant to the terms of or upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities.

(ii) Issuance of Convertible Securities. If the Company in any manner issues or sells (or enters into any agreement to issue or sell) any Convertible Securities and the lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof is less than the Applicable Price, then such share of Common Stock shall be deemed to be outstanding and to have been issued and sold by the Company at the time of the issuance or sale (or the time of execution of such agreement to issue or sell, as applicable) of such Convertible Securities for such price per share. For the purposes of this Section 2(b)(ii), the "lowest price per share for which one share of Common Stock is at any time issuable upon the conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof" shall be equal to (1) the lower of (x) the sum of the lowest amounts of consideration (if any) received or receivable by the Company with respect to one share of Common Stock upon the issuance or sale (or pursuant to the agreement to issue or sell, as applicable) of the Convertible Security and upon conversion, exercise or exchange of such Convertible Security or otherwise pursuant to the terms thereof and (y) the lowest conversion price set forth in such Convertible Security for which one share of Common Stock is issuable (or may become issuable assuming all possible market conditions) upon conversion, exercise or exchange thereof or otherwise pursuant to the terms thereof minus (2) the sum of all amounts paid or payable to the holder of such Convertible Security (or any other Person) upon the issuance or sale (or the agreement to issue or sell, as applicable) of such Convertible Security plus the value of any other consideration received or receivable by, or benefit conferred on, the holder of such Convertible Security (or any other Person). Except as contemplated below, no further adjustment of the Exercise Price shall be made upon the actual issuance of such shares of Common Stock upon conversion, exercise or exchange of such Convertible Securities or otherwise pursuant to the terms thereof, and if any such issuance or sale of such Convertible Securities is made upon exercise of any Options for which adjustment of this Warrant has been or is to be made pursuant to other provisions of this Section 2(b), except as contemplated below, no further adjustment of the Exercise Price shall be made by reason of such issuance or sale.

(iii) Change in Option Price or Rate of Conversion. If the purchase or exercise price provided for in any Options, the additional consideration, if any, payable upon the issue, conversion, exercise or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or exercisable or exchangeable for shares of Common Stock increases or decreases at any time (other than proportional changes in conversion or exercise prices, as applicable, in connection with an event referred to in Section 2(a)), the Exercise Price in effect at the time of such increase or decrease shall be adjusted to the Exercise Price which would have been in effect at such time had such Options or Convertible Securities provided for such increased or decreased purchase price, additional consideration or increased or decreased conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of this Section 2(b)(iii), if the terms of any Option or Convertible Security (including, without limitation, any Option or Convertible Security that was outstanding as of the Subscription Date) are increased or decreased in the manner described in the immediately preceding sentence, then such Option or Convertible Security and the shares of Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such increase or decrease. No adjustment pursuant to this Section 2(b) shall be made if such adjustment would result in an increase of the Exercise Price then in effect.

(iv) Calculation of Consideration Received. If any Option and/or Convertible Security and/or Adjustment Right is issued in connection with the issuance or sale or deemed issuance or sale of any other securities of the Company (as determined by the Holder, the "**Primary Security**", and such Option and/or Convertible Security and/or Adjustment Right, the "**Secondary Securities**" and together with the Primary Security, each a "**Unit**"), together comprising one integrated transaction, the aggregate consideration per share of Common Stock with respect to such Primary Security shall be deemed to be the lower of (x) the purchase price of such Unit, (y) if such Primary Security is an Option and/or Convertible Security, the lowest price per share for which one share of Common Stock is at any time issuable upon the exercise or conversion of the Primary Security in accordance with Sections 2(b)(i) or 2(b)(ii) above and (z) the lowest VWAP of the shares of Common Stock on any Trading Day during the five (5) Trading Day period (the "**Adjustment Period**") immediately following the public announcement of such Dilutive Issuance (for the avoidance of doubt, if such public announcement is released prior to the opening of the Principal Market on a Trading Day, such Trading Day shall be the first Trading Day in such five Trading Day period and if this Warrant is exercised, on any given Exercise Date during any such Adjustment Period, solely with respect to such portion of this Warrant exercised on such applicable Exercise Date, such applicable Adjustment Period shall be deemed to have ended on, and included, the Trading Day immediately prior to such Exercise Date). If any shares of Common Stock, Options or Convertible Securities are issued or sold or deemed to have been issued or sold for cash, the consideration received therefor will be deemed to be the net amount of consideration received by the Company therefor. If any shares of Common Stock, Options or Convertible Securities are issued or sold for a consideration other than cash, the amount of such consideration received by the Company will be the fair value of such consideration, except where such consideration consists of publicly traded securities, in which case the amount of consideration received by the Company for such securities will be the arithmetic average of the VWAPs of such security for each of the five (5) Trading Days immediately preceding the date of receipt. If any shares of Common Stock, Options or Convertible Securities are issued to the owners of the non-surviving entity in connection with any merger in which the Company is the surviving entity, the amount of consideration therefor will be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such shares of Common Stock, Options or Convertible Securities (as the case may be). The fair value of any consideration other than cash or publicly traded securities will be determined jointly by the Company and the Holder. If such parties are unable to reach agreement within ten (10) days after the occurrence of an event requiring valuation (the "**Valuation Event**"), the fair value of such consideration will be determined within five (5) Trading Days after the tenth (10th) day following such Valuation Event by an independent, reputable appraiser jointly selected by the Company and the Holder. The determination of such appraiser shall be final and binding upon all parties absent manifest error and the fees and expenses of such appraiser shall be borne by the Company.

(v) Record Date. If the Company takes a record of the holders of shares of Common Stock for the purpose of entitling them (A) to receive a dividend or other distribution payable in shares of Common Stock, Options or in Convertible Securities or (B) to subscribe for or purchase shares of Common Stock, Options or Convertible Securities, then such record date will be deemed to be the date of the issuance or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or the making of such other distribution or the date of the granting of such right of subscription or purchase (as the case may be).

(c) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to Section 2(a), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the adjusted number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment (without regard to any limitations on exercise contained herein).

(d) Board Reconstitution Black Scholes Value. In addition, if there is a reconstitution of the board of directors of the Company whereby three or more members of such board of directors resign or are replaced (a "**Board Reconstitution**"), the Company shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the Board Reconstitution, purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Board Reconstitution Black Scholes Value (as defined herein) of the remaining unexercised portion of this Warrant on the date of the Board Reconstitution. For purposes hereof, "**Board Reconstitution Black Scholes Value**" means the value of the unexercised portion of this Warrant remaining on the date of the Holder's request pursuant to this Section 2(d), which value is calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the highest Closing Sale Price of the Common Stock during the period beginning on the Trading Day immediately preceding the announcement of the Board Reconstitution and ending on the Trading Day of the Holder's request pursuant to this Section 2(d), (ii) a strike price equal to the Exercise Price in effect on the date of the Holder's request pursuant to this Section 2(d), (iii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the greater of (1) the remaining term of this Warrant as of the date of the Holder's request pursuant to this Section 2(d) and (2) the remaining term of this Warrant as of the date of the Holder's request pursuant to this Section 2(d), provided that, for purposes of determining the remaining term and calculating such value, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in such calculation, (iv) a zero cost of borrow and (v) an expected volatility equal to the greater of 100% and the 60 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the earliest to occur of (A) the public disclosure of the applicable Board Reconstitution and (B) the date of the Holder's request pursuant to Section 4(d).

(e) Stock Combination Event Adjustment. If at any time and from time to time on or after the Issuance Date there occurs any stock split, stock dividend, stock combination, reverse stock split, recapitalization or other similar transaction involving the outstanding Common Stock (each, a "**Stock Combination Event**", and such date thereof, the "**Stock Combination Event Date**") and the Event Market Price is less than the Exercise Price then in effect (after giving effect to the adjustment in clause 2(a) above), then on the sixteenth (16th) Trading Day immediately following such Stock Combination Event, the Exercise Price then in effect on such sixteenth (16th) Trading Day (after giving effect to the adjustment in clause 2(a) above) shall be reduced (but in no event increased) to the Event Market Price. For the avoidance of doubt, if the adjustment in the immediately preceding sentence would otherwise result in an increase in the Exercise Price hereunder, no adjustment shall be made.

(f) Other Events. In the event that the Company (or any Subsidiary (as defined in the Securities Purchase Agreement)) shall take any action to which the provisions hereof are not strictly applicable, or, if applicable, would not operate to protect the Holder from dilution or if any event occurs of the type contemplated by the provisions of this Section 2 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features), then the Company's board of directors shall in good faith determine and implement an appropriate adjustment in the Exercise Price and the number of Warrant Shares (if applicable) so as to protect the rights of the Holder, provided that no such adjustment pursuant to this Section 2(f) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2, provided further that if the Holder does not accept such adjustments as appropriately protecting its interests hereunder against such dilution, then the Company's board of directors and the Holder shall agree, in good faith, upon an independent investment bank of nationally recognized standing to make such appropriate adjustments, whose determination shall be final and binding absent manifest error and whose fees and expenses shall be borne by the Company.

(g) Calculations. All calculations under this Section 2 shall be made by rounding to the nearest cent or the nearest 1/100th of a share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company, and the disposition of any such shares shall be considered an issuance or sale of shares of Common Stock.

(h) Voluntary Adjustment By Company. Subject to the rules and regulations of the Principal Market, the Company may at any time during the term of this Warrant, with the prior written consent of the Required Holders (as defined in the Securities Purchase Agreement), reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

3. RIGHTS UPON DISTRIBUTION OF ASSETS. In addition to any adjustments pursuant to Section 2 above or Section 4(a) below, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property, options, evidence of indebtedness or any other assets by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations or restrictions on exercise of this Warrant, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Distribution to the extent of the Maximum Percentage (and shall not be entitled to beneficial ownership of such shares of Common Stock as a result of such Distribution (and beneficial ownership) to the extent of any such excess) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time or times, if ever, as its right thereto would not result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, at which time or times the Holder shall be granted such Distribution (and any Distributions declared or made on such initial Distribution or on any subsequent Distribution held similarly in abeyance) to the same extent as if there had been no such limitation).

4. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS.

(a) Purchase Rights. In addition to any adjustments pursuant to Sections 2 or 3 above, if at any time the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations or restrictions on exercise of this Warrant, including without limitation, the Maximum Percentage) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issuance or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, then the Holder shall not be entitled to participate in such Purchase Right to the extent of the Maximum Percentage (and shall not be entitled to beneficial ownership of such shares of Common Stock as a result of such Purchase Right (and beneficial ownership) to the extent of any such excess) and such Purchase Right to such extent shall be held in abeyance for the benefit of the Holder until such time or times, if ever, as its right thereto would not result in the Holder and the other Attribution Parties exceeding the Maximum Percentage, at which time or times the Holder shall be granted such right (and any Purchase Right granted, issued or sold on such initial Purchase Right or on any subsequent Purchase Right held similarly in abeyance) to the same extent as if there had been no such limitation).

(b) Fundamental Transactions. The Company shall not enter into or be party to a Fundamental Transaction unless (i) the Successor Entity assumes in writing all of the obligations of the Company under this Warrant and the other Transaction Documents (as defined in the Securities Purchase Agreement) in accordance with the provisions of this Section 4(b) pursuant to written agreements in form and substance satisfactory to the Holder and approved by the Holder prior to such Fundamental Transaction, including agreements to deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant, including, without limitation, which is exercisable for a corresponding number of shares of capital stock equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such adjustments to the number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction) and (ii) the Successor Entity (including its Parent Entity) is a publicly traded corporation whose common stock is quoted on or listed for trading on an Eligible Market. Upon the consummation of each Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of the applicable Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of each Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the applicable Fundamental Transaction, in lieu of the shares of Common Stock (or other securities, cash, assets or other property (except such items still issuable under Sections 3 and 4(a) above, which shall continue to be receivable thereafter)) issuable upon the exercise of this Warrant prior to the applicable Fundamental Transaction, such shares of publicly traded common stock (or its equivalent) of the Successor Entity (including its Parent Entity) which the Holder would have been entitled to receive upon the happening of the applicable Fundamental Transaction had this Warrant been exercised immediately prior to the applicable Fundamental Transaction (without regard to any limitations on the exercise of this Warrant), as adjusted in accordance with the provisions of this Warrant. Notwithstanding the foregoing, and without limiting Section 1(f) hereof, the Holder may elect, at its sole option, by delivery of written notice to the Company to waive this Section 4(b) to permit the Fundamental Transaction without the assumption of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of each Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the applicable Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property (except such items still issuable under Sections 3 and 4(a) above, which shall continue to be receivable thereafter)) issuable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of the applicable Fundamental Transaction had this Warrant been exercised immediately prior to the applicable Fundamental Transaction (without regard to any limitations on the exercise of this Warrant). Provision made pursuant to the preceding sentence shall be in a form and substance reasonably satisfactory to the Holder.

(c) Black Scholes Value. Notwithstanding the foregoing and the provisions of Section 4(b) above, at the request of the Holder delivered at any time commencing on the earliest to occur of (x) the public disclosure of any Fundamental Transaction, (y) the consummation of any Fundamental Transaction and (z) the Holder first becoming aware of any Fundamental Transaction through the date that is ninety (90) days after the public disclosure of the consummation of such Fundamental Transaction by the Company pursuant to a Current Report on Form 8-K filed with the SEC, the Company or the Successor Entity (as the case may be) shall purchase this Warrant from the Holder on the date of such request by paying to the Holder cash in an amount equal to the Black Scholes Value of the remaining unexercised portion of this Warrant (calculated as set forth in Section 2(d), including, without limitation, Section 2(d)(iii)(2)). Payment of such amounts shall be made by the Company (or at the Company's direction) to the Holder on or prior to the later of (x) the second (2nd) Trading Day after the date of such request and (y) the date of consummation of such Fundamental Transaction.

(d) Application. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied as if this Warrant (and any such subsequent warrants) were fully exercisable and without regard to any limitations on the exercise of this Warrant (provided that the Holder shall continue to be entitled to the benefit of the Maximum Percentage, applied however with respect to shares of capital stock registered under the 1934 Act and thereafter receivable upon exercise of this Warrant (or any such other warrant)).

5. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation (as defined in the Securities Purchase Agreement), Bylaws (as defined in the Securities Purchase Agreement) or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issuance or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (a) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, and (b) shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and non-assessable shares of Common Stock upon the exercise of this Warrant. Notwithstanding anything herein to the contrary, if after the sixty (60) calendar day anniversary of the Issuance Date, the Holder is not permitted to exercise this Warrant in full for any reason (other than pursuant to restrictions set forth in Section 1(f) hereof), the Company shall use its best efforts to promptly remedy such failure, including, without limitation, obtaining such consents or approvals as necessary to permit such exercise into shares of Common Stock.

6. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in its capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of capital stock of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in its capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company. Notwithstanding this Section 6, the Company shall provide the Holder with copies of the same notices and other information given to the stockholders of the Company generally, contemporaneously with the giving thereof to the stockholders; provided that the Company shall have no such obligation to the extent such information is filed with the SEC through EDGAR and are available to the public through the EDGAR system.

7. REISSUANCE OF WARRANTS.

(a) Transfer of Warrant. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 7(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 7(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant (as to which a written certification and the indemnification contemplated below shall suffice as such evidence), and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary and reasonable form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 7(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 7(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, no warrants for fractional shares of Common Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 7(a) or Section 7(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

(e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

8. NOTICES. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in accordance with Section 9(f) of the Securities Purchase Agreement. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant (other than the issuance of shares of Common Stock upon exercise in accordance with the terms hereof), including in reasonable detail a description of such action and the reason therefor. Without limiting the generality of the foregoing, the Company will give written notice to the Holder (i) immediately upon each adjustment of the Exercise Price and the number of Warrant Shares, setting forth in reasonable detail, and certifying, the calculation of such adjustment(s), (ii) at least fifteen (15) days prior to the date on which the Company closes its books or takes a record (A) with respect to any dividend or distribution upon the Common Stock, (B) with respect to any grants, issuances or sales of any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property to holders of Common Stock or (C) for determining rights to vote with respect to any Fundamental Transaction, dissolution or liquidation, provided in each case that such information shall be made known to the public prior to or in conjunction with such notice being provided to the Holder, and (iii) at least ten (10) Trading Days prior to the consummation of any Fundamental Transaction. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its Subsidiaries, the Company shall simultaneously file such notice with the SEC (as defined in the Securities Purchase Agreement) pursuant to a Current Report on Form 8-K. If the Company or any of its Subsidiaries provides material non-public information to the Holder that is not simultaneously filed in a Current Report on Form 8-K and the Holder has not agreed to receive such material non-public information, the Company hereby covenants and agrees that the Holder shall not have any duty of confidentiality to the Company, any of its Subsidiaries or any of their respective officers, directors, employees, affiliates or agents with respect to, or a duty to any of the foregoing not to trade on the basis of, such material non-public information. It is expressly understood and agreed that the time of execution specified by the Holder in each Exercise Notice shall be definitive and may not be disputed or challenged by the Company.

9. DISCLOSURE. Upon delivery by the Company to the Holder (or receipt by the Company from the Holder) of any notice in accordance with the terms of this Warrant, unless the Company has in good faith determined that the matters relating to such notice do not constitute material, non-public information relating to the Company or any of its Subsidiaries, the Company shall on or prior to 9:00 am, New York City time on the Business Day immediately following such notice delivery date, publicly disclose such material, non-public information on a Current Report on Form 8-K or otherwise. In the event that the Company believes that a notice contains material, non-public information relating to the Company or any of its Subsidiaries, the Company so shall indicate to the Holder explicitly in writing in such notice (or immediately upon receipt of notice from the Holder, as applicable), and in the absence of any such written indication in such notice (or notification from the Company immediately upon receipt of notice from the Holder), the Holder shall be entitled to presume that information contained in the notice does not constitute material, non-public information relating to the Company or any of its Subsidiaries. Nothing contained in this Section 9 shall limit any obligations of the Company, or any rights of the Holder, under Section 4(i) of the Securities Purchase Agreement.

10. ABSENCE OF TRADING AND DISCLOSURE RESTRICTIONS. The Company acknowledges and agrees that the Holder is not a fiduciary or agent of the Company and that the Holder shall have no obligation to (a) maintain the confidentiality of any information provided by the Company or (b) refrain from trading any securities while in possession of such information in the absence of a written non-disclosure agreement signed by an officer of the Holder that explicitly provides for such confidentiality and trading restrictions. In the absence of such an executed, written non-disclosure agreement, the Company acknowledges that the Holder may freely trade in any securities issued by the Company, may possess and use any information provided by the Company in connection with such trading activity, and may disclose any such information to any third party.

11. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant (other than Section 1(f)) may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Required Holders (as defined in the Securities Purchase Agreement). No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

12. SEVERABILITY. If any provision of this Warrant is prohibited by law or otherwise determined to be invalid or unenforceable by a court of competent jurisdiction, the provision that would otherwise be prohibited, invalid or unenforceable shall be deemed amended to apply to the broadest extent that it would be valid and enforceable, and the invalidity or unenforceability of such provision shall not affect the validity of the remaining provisions of this Warrant so long as this Warrant as so modified continues to express, without material change, the original intentions of the parties as to the subject matter hereof and the prohibited nature, invalidity or unenforceability of the provision(s) in question does not substantially impair the respective expectations or reciprocal obligations of the parties or the practical realization of the benefits that would otherwise be conferred upon the parties. The parties will endeavor in good faith negotiations to replace the prohibited, invalid or unenforceable provision(s) with a valid provision(s), the effect of which comes as close as possible to that of the prohibited, invalid or unenforceable provision(s).

13. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. The Company hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to the Company at the address set forth in Section 9(f) of the Securities Purchase Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. The Company hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Nothing contained herein shall be deemed or operate to preclude the Holder from bringing suit or taking other legal action against the Company in any other jurisdiction to collect on the Company's obligations to the Holder, to realize on any collateral or any other security for such obligations, or to enforce a judgment or other court ruling in favor of the Holder. **THE COMPANY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS WARRANT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

14. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any Person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant. Terms used in this Warrant but defined in the other Transaction Documents shall have the meanings ascribed to such terms on the Closing Date (as defined in the Securities Purchase Agreement) in such other Transaction Documents unless otherwise consented to in writing by the Holder.

15. DISPUTE RESOLUTION.

(a) Submission to Dispute Resolution.

(i) In the case of a dispute relating to the Exercise Price, the Closing Sale Price, the Bid Price, Black Scholes Consideration Value, Black Scholes Value or fair market value or the arithmetic calculation of the number of Warrant Shares (as the case may be) (including, without limitation, a dispute relating to the determination of any of the foregoing), the Company or the Holder (as the case may be) shall submit the dispute to the other party via electronic mail (A) if by the Company, within two (2) Business Days after the occurrence of the circumstances giving rise to such dispute or (B) if by the Holder, at any time after the Holder learned of the circumstances giving rise to such dispute. If the Holder and the Company are unable to promptly resolve such dispute relating to such Exercise Price, such Closing Sale Price, such Bid Price, such Black Scholes Consideration Value, Black Scholes Value or such fair market value or such arithmetic calculation of the number of Warrant Shares (as the case may be), at any time after the second (2nd) Business Day following such initial notice by the Company or the Holder (as the case may be) of such dispute to the Company or the Holder (as the case may be), then the Holder may, at its sole option, select an independent, reputable investment bank to resolve such dispute.

(ii) The Holder and the Company shall each deliver to such investment bank (A) a copy of the initial dispute submission so delivered in accordance with the first sentence of this Section 15 and (B) written documentation supporting its position with respect to such dispute, in each case, no later than 5:00 p.m. (New York time) by the fifth (5th) Business Day immediately following the date on which the Holder selected such investment bank (the "**Dispute Submission Deadline**") (the documents referred to in the immediately preceding clauses (A) and (B) are collectively referred to herein as the "**Required Dispute Documentation**") (it being understood and agreed that if either the Holder or the Company fails to so deliver all of the Required Dispute Documentation by the Dispute Submission Deadline, then the party who fails to so submit all of the Required Dispute Documentation shall no longer be entitled to (and hereby waives its right to) deliver or submit any written documentation or other support to such investment bank with respect to such dispute and such investment bank shall resolve such dispute based solely on the Required Dispute Documentation that was delivered to such investment bank prior to the Dispute Submission Deadline). Unless otherwise agreed to in writing by both the Company and the Holder or otherwise requested by such investment bank, neither the Company nor the Holder shall be entitled to deliver or submit any written documentation or other support to such investment bank in connection with such dispute (other than the Required Dispute Documentation).

(iii) The Company and the Holder shall cause such investment bank to determine the resolution of such dispute and notify the Company and the Holder of such resolution no later than ten (10) Business Days immediately following the Dispute Submission Deadline. The fees and expenses of such investment bank shall be borne solely by the Company, and such investment bank's resolution of such dispute shall be final and binding upon all parties absent manifest error.

(b) Miscellaneous. The Company expressly acknowledges and agrees that (i) this Section 15 constitutes an agreement to arbitrate between the Company and the Holder (and constitutes an arbitration agreement) under the rules then in effect under § 7501, et seq. of the New York Civil Practice Law and Rules ("**CPLR**") and that the Holder is authorized to apply for an order to compel arbitration pursuant to CPLR § 7503(a) in order to compel compliance with this Section 15, (ii) the terms of this Warrant and each other applicable Transaction Document shall serve as the basis for the selected investment bank's resolution of the applicable dispute, such investment bank shall be entitled (and is hereby expressly authorized) to make all findings, determinations and the like that such investment bank determines are required to be made by such investment bank in connection with its resolution of such dispute, (iii) the Holder (and only the Holder), in its sole discretion, shall have the right to submit any dispute described in this Section 15 to any state or federal court sitting in The City of New York, Borough of Manhattan in lieu of utilizing the procedures set forth in this Section 15 and
(iv) nothing in this Section 15 shall limit the Holder from obtaining any injunctive relief or other equitable remedies (including, without limitation, with respect to any matters described in this Section 15).

16. REMEDIES, CHARACTERIZATION, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remediesp rovided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant and the other Transaction Documents, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Warrant. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, exercises and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holder of this Warrant shall be entitled, in addition to all other available remedies, to specific performance and/or temporary, preliminary and permanent injunctive or other equitable relief from any court of competent jurisdiction in any such case without the necessity of proving actual damages and without posting a bond or other security. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Warrant (including, without limitation, compliance with Section 2 hereof). The issuance of shares and certificates for shares as contemplated hereby upon the exercise of this Warrant shall be made without charge to the Holder or such shares for any issuance tax or other costs in respect thereof, provided that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than the Holder or its agent on its behalf.

17. PAYMENT OF COLLECTION, ENFORCEMENT AND OTHER COSTS. If (a) this Warrant is placed in the hands of an attorney for collection or enforcement or is collected or enforced through any legal proceeding or the holder otherwise takes action to collect amounts due under this Warrant or to enforce the provisions of this Warrant or (b) there occurs any bankruptcy, reorganization, receivership of the company or other proceedings affecting company creditors' rights and involving a claim under this Warrant, then the Company shall pay the costs incurred by the Holder for such collection, enforcement or action or in connection with such bankruptcy, reorganization, receivership or other proceeding, including, without limitation, attorneys' fees and disbursements.

18. TRANSFER. This Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company, except as may otherwise be required by Section 2(g) of the Securities Purchase Agreement and applicable securities laws.

19. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**1933 Act**" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

(b) "**1934 Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

(c) "**Adjustment Right**" means any right granted with respect to any securities issued in connection with, or with respect to, any issuance or sale (or deemed issuance or sale in accordance with Section 2) of Common Stock (other than rights of the type described in Section 3 and 4 hereof) that could result in a decrease in the net consideration received by the Company in connection with, or with respect to, such securities (including, without limitation, any cash settlement rights, cash adjustment or other similar rights).

(d) "**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such Person, it being understood for purposes of this definition that "control" of a Person means the power directly or indirectly either to vote 10% or more of the stock having ordinary voting power for the election of directors of such Person or direct or cause the direction of the management and policies of such Person whether by contract or otherwise.

(e) "**Attribution Parties**" means, collectively, the following Persons and entities: (i) any investment vehicle, including, any funds, feeder funds or managed accounts, currently, or from time to time after the Issuance Date, directly or indirectly managed or advised by the Holder's investment manager or any of its Affiliates or principals, (ii) any direct or indirect Affiliates of the Holder or any of the foregoing, (iii) any Person acting or who could be deemed to be acting as a Group together with the Holder or any of the foregoing and (iv) any other Persons whose beneficial ownership of the Company's Common Stock would or could be aggregated with the Holder's and the other Attribution Parties for purposes of Section 13(d) of the 1934 Act. For clarity, the purpose of the foregoing is to subject collectively the Holder and all other Attribution Parties to the Maximum Percentage.

(f) "**Bid Price**" means, for any security as of the particular time of determination, the bid price for such security on the Principal Market as reported by Bloomberg as of such time of determination, or, if the Principal Market is not the principal securities exchange or trading market for such security, the bid price of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg as of such time of determination, or if the foregoing does not apply, the bid price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg as of such time of determination, or, if no bid price is reported for such security by Bloomberg as of such time of determination, the average of the bid prices of any market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices) as of such time of determination. If the Bid Price cannot be calculated for a security as of the particular time of determination on any of the foregoing bases, the Bid Price of such security as of such time of determination shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during such period.

(g) "**Black Scholes Consideration Value**" means the value of the applicable Option, Convertible Security or Adjustment Right (as the case may be) as of the date of issuance thereof calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the Closing Sale Price of the Common Stock on the Trading Day immediately preceding the public announcement of the execution of definitive documents with respect to the issuance of such Option or Convertible Security (as the case may be), (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of such Option, Convertible Security or Adjustment Right (as the case may be) as of the date of issuance of such Option, Convertible Security or Adjustment Right (as the case may be), (iii) a zero cost of borrow and (iv) an expected volatility equal to the greater of 100% and the 30 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the date of issuance of such Option, Convertible Security or Adjustment Right (as the case may be), provided that, for purposes of this definition and any calculations hereunder, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in any such calculation.

(h) "**Black Scholes Value**" means the value of the unexercised portion of this Warrant remaining on the date of the Holder's request pursuant to Section 4(c)(i), which value is calculated using the Black Scholes Option Pricing Model obtained from the "OV" function on Bloomberg utilizing (i) an underlying price per share equal to the greater of (1) the highest Closing Sale Price of the Common Stock during the period beginning on the Trading Day immediately preceding the announcement of the applicable Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to Section 4(c)(i) and (2) the sum of the price per share being offered in cash in the applicable Fundamental Transaction (if any) plus the value of the non-cash consideration being offered in the applicable Fundamental Transaction (if any), (ii) a strike price equal to the Exercise Price in effect on the date of the Holder's request pursuant to Section 4(c)(i), (iii) a risk- free interest rate corresponding to the U.S. Treasury rate for a period equal to the greater of (1) the remaining term of this Warrant as of the date of the Holder's request pursuant to Section 4(c)(i) and (2) the remaining term of this Warrant as of the date of consummation of the applicable Fundamental Transaction or as of the date of the Holder's request pursuant to Section 4(c)(i) if such request is prior to the date of the consummation of the applicable Fundamental Transaction, (iv) a zero cost of borrow and (v) an expected volatility equal to the greater of 100% and the 30 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the earliest to occur of (A) the public disclosure of the applicable Fundamental Transaction and (B) the date of the Holder's request pursuant to Section 4(c)(i), provided that for purposes of this definition and any calculations hereunder, the remaining term of this Warrant shall be deemed to be the remaining term of the SPA Warrants originally issued under the Securities Purchase Agreement, as such term may be modified from time to time and, provided, further, that if none of those SPA Warrants remain outstanding at the time of any such calculation, the then remaining term of this Warrant shall be used in any such calculation.

(i) "**Bloomberg**" means Bloomberg, L.P.

(j) "**Business Day**" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; p rovided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

(k) "**Closing Sale Price**" means, for any security as of any date, the last closing trade price for such security on the Principal Market, as reported by Bloomberg, or, if the Principal Market begins to operate on an extended hours basis and does not designate the closing trade price, then the last trade price of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Principal Market is not the principal securities exchange or trading market for such security, the last trade price of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing does not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no last trade price is reported for such security by Bloomberg, the average of the ask prices of any market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices). If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during such period.

(l) "**Common Stock**" means (i) the Company's shares of common stock, $0.0001 par value per share, and (ii) any capital stock into which such common stock shall have been changed or any capital stock resulting from a reclassification of such common stock.

(m) "**Convertible Securities**" means any stock or other security (other than Options) that is at any time and under any circumstances, directly or indirectly, convertible into, exercisable or exchangeable for, or which otherwise entitles the holder thereof to acquire, any Common Stock.

(n) "**Eligible Market**" means The New York Stock Exchange, the NYSE American, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or the Principal Market.

(o) **[Reserved]**

(p) "**Event Market Price**" means, with respect to any Stock Combination Event Date, the quotient determined by dividing (x) the sum of the VWAP of the Common Stock for each of the five (5) lowest Trading Days during the twenty (20) consecutive Trading Day period ending and including the Trading Day immediately preceding the sixteenth (16th) Trading Day after such Stock Combination Event Date, divided by (y) five (5). All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination, recapitalization or other similar transaction during such period.

(o) "**Expiration Date**" means the date that is the fifth (5th) anniversary of the Issuance Date or, if such date falls on a day other than a Trading Day or on which trading does not take place on the Principal Market (a "**Holiday**"), the next date that is not a Holiday.

(q) "**Fundamental Transaction**" means (A) that the Company shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Subject Entity, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company or any of its "significant subsidiaries" (as defined in Rule 1-02 of Regulation S-X) to one or more Subject Entities, or (iii) make, or allow one or more Subject Entities to make, or allow the Company to be subject to or have its Common Stock be subject to or party to one or more Subject Entities making, a purchase, tender or exchange offer that is accepted by the holders of at least either (x) 50% of the outstanding shares of Common Stock, (y) 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all Subject Entities making or party to, or Affiliated with any Subject Entities making or party to, such purchase, tender or exchange offer were not outstanding; or (z) such number of shares of Common Stock such that all Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such purchase, tender or exchange offer, become collectively the beneficial owners (as defined in Rule 13d-3 under the 1934 Act) of at least 50% of the outstanding shares of Common Stock, or (iv) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with one or more Subject Entities whereby all such Subject Entities, individually or in the aggregate, acquire, either (x) at least 50% of the outstanding shares of Common Stock, (y) at least 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all the Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such stock purchase agreement or other business combination were not outstanding; or (z) such number of shares of Common Stock such that the Subject Entities become collectively the beneficial owners (as defined in Rule 13d-3 under the 1934 Act) of at least 50% of the outstanding shares of Common Stock, or (v) reorganize, recapitalize or reclassify its Common Stock, (B) that the Company shall, directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, allow any Subject Entity individually or the Subject Entities in the aggregate to be or become the "beneficial owner" (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, whether through acquisition, purchase, assignment, conveyance, tender, tender offer, exchange, reduction in outstanding shares of Common Stock, merger, consolidation, business combination, reorganization, recapitalization, spin-off, scheme of arrangement, reorganization, recapitalization or reclassification or otherwise in any manner whatsoever, of either (x) at least 50% of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock, (y) at least 50% of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock not held by all such Subject Entities as of the date of this Warrant calculated as if any shares of Common Stock held by all such Subject Entities were not outstanding, or (z) a percentage of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock or other equity securities of the Company sufficient to allow such Subject Entities to effect a statutory short form merger or other transaction requiring other stockholders of the Company to surrender their shares of Common Stock without approval of the stockholders of the Company or (C) directly or indirectly, including through subsidiaries, Affiliates or otherwise, in one or more related transactions, the issuance of or the entering into any other instrument or transaction structured in a manner to circumvent, or that circumvents, the intent of this definition in which case this definition shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this definition to the extent necessary to correct this definition or any portion of this definition which may be defective or inconsistent with the intended treatment of such instrument or transaction.

(r) "**Group**" means a "group" as that term is used in Section 13(d) of the 1934 Act and as defined in Rule 13d-5 thereunder.

(s) **[Reserved]**

(t) **[Reserved]**

(u) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(v) "**Parent Entity**" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(w) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity or a government or any department or agency thereof.

(x) "**Principal Market**" means the Nasdaq Capital Market.

(y) "**Registration Rights Agreement**" means that certain registration rights agreement, dated as of the Closing Date, by and among the Company and the Buyers of the Preferred Shares and SPA Warrants relating to, among other things, the registration of the resale of the shares of Common Stock issuable upon conversion of the Preferred Shares or otherwise pursuant to the terms of the Certificate of Designations and exercise of the SPA Warrants, as may be amended from time to time.

(z) "**SEC**" means the United States Securities and Exchange Commission or the successor thereto.

(aa) "**Subject Entity**" means any Person, Persons or Group or any Affiliate or associate of any such Person, Persons or Group.

(ab) "**Successor Entity**" means the Person (or, if so elected by the Holder, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Holder, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(ac) "**Trading Day**" means, as applicable, (x) with respect to all price or trading volume determinations relating to the Common Stock, any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded, provided that "Trading Day" shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock is suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time) unless such day is otherwise designated as a Trading Day in writing by the Holder or (y) with respect to all determinations other than price or trading volume determinations relating to the Common Stock, any day on which The New York Stock Exchange (or any successor thereto) is open for trading of securities.

(ad) **[Reserved]**

(ae) "**VWAP**" means, for any security as of any date, the dollar volume-weighted average price for such security on the Principal Market (or, if the Principal Market is not the principal trading market for such security, then on the principal securities exchange or securities market on which such security is then traded), during the period beginning at 9:30 a.m., New York time, and ending at 4:00 p.m., New York time, as reported by Bloomberg through its "VAP" function (set to 09:30 start time and 16:00 end time) or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30 a.m., New York time, and ending at 4:00 p.m., New York time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices). If the VWAP cannot be calculated for such security on such date on any of the foregoing bases, the VWAP of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved in accordance with the procedures in Section 15. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination, recapitalization or other similar transaction during such period.

[*signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

PHARMACYTE BIOTECH, INC.

By: _____

Name: Carlos A. Trujillo
Title: Chief Financial Officer

EXHIBIT A

EXERCISE NOTICE
TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS
WARRANT TO PURCHASE COMMON STOCK
PHARMACYTE BIOTECH, INC.

The undersigned holder hereby elects to exercise the Warrant to Purchase Common Stock No._____(the "**Warrant**") of PHARMACYTE BIOTECH, INC., a Nevada corporation (the "**Company**"), as specified below. Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Form of Exercise Price. The Holder intends that payment of the Aggregate Exercise Price shall be made as:
☐ a "Cash Exercise" with respect to_____ Warrant Shares; and/or
☐ a "Cashless Exercise" with respect to_____ Warrant Shares.

In the event that the Holder has elected a Cashless Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the Holder hereby represents and warrants that (i) this Exercise Notice was executed by the Holder at_____ [a.m.][p.m.] on the date set forth below and (ii) if applicable, the Bid Price as of such time of execution of this Exercise Notice was
$_____

2. Payment of Exercise Price. In the event that the Holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the Holder shall pay the Aggregate Exercise Price in the sum of $_____
to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver to Holder, or its designee or agent as specified below,_____ shares of Common Stock in accordance with the terms of the Warrant. Delivery shall be made to Holder, or for its benefit, as follows:

☐ Check here if requesting delivery as a certificate to the following name and to the following address: Issue to:
_____
_____
_____

☐ Check here if requesting delivery by Deposit/Withdrawal at Custodian as follows:
DTC Participant: _____

DTC Number: _____

Account Number: _____

_____

Date:_____
Name of Registered Holder

By:_____
Name:
Title:

Tax ID: _____
E-mail:
Address: _____

EXHIBIT B

ACKNOWLEDGMENT

The Company hereby acknowledges this Exercise Notice and hereby directs_____to issue the above indicated number of shares of Common Stock in accordance with the Transfer Agent Instructions dated_____, 2023, from the Company and acknowledged and agreed to by_____.

PHARMACYTE BIOTECH, INC.

By:_____
Name:
Title:

Exhibit 10.43

EXECUTIVE COMPENSATION AGREEMENT

This Executive Compensation Agreement ("Agreement") is entered into as of August 8, 2025, effective as of January 1, 2025 ("Effective Date"), by and between PharmaCyte Biotech, Inc. a Nevada corporation (together with its successors and assigns, "Company"), and Josh Silverman ("Executive"). The Company and Executive are each referred to in this Agreement as a "Party" and collectively as "Parties."

RECITALS

WHEREAS, the Company currently employs Executive as its Interim Chief Executive Officer, President and Executive Chairman; and

WHEREAS, the Company desires to continue to employ Executive, and Executive desires to continue to serve, as the Company's Chief Executive Officer, President and Executive Chairman in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the promises, mutual covenants, the above recitals, and the agreements herein set forth, and for other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. TERM. This Agreement shall be for a term commencing on the Effective Date and ending on the third anniversary of the Effective Date (such period of employment "Initial Term"), followed by automatic renewals of one (1) year thereafter (each a "Renewal Term" and, together with the Initial Term, "Term") unless the Company or Executive provides written notice of termination to the other Party at least ninety (90) days prior to the end of the Initial Term or any Renewal Term. For the purposes hereof, the termination of this Agreement due to the Company providing written notice of termination pursuant to this Section 1 at least ninety (90) days prior to the end of the Initial Term or any Renewal Term will be deemed to be a termination of Executive's employment by Company without Cause.

2. POSITION; DUTIES. Executive shall be employed as: (i) a member of the Company's Board of Directors ("Board"); and (ii) Chief Executive Officer, President and Executive Chairman of the Company and shall have the authorities and responsibilities customarily associated with the status of such positions at Nasdaq listed biotechnology companies of the same size as the Company. In his capacity as Chief Executive Officer, Executive shall report directly to the Board and shall have ultimate responsibility for all the Company's current and future operations in the U.S. and abroad. Upon termination of Executive's employment for any reason, if and to the extent requested by the Company, Executive shall remain on the Board but shall promptly resign from all other positions that Executive then holds with the Company or any affiliate and promptly execute all documentation for such resignations.

Executive shall devote a reasonable amount of his business time, effort and energies to the business of the Company as is necessary to fulfill his duties and responsibilities hereunder; provided, however, that notwithstanding the foregoing, Executive may: (i) serve as an officer or director of any of the entities for whom he serves as such on the Effective Date or any other entity that engages Executive as an officer or director in the future; (ii) engage in civic, charitable, public service and community activities and affairs; (iii) accept and fulfill a reasonable number of speaking engagements; and (iv) manage his personal investments and affairs, as long as such activities do not, in Executive's reasonable and good faith judgment, interfere, individually or in the aggregate, with his obligations and the proper performance his duties and responsibilities to the Company under this Agreement in any material respect.

3. COMPENSATION AND BENEFITS. Subject in each case to the provisions of Section 4 of this Agreement in the event that his employment hereunder terminates, Executive shall be entitled to the following compensation and benefits during the Term.

(A) Base Salary. The Company will pay Executive a base salary at an annual rate of $375,000 payable in accordance with the Company's usual payroll practices. The Compensation Committee of the Board may increase the base salary annually in its discretion. The annual rate of Executive's base salary as in effect from time to time is referred to herein as "Base Salary."

(B) Bonus. With respect to each calendar year during the Term, Executive shall be eligible to earn an annual performance-based bonus pursuant to the terms of the applicable annual bonus plan established by the Company (the "Annual Bonus"). Any earned Annual Bonus with respect to any calendar year during the Term shall be paid to Executive between January 1st and March 15th of the immediately following calendar year, provided that, Executive is employed by the Company on the date such Annual Bonus is paid. The payment of any Annual Bonus shall be subject to all federal, state and withholding taxes, social security deductions and other general withholding obligations. Award of an Annual Bonus with respect to a particular calendar year does not guarantee the award of an Annual Bonus in any subsequent calendar year.

(C) Equity Compensation. As soon as administratively practicable following the Effective Date (and, in any event, no later than 30 days following the Effective Date), the Company shall grant to Executive long-term incentive awards under the Company's long-term equity incentive plan (the "LTIP") on such terms and conditions as the Board and the Compensation Committee of the Board shall determine and approve in their sole discretion. In addition, with respect to each calendar year during the Term, provided that Executive is employed by the Company on the applicable date of grant, Executive shall receive annual long-term incentive awards under the LTIP on such terms and conditions as the Board and the Compensation Committee of the Board shall determine in their sole discretion, with Executive's target annual equity award grant date fair value to equal 300% of Executive's Base Salary. All awards granted to Executive under the LTIP shall be subject to and governed by the terms and provisions of the LTIP as in effect from time to time and the award agreements evidencing such awards.

(D) Board Fees. Executive will not be entitled to any cash fees or other payments or equity grants for service as a director.

(E) Expense Reimbursement. The Company will reimburse Executive for business expenses reasonably incurred by him in the performance of his duties with the Company, in accordance with the Company's usual practices.

(F) Other Benefits. Executive will be entitled to participate in the Company's incentive and employee benefit plans and programs applicable to senior executives generally as in effect from time to time, including, without limitation, medical, dental, vision and term life insurance, and on a basis no less favorable than those provided to other senior executives. Executive will also be entitled to participate in the Company's 401(k) plan, if any.

(G) Vacation. Executive will be entitled to five (5) weeks of vacation annually (or such greater amount provided in applicable Company policies or as may be provided to any other senior executive of the Company) to be taken at times determined by Executive; provided, however, that unused vacation for one (1) year may be carried over to the next year if and to the extent that the unused vacation is attributable to business exigencies of the Company. Executive will also be entitled to two (2) weeks of paid sick leave subject to the Company's paid sick leave policy as in effect from time to time.

4. CONSEQUENCES OF TERMINATION. The payments under this Section 4 are the only termination payments to which Executive is entitled upon termination of his employment prior to the end of the Term regardless of the date during the Term in which employment is terminated.

(A) Termination by Company for Cause or Termination by Executive without Good Reason. If Executive's employment under this Agreement is terminated prior to the end of the Term by the Company for Cause (as defined below) or by Executive without Good Reason (as defined below), Executive will be entitled to receive the following (promptly following such termination in the case of clause (i)):

(i) Base Salary earned through the date that Executive's employment hereunder terminates ("Termination Date"); and

(ii) unpaid expense reimbursements and vested amounts and benefits, if any, in accordance with the terms of any applicable plan, program, corporate governance document, policy, agreement or arrangement of the Company other than the additional benefits provided to Executive under the terms of this Agreement (collectively, "Accrued Compensation").

"Cause" shall mean: a good faith determination by the Board, that any of the following has occurred: (i) Executive's conviction of, or plea of guilty or nolo contendere to, a felony; (ii) Executive's theft of material Company property; (iii) willful misconduct or an act of moral turpitude which is materially injurious to the Company, monetarily or otherwise; or (iv) Executive's material breach of this Agreement, including, without limitation, the confidentiality obligations set forth in Section 5 below. No termination of Executive's employment will be treated as for "Cause" unless, prior to such termination, Executive has been provided written notice from a majority of the Board setting forth in reasonable detail the basis on which the Company is terminating his employment for "Cause" and, if the condition is curable, Executive will then have fifteen (15) days from receipt of such notice during which he may remedy the condition. If full cure is made by Executive within such fifteen (15) day cure period, Cause shall be deemed not to have occurred and Executive's employment will be deemed to have continued under and subject to the provisions of this Agreement.

(B) Termination by the Company without Cause or Termination by Executive for Good Reason. If Executive's employment under this Agreement is terminated prior to the end of the Term by the Company without Cause or by Executive for Good Reason, Executive will be entitled to receive the following:

(i) Accrued Compensation;

(ii) Severance equal to two times the sum of (A) Executive's Base Salary in effect at the time his employment terminates and (B) the target bonus for the year of termination prorated based upon the number of days worked for the year of termination (collectively, "Severance Payment"); and

(iii) Accelerated vesting of the unvested portion of any outstanding equity awards.

Subject to satisfaction of the release requirements set forth in the immediately following paragraph, as applicable, any compensation payable pursuant to clause (i) and (iii) of this paragraph (B) shall be paid promptly after the Termination Date. Subject to satisfaction of the release requirements set forth in the immediately following paragraph, as applicable, any amounts payable pursuant to clause (ii) of this paragraph (B) shall be paid ratably for a period of twenty-four (24) months following termination of employment as if it were salary, payable in accordance with the Company's normal payroll practices, provided, however, that the initial installment will begin on the 60th day following the Termination Date and will include the payments that would otherwise have been made during such sixty (60) day period; provided that, to the extent necessary to prevent Executive from being subject to adverse tax consequences under Section 409A of the Internal Revenue Code and the regulations promulgated thereunder ("Section 409A"), the first six (6) months of the continued Severance Payment shall not be paid until, and shall be paid in a single sum payment on, the first day after the six (6) month anniversary of the Termination Date, with the remaining monthly payments to begin on the first day of the seventh month following the Termination Date. For the purposes hereof, if the Company elects not to extend the Term pursuant to Section 1 above, Executive's employment will be deemed to have been terminated by the Company without Cause.

In order to receive any payments or benefits under clauses (ii) and (iii) of this paragraph (B), Executive must execute and deliver to the Company a mutual release of claims provided by the Company in substantially the form of Exhibit A annexed hereto and such release must become irrevocable on or before the 60th day following the Termination Date.

As of the Termination Date, except as set forth herein, Executive shall not be entitled to any further payments or benefits from the Company.

"Good Reason" shall mean the occurrence of any of the following events without Executive's express written consent: (i) a material diminution in Executive's position, title, authority, duties, working conditions or responsibilities, except for a salary reduction implemented as part of across the board salary reductions affecting all similarly situated executives; (ii) a material breach of this Agreement by the Company; or (iii) in connection with a Change of Control, the failure or refusal by the successor or acquiring company (or parent thereof) to expressly assume the obligations of the Company under this Agreement. Executive must provide written notice to the Company of the existence of the condition constituting the Good Reason within thirty (30) days of Executive's having actual knowledge of the existence of the condition and, if the condition is curable, the Company will then have fifteen (15) days from receipt of such notice during which the Company may remedy the condition and not be required to pay the amounts set forth in this Section 4(B). If full cure is made by the Company within such fifteen (15) day cure period, Good Reason shall be deemed not to have occurred and Executive's employment will be deemed to have continued under and subject to the provisions of this Agreement.

(C) Termination on Disability or Death. In the event that the employment of Executive terminates prior to the end of the Term by reason of Disability (as defined below), Executive shall be entitled to the payments set forth in clauses (i), (ii), and (vi) of Section 4(B) including payments under the Company's long term disability insurance plan to the extent provided for therein. The Company may terminate Executive's employment by reason of "Disability" if (and only if) Executive is absent from work for at least one-hundred eighty (180) consecutive days or for one-hundred eighty (180) days (whether or not consecutive) in any calendar year by reason of a physical or mental illness or injury. In the event that the employment of Executive terminates before the end of the Term by reason of death, the amounts set forth in clauses (i), (iii), (iv) and (v) of Section 4(B) shall be paid to his estate and the death benefit under the Company's life insurance program, if any, shall be paid to his designated beneficiary, or estate in the absence of designated beneficiary.

In addition, if Executive's employment under this Agreement is terminated prior to the end of the Term by reason of Disability or death, any unvested equity compensation and any additional option awards that are granted to Executive shall become immediately vested and non-forfeitable on the Termination Date and shall be transferable or exercisable for the remainder of their terms.

(D) Change of Control. If Executive's employment under this Agreement is terminated prior to the end of the Term by the Company without Cause or by Executive for Good Reason within two (2) years after a Change in Control or within six (6) months prior to a Change in Control, Executive will be entitled to the payments and benefits set forth in Section 4(B), provided that the term "two times" in Section 4(B)(ii) shall be changed to "three times", and such amounts under Section 4(B)(ii) shall be paid in a single sum cash payment on the 60th day following his termination of employment, and otherwise subject to the terms thereof (including, without limitation, acceleration of vesting and continuing exercisability of any equity awards).

"Change in Control" means any of the following:

(i) any one person or more than one person acting as a group directly or indirectly acquires ownership of shares of the Company that, together with the shares of the Company held by such person or group, constitutes more than thirty percent (30%) of the total fair market value or total voting power of the shares of the Company; provided, however, that if any one person or more than one person acting as a group is considered to own more than thirty percent (30%) of the total fair market value or total voting power of the shares of the Company, the acquisition of additional shares by the same person or persons shall not constitute a Change of Control under this clause (i). An increase in the percentage of shares of the Company owned by any one person or persons acting as a group as a result of a transaction in which the Company acquires its own shares in exchange for property will be treated as an acquisition of shares of the Company by such person or persons for purposes of this clause (i);

(ii) a majority of the members of the Company's Board are replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the Company's Board prior to the date of such appointment or election; or

(iii) the sale of all or substantially all of the Company's assets.

Notwithstanding the foregoing, a Change in Control shall not occur unless such transaction constitutes a change in the ownership of the Company, a change in effective control of the Company or a change in the ownership of a substantial portion of the Company's assets under Section 409A.

(E) No Mitigation. In the event of any termination of the employment of Executive hereunder prior to the end of the Term, Executive shall be under no obligation to seek other employment, and there shall be no offset against any amounts due him on account of any remuneration attributable to any subsequent employment that he may obtain.

5. CONFIDENTIALITY. Executive recognizes and acknowledges that the continued success of the Company and its affiliates ("Company Group") depends upon the use and protection of a large body of confidential and proprietary information and that Executive will have access to certain Confidential Information (as defined below) of the Company Group, and that such Confidential Information constitutes valuable, special and unique property of the Company Group. "Confidential Information" will be interpreted to include, without limitation, with respect to the Company Group: (i) inventions, technology, know-how, documentation, devices, methods, algorithms, processes, designs, manuals, analyses, improvements, research and development, non-public scientific and medical data and methods, clinical plans, trials and strategies, technical procedures and products; (ii) computer software (including operating systems, applications and program listings); (iii) identities and lists of, individual requirements of, specific contractual arrangements with and information about, employees, customers, vendors, distributors, independent contractors or other business relations and their confidential information; (iv) existing or future products and services (including those under development) and related costs and pricing structures; (v) financial data, accounting and business methods and practices, marketing information and business strategies and operations; (vi) non-public information concerning legal and professional dealings, real property, tangible property and investment activities, and (vii) similar and related confidential information and sensitive information and trade secrets. "Confidential Information" shall not include information that: (i) was in the possession of or known by Executive free of any obligation prior to disclosure by the Company; (ii) is or becomes generally known to the public through disclosure in a printed publication (without breach of any of Executive's obligations hereunder); (iii) was acquired by Executive from a third party who independently generated such information; or (iv) is disclosed pursuant to judicial or governmental order, provided that Executive promptly notifies the Company so that the Company has an adequate opportunity to respond to such order.

Executive shall, during and after his employment by the Company and except in connection with performing services on behalf of (or for the benefit of) the Company or the Company Group, keep secret and retain in the strictest confidence all Confidential Information and shall not disclose such information to any person, entity or any federal, state or local agency or authority, except as may be required by law. Notwithstanding the foregoing, nothing contained herein shall prohibit Executive from filing a charge with, reporting possible violations of federal law or regulation to, participating in any investigation by, or cooperating with any governmental agency or entity or making other disclosures that are protected under the whistleblower provisions of applicable law or regulation.

Upon termination of his employment with the Company, Executive shall return to the Company all confidential, proprietary and non-public materials, and any other property of the Company, in his possession. The personal property of Executive, including documents relating to his benefits, compensation, tax liabilities, personal obligations (e.g., restrictive covenants) and the like, shall not be subject to return pursuant to the preceding sentence.

6. NONDISPARAGEMENT. Executive agrees that the Company's goodwill and reputation are assets of great value to the Company which have been obtained and maintained through great costs, time and effort. Therefore, Executive agrees that during Executive's employment and after the termination of Executive's employment, Executive shall not in any way disparage, libel or defame the Company, its business or business practices, its products or services, or its employees, officers or directors. A violation or threatened violation of this prohibition may be enjoined by the courts. The rights afforded the Company under this provision are in addition to any and all rights and remedies otherwise afforded by law. Nothing in this provision shall prohibit (i) Executive from making truthful statements in good faith in connection with any litigation, arbitration, governmental proceeding or similar proceeding, to defend or prosecute any claim or to the extent required by applicable law, legal process, subpoena, court order or similar requirement; and (ii) Executive from engaging in any criticism or other statements made internally within the Company on a need-to-know basis, and provided such criticism or other statement is not presented in a disruptive or insubordinate manner, concerning the Company's or any employee's or other service provider's performance or nonperformance.

7. COOPERATION. Following any termination of employment, Executive shall reasonably cooperate with the Company in the winding up of pending work on behalf of the Company and the orderly transfer of work to other employees. Executive shall also cooperate with the Company in the defense of any action brought by any third party against the Company that relates to Executive's employment by the Company. In the event that Executive is subpoenaed in connection with any litigation or investigation relating to the Company or its affiliates, Executive will promptly notify the Company. For the avoidance of doubt, Executive will be reimbursed for Executive's reasonable costs and expenses incurred by Executive in complying with the terms of this Section 8. Executive acknowledges that Executive's agreement to provide cooperation as set forth in this Section 8 is material to the Company.

8. REMEDY FOR BREACH AND MODIFICATION. The Parties acknowledge that the provisions of this Agreement are reasonable and necessary for the protection of the Parties and that a Party may be irreparably damaged if these provisions are not specifically enforced. Accordingly, each Party agrees that, in addition to any other relief or remedies available to the Parties, the each Party shall be entitled to obtain appropriate temporary, preliminary and permanent injunctive or other equitable relief for the purposes of restraining the other Party from any actual or threatened breach of or otherwise enforcing these provisions and no bond or security will be required in connection therewith.

9. SEVERABILITY; BLUE PENCIL. If any provision of this Agreement is deemed invalid or unenforceable, such provision shall be deemed modified and limited to the extent necessary to make it valid and enforceable. Executive and the Company agree that the covenants contained in Sections 5 and 6 are reasonable covenants under the circumstances and further agree that if, in the opinion of any court of competent jurisdiction such covenants are not reasonable in any respect, such court shall have the right, power and authority to excise or modify such provision or provisions of these covenants to such narrower scope as it determines to be enforceable and to enforce the remainder of these covenants as so amended. Executive and the Company further agree that if any provision of this Agreement is determined to be unenforceable for any reason, and such provision cannot be reformed by the court as anticipated above, such provision shall be deemed separate and severable and the unenforceability of any such provision shall not invalidate or render unenforceable any of the remaining provisions hereof.

10. COUNTERPARTS; FACSIMILES. This Agreement may be executed in two (2) or more counterparts, each of which shall be considered an original, but all of which together shall constitute the same instrument. Signatures delivered by facsimile or email shall be effective for all purposes.

11. GOVERNING LAW; JURISDICTION.

(A) As a corporation with headquarters in New York, the Company has an interest in having New York law applied to contracts with its employees, as well as disputes with them. Applying New York law in this fashion affords the parties predictability as to the law to be applied, as well as uniformity across the Company's workforce. Consequently, this Agreement and the legal relations thus created between the Parties shall be governed by, and construed and interpreted in accordance with its express terms, and otherwise in accordance with the laws of the State of New York, without regard to its choice of laws or conflicts of laws principles (whether of the State of New York or any other jurisdiction) that would cause the application of the law of any jurisdiction other than the State of New York.

(B) Either Party may seek to enforce this Agreement in the courts of the State of New York. Each Party hereby consents to the non-exclusive jurisdiction of such courts (and the appropriate appellate courts) and waives any objection to lack of jurisdiction or improper or inconvenient venue of any such court. Process in any action or proceeding referred to in the preceding sentence may be served on either Party anywhere in the world, whether within or without the State of New York. By signing below, Executive acknowledges that the Company has advised Executive to obtain legal counsel in negotiating the terms of this Agreement including without limitation this Section 12.

12. NOTICES. Any notice or other communication made or given in connection with this Agreement may be given by counsel, shall be in writing, and, if to a Party, shall be deemed to have been duly given when: (i) delivered to the appropriate address by hand or by nationally recognized overnight courier service (costs prepaid); (ii) sent by electronic mail or facsimile with confirmation of transmission by the transmitting equipment; or (iii) received or rejected by the addressee, if sent by certified mail, return receipt requested, in each case to a Party at his or its address or facsimile number set forth below or at such other address or facsimile number as a Party may specify by notice to the other Party:

To Executive:

Email:
Fax No.:

To the Company:

Fax No.:

13. **ENTIRE AGREEMENT; AMENDMENT**. This Agreement supersedes all prior agreements between the Parties with respect to its subject matter and cannot be changed or terminated orally. Any amendment thereof must be in writing and signed by the Parties.

14. **WAIVER**. The failure of any Party or person to insist upon strict adherence to any term of this Agreement (including all attachments) on any occasion shall not be considered a waiver or deprive that Party or person of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement (including all attachments). Any waiver must be in writing and must specifically identify the provision(s) of this Agreement (including all attachments) being affected.

15. **END OF TERM**. The provisions of Sections 4, 5, 6, 7, 10, 11, 12, and 13 shall continue after the end of the Term.

16. **ASSIGNMENT**. Except as otherwise provided in this Section 17, this Agreement shall inure to the benefit of and be binding upon the Parties and their respective heirs, representatives, successors and assigns. This Agreement shall not be assignable by Executive, and shall be assignable by the Company only to any corporation or other entity that succeeds to all, or substantially all, of the Company's business or assets, and that expressly assumes (or assumes by operation of law in any merger or consolidation) the Company's obligations hereunder; provided, however, that no such assignment shall invalidate or negate the rights of Executive pursuant to the provisions hereof, including, without limitation, any such rights relating to a Change of Control. In any such event, the term "Company," as used herein shall mean the Company, as defined above, and any such successor or assignee. In the event of Executive's death or a judicial determination of his incapacity, references in this Agreement (including its attachments) to the "Executive" shall be deemed to include, as appropriate, his estate, heirs and/or legal representatives.

17. **CODES**. The Board has adopted a Code of Business Conduct and Ethics. Executive is expected to require compliance with those codes by the Company's employees and to comply himself.

18. **DEDUCTIONS**. The Company may deduct from the compensation described herein any applicable Federal, state and/or city withholding taxes, any applicable social security contributions, and any other amounts which may be required to be deducted or withheld by the Company pursuant to any Federal, state or city laws, rules or regulations or any election he shall have made.

19. **SECTION 409A**. Anything in this Agreement to the contrary notwithstanding:

(A) It is intended that any amounts payable under this Agreement will either be exempt from or comply with Section 409A and all regulations, guidance and other interpretive authority issued thereunder so as not to subject Executive to payment of any additional tax penalty or interest imposed under Section 409A, and this Agreement will be interpreted on a basis consistent with such intent. References to Termination Date or termination of employment herein mean a termination of employment that constitutes a "separation from service" within the meaning of Section 409A.

(B) To the extent that the reimbursement of any expenses or the provision of any in- kind benefits under this Agreement is subject to Section 409A: (i) the amount of such expenses eligible for reimbursement, or in-kind benefits to be provided during any one (1) calendar year shall not affect the amount of such expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year (provided that this clause (i) will not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect); (ii) reimbursement of any such expense shall be made by no later than December 31 of the year following the calendar year in which such expense is incurred; and (iii) Executive's right to receive such reimbursements or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

(C) Whenever payments under this Agreement are to be made in installments, each such installment shall be deemed to be a separate payment for purposes of Section 409A. Whenever a payment under this Agreement specifies a payment period with reference to a number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company.

(D) To the extent any amount payable to Executive is subject to his entering into a release of claims with the Company and any such amount is a deferral of compensation under Section 409A and which amount could be payable to Executive in either of two (2) taxable years, and the timing of such payment is not subject to terms and conditions under another plan, program or agreement of the Company that otherwise satisfies Section 409A, such payments shall be made or commence, as applicable, on January 15 (or any later date that is not earlier than eight (8) days after the date that the release becomes irrevocable) of such later taxable year and shall include all payments that otherwise would have been made before such date.

20. CLAWBACK. To the extent required by Company policy, applicable law, government regulation or any applicable securities exchange listing standards, amounts paid or payable under this Agreement or under any equity plan or any incentive plan of the Company shall be subject to the provisions of any applicable clawback policies or procedures adopted by the Company and applicable to executives of the Company generally, including pursuant to applicable law, government regulation or applicable securities exchange listing requirements, which clawback policies or procedures may provide for forfeiture and/or recoupment of amounts paid or payable under this Agreement or under any equity plan or any incentive plan of the Company in the event of material misstatements, financial restatements, other bad acts (or inaction), or other events or occurrences consistent with any government regulation or securities exchange listing requirement. The Company reserves the right, without the consent of Executive, to adopt any such clawback policies and procedures that are consistent with the immediately preceding sentence, including such policies and procedures applicable to this Agreement and under any equity plan or any incentive plan of the Company with retroactive effect.

22. CAPTIONS. The captions in this Agreement are for convenience of reference only and shall not be given any effect in the interpretation of this Agreement.

[Balance of this page left blank intentionally]

IN WITNESS WHEREOF, Executive and the Company have signed this Agreement as of the date first set forth above.

PHARMACYTE BIOTECH, INC

By: _____
Name:
Title:

EXECUTIVE

By: _____
Josh Silverman

Exhibit A

GENERAL RELEASE

1. MUTUAL RELEASE OF ALL CLAIMS

The undersigned individual ("Executive") hereby irrevocably releases and forever discharges any and all known and unknown liabilities, debts, obligations, causes of action, demands, covenants, contracts, liens, controversies and any other claim of whatsoever kind or nature that Executive ever had, now has or may have in the future against PharmaCyte Biotech, Inc. ("Company"), its shareholders, subsidiaries, affiliates, successors, assigns, officers, directors, attorneys, fiduciaries, representatives, employees, licensees, agents and assigns ("Releasees"), to the extent arising out of or related to the performance of any services to or on behalf of the Company or the termination of those services and, other than claims for payments, benefits or entitlements preserved by Section 4 and claims for indemnification, advancement of expenses or coverage under the Company's directors and officers liability insurance, of the Executive Compensation Agreement dated as of _____, 2025, between the Company and Executive ("Employment Agreement"), including without limitation: (i) any such claims arising out of or related to any federal, state and/or local labor or civil rights laws including, without limitation, the federal Civil Rights Acts of 1866, 1871, 1964, the Equal Pay Act, the Older Workers Benefit Protection Act, the Rehabilitation Act, the Jury Systems Improvement Act, the Uniformed Services Employment and Reemployment Rights Act, the Vietnam Era Veterans Readjustment Assistance Act, the National Labor Relations Act, the Worker Adjustment and Retraining Notification Act, the Family and Medical Leave Act of 1993, the Employee Retirement Income Security Act of 1974, the Age Discrimination in Employment Act, the Americans with Disabilities Act of 1990, the Fair Labor Standards Act of 1938, the New York City and State Human Rights Laws, the California Fair Employment and Housing Act, the California Labor Code, the California Constitution, the California Family Rights Act, the Nevada Fair Employment Practices Act, the Maryland Fair Employment Practices Act, the Health Care Worker Whistleblower Protection Act, the Maryland False Claims Act, the Maryland Parental Leave Act, the Maryland Health Working Families Act, the Maryland Wage and Hour Law, the Maryland Wage Payment and Collection Law and the Maryland Equal Pay for Equal Work Law, all including any amendments and their respective implementing regulations; (ii) any and all other such claims arising out of or related to any contract, any and all other federal, state or local constitutions, statutes, rules, regulations or executive orders; or (iii) any and all such claims arising from any common law right of any kind whatsoever, including, without limitation, any claims for any kind of tortious conduct, promissory or equitable estoppel, defamation, breach of the Company's policies, rules, regulations, handbooks or manuals, breach of express or implied contract or covenants of good faith, wrongful discharge or dismissal, and/or failure to pay, in whole or part, any compensation of any kind whatsoever (collectively, "Executive's Claims").

Executive is not releasing any unemployment claims, workers' compensation claims, right to COBRA benefits, or any other claim which as a matter of law. To the extent any local, state or federal administrative agency files any claims on Executive's behalf arising out of or related to Executive's employment, Executive waives, to the fullest extent permitted by law, to any right to any monetary or other recovery as a result of such action, with the exception of monetary recovery on whistleblower awards.

The Company hereby irrevocably releases and forever discharges any and all known and unknown liabilities, debts, obligations, causes of action, demands, covenants, contracts, liens, controversies and any other claim of whatsoever kind or nature that the Company ever had, now has or may have in the future against Executive (collectively, the "Company's Claims"). Notwithstanding the foregoing, the Company is not releasing any claims hereunder with respect to (a) the Company's rights with respect to this Agreement, (b) any claims of fraud, fraudulent activity, or otherwise illegal conduct, or (c) any claims that are not otherwise waivable under applicable law.

Execution of this Release by each party operates as a complete bar and defense against any and all of Executive's Claims and the Company's Claims. If either party should hereafter assert any Executive's Claims or the Company's Claims in any action or proceeding against the other, as applicable, in any forum, this Release may be raised as and shall constitute a complete bar to any such action or proceeding and the applicable party shall be entitled to recover from the other asserting party all costs incurred, including attorneys' fees, in defending against any such claims.

For the purpose of implementing a full and complete release, each party expressly acknowledges that the release given in this Agreement is intended to include, without limitation, claims that such party did not know or suspect to exist in such party's favor at the time of execution of the Agreement, regardless of whether the knowledge of such claims, or the facts upon which they might be based, would materially have affected the settlement in this matter, and that the consideration provided under this Agreement is also for the release of those claims and contemplates extinguishment of any such unknown claims. Executive further waives and relinquishes any rights and benefits which he has or may have under California Civil Code § 1542 to the fullest extent that he may lawfully waive all such rights and benefits pertaining to the subject matter of this Release. Civil Code § 1542 provides that a general release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the release, which if known by him must have materially affected his settlement with the debtor. Each party acknowledges that he or it is aware that he or it may later discover facts in addition to or different from those which he or it now knows or believes to be true with respect to the subject matter of this Release, but it is his and its intention to fully and finally forever settle and release any and all claims, matters, disputes, and differences, known or unknown, suspected and unsuspected, which now exist, may later exist or may previously have existed between the parties to the extent set forth herein, and that in furtherance of this intention this Release shall be and remain in effect as a full and complete general release to the extent set forth in herein, notwithstanding discovery or existence of any such additional or different facts.

2. OPPORTUNITY FOR REVIEW

This Agreement constitutes a voluntary waiver and release of any and all rights and claims Employee may have under the Age Discrimination in Employment Act (ADEA). Executive acknowledges that he has had a reasonable opportunity to review and consider the terms of this Release for a period of at least twenty-one (21) days, that the Company has advised Executive, in writing, to consult an attorney prior to signing this Agreement and that Executive has had the opportunity to receive counsel regarding his/ her respective rights, obligations and liabilities under this Release and that to the extent that Executive has taken less than twenty-one (21) days to consider this Release, Executive acknowledges that he has had sufficient time to consider this Release and to consult with counsel and that he does not desire additional time to consider this Release. As long as Executive signs and delivers this Release within such twenty- one (21) daytime period, he will have seven (7) days after such delivery to revoke his decision by delivering written notice of such revocation to the Company to [Physical or Email Address]. If Executive does not revoke his decision during that seven (7) day period, then this Release shall become effective on the eighth (8^{th}) day after being delivered by Executive.

3. COVENANT NOT TO SUE.

To the maximum extent permitted by law, each party covenants not to sue or to institute or cause to be initiated, or maintain, any action in federal, state or local agency or court against the other, including, but not limited to, any of the claims released above.

4. BINDING EFFECT.

This Release is binding on Executive's heirs and personal representative and the Company's successors and assigns.

5. NO ASSIGNMENT OF CLAIMS

Executive represents and warrants that Executive has not assigned or otherwise transferred or subrogated, or purported to assign, transfer, or subrogate, to any person or entity, any claim or portion thereof or interest therein that Executive may have against the Releasees.

6. GOVERNING LAW; MISCELLANEOUS

The provisions of Sections 8, 9, 10, 11 and 13 of the Employment Agreement shall be deemed incorporated into this Release as if fully set forth herein. Any claim or dispute arising under or relating to this Release, or the breach, termination or validity of this Release, shall be subject to Section 11 of the Employment Agreement.

PHARMACYTE BIOTECH, INC

By: _____
Name:
Title:

EXECUTIVE

By: _____
Josh Silverman

EXHIBIT 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Organization
Viridis Biotech, Inc.	Nevada, USA
PharmaCyte Biotech Australia Pty. Ltd.	Australia
PharmaCyte Biotech Europe Limited	Ireland

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No.'s 333-260849, and 333-272569) and Form S-8 (No. 333-283613) of our report dated August 8, 2025, with respect to the consolidated financial statements as of and for the year ended April 30, 2025 of PharmaCyte Biotech, Inc. included in this Annual Report on Form 10-K for the year ended April 30, 2025.

/s/ CBIZ CPAs P.C.

Morristown, New Jersey
August 8, 2025

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No.'s 333-260849, and 333-272569) and Form S-8 (No. 333-283613) of our report dated August 13, 2024 with respect to the consolidated financial statements as of and for the year ended April 30, 2024 of PharmaCyte Biotech, Inc. included in this Annual Report on Form 10-K for the year ended April 30, 2025.

/s/ Marcum LLP

Morristown, New Jersey
August 8, 2025

EXHIBIT 31.1

CERTIFICATION

I, Joshua N. Silverman, certify that:

1. I have reviewed the Annual Report on Form 10-K of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2025;

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

(d) Disclosed in this Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 8, 2025

By: /s/ Joshua N. Silverman
Name: Joshua N. Silverman
Title: Chief Executive Officer
(Principal Executive Officer on behalf of Registrant)

EXHIBIT 31.2

CERTIFICATION

I, Carlos A. Trujillo, certify that:

1. I have reviewed the Annual Report on Form 10-K of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2025;

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and

(d) Disclosed in this Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 8, 2025

By: /s/ Carlos A. Trujillo
Name: Carlos A. Trujillo
Title: Chief Financial Officer
(Principal Financial and Principal Accounting Officer
on behalf of Registrant)

EXHIBIT 32.1

WRITTEN STATEMENT
PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-K for the year ended April 30, 2025 as filed with the U.S. Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Joshua N. Silverman, Chief Executive Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 8, 2025

By: /s/ Joshua N. Silverman
Name: Joshua N. Silverman
Title: Chief Executive Officer
(Principal Executive Officer on behalf of Registrant)

A signed original of this written statement required by Section 906 of the Sarbanes Oxley Act of 2002 has been provided to the Company and will be retained by the Company and will be furnished to the Commission or its staff upon request. This exhibit is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, but is instead furnished as provided by applicable rules of the Commission.

EXHIBIT 32.2

WRITTEN STATEMENT
PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-K for the year ended April 30, 2025 as filed with the U.S. Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Carlos A. Trujillo, Chief Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 8, 2025

By: /s/ Carlos A. Trujillo
Name: Carlos A. Trujillo
Title: Chief Financial Officer
(Principal Financial and Principal Accounting Officer
on behalf of Registrant)

A signed original of this written statement required by Section 906 of the Sarbanes Oxley Act of 2002 has been provided to the Company and will be retained by the Company and will be furnished to the Commission or its staff upon request. This exhibit is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, but is instead furnished as provided by applicable rules of the Commission.