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, 2019

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 333-68008

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.)

23046 Avenida de la Carlota, Suite 600, Laguna Hills, CA 92653
(Address of principal executive offices)

(917) 595-2850
(Registrant's telephone number, including area code)

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

Title of each class	**Name of each exchange on which registered**
N/A	N/A

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) 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 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, 2018: $58,830,398.

As of August 12, 2019, the registrant had 1,328,171,172 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Cautionary Note Regarding Forward-Looking Statements

This Report on Form 10-K ("Report") includes "forward-looking statements" within the meaning of the federal securities laws. All 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 United States 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, our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; whether the United States Food and Drug Administration ("FDA") approves our Investigational New Drug Application ("IND") after it has been submitted to, and reviewed by the FDA so that we can commence our planned clinical trial involving locally advanced, inoperable, non-metastatic pancreatic cancer; 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; and whether the FDA will approve our product candidates. 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. 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.

Overview

We are a clinical stage biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer and diabetes 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 non-metastatic pancreatic cancer ("LAPC") and Type 1 and insulin dependent Type 2 diabetes will be developed.

We are developing therapies for pancreatic and other solid cancerous tumors by using genetically engineered live human cells that are capable of converting a cancer prodrug into its cancer-killing form, encapsulating those cells using the Cell-in-a-Box® technology and placing those capsules in the body as close as possible to the tumor. In this way, when the 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 tumor may be optimized.

We are also examining ways to exploit the benefits of the Cell-in-a-Box® technology to develop therapies for cancer that involve prodrugs based upon certain constituents of the *Cannabis* plant; these constituents are of the class of compounds known as "cannabinoids".

In addition, we are involved in preclinical studies to determine if our cancer therapy can slow the production and/or accumulation of malignant ascites fluid in the abdomen that accompanies the growth of several types of abdominal cancers.

Finally, we are developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes based upon the encapsulation of a human liver cell line that has been genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body. We are also considering an alternative route to bringing a biological treatment for diabetes into human clinical trials. We are exploring the possibility of encapsulating human insulin-producing stem cells and islet cells and then transplanting them into a diabetic patient.

The encapsulation for each type of cell will be done using the Cell-in-a-Box® technology. Each approach is designed to function as a bio-artificial pancreas for the purpose of insulin production.

The Cell-in-a-Box® encapsulation technology potentially enables genetically engineered live human cells to be used as miniature factories. The technology results in the formation of pin-head sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In the laboratory setting, which involves the large-scale amplification and production of useful biotech products outside the body of a person or animal, the proprietary live cell encapsulation technology has been shown to create a micro-environment in which these encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors, passage through catheters and needles, etc., enabling greater growth and production of the end-product. The capsules are largely composed of cellulose (cotton) and are bio-inert.

Cancer Therapy

Targeted Chemotherapy

Our live-cell encapsulation technology-based therapies consist of encapsulating different types of genetically modified living cells depending on the disease being treated. For our leading product candidate, a therapy for pancreatic cancer, approximately 20,000 genetically modified live cells that produce an enzyme (an isoform of cytochrome P450) which we believe will convert the chemotherapy prodrug ifosfamide into its cancer-killing form are encapsulated in porous, spherical, pinhead-sized capsules, composed largely of cellulose. Then approximately 300 of these capsules will be placed in the patients' blood supply and guided into place using interventional radiography so that they finally reside as close to the tumor in the pancreas as possible. Low doses (one gram per square meter of body surface area of the patient) of the chemotherapy prodrug ifosfamide will then be given to the patient intravenously.

The prodrug ifosfamide is normally activated in the patient's liver. By activating the prodrug near the tumor using the Cell-in-a-Box® capsules, our cellular therapy acts as a type of "bio-artificial liver." Using this "targeted chemotherapy," we are seeking to create an environment that enables optimal concentrations of the "cancer-killing" form of ifosfamide at the site of the tumor. Because the cancer-killing form of ifosfamide has a short biological half-life, we believe that this approach results in little to no collateral damage to other organs in the body. We also believe this treatment will significantly reduce tumor size with no treatment-related side effects.

Figure 1: Proposed treatment for pancreatic cancer by targeted deployment and activation of chemotherapy using Cell-in-a-Box® encapsulated cells.

Note: Charts A and B are generalized graphic depictions of the principal mechanisms of our proposed treatment for pancreatic cancer using our product candidate, the combination of Cell-in-a-Box® encapsulated cells plus low-doses of ifosfamide, under expected conditions. This combination therapy will be the subject of a Phase 2b clinical trial we plan to conduct, subject to FDA approval. No regulatory authority has granted marketing approval for the Cell-in-a-Box® technology, the related encapsulated cells, or Cell-in-a-Box® and encapsulated cells plus low-dose ifosfamide combination.

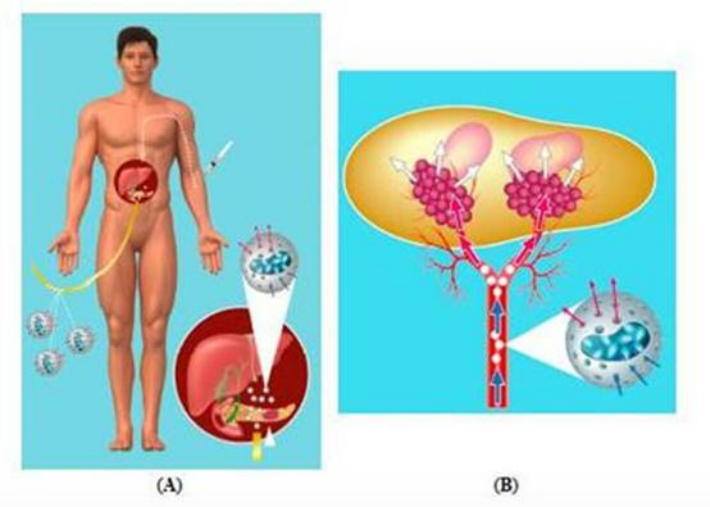


Chart (A)

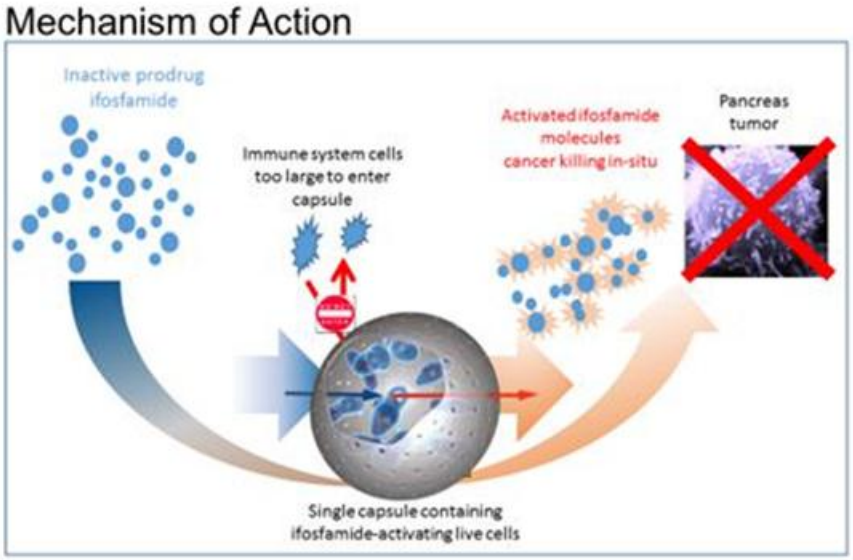
Cell-in-a-Box® capsules containing live ifosfamide-activating cells (shown in white) are implanted in the blood vessels leading to the tumor in the pancreas. Then low-dose ifosfamide is given intravenously.

Chart (B)

Chart B shows the human pancreas and generalized depictions of two pancreatic cancer tumors (shown in pink) as examples. In this chart, ifosfamide is converted to its cancer-killing form by the encapsulated live cells implanted near the tumors (shown in maroon).

Legend
Blue Arrows: Ifosfamide enters capsules
Red Arrows: Conversion to active form
White Arrows: Activated ifosfamide targets tumors

Figure 2: Mechanism of action of treatment for pancreatic cancer by targeted deployment of the encapsulated live cells and activation of the chemotherapy prodrug drug ifosfamide.



Pancreatic Cancer Therapy

A critical unmet medical need exists for patients with LAPC whose pancreas tumor no longer responds after 4-6 months of treatment with either Abraxane® plus gemcitabine or the 4-drug combination known as FOLFIRINOX (both combinations are the current standards of care for pancreatic cancer). We believe that these patients have no effective treatment alternative once their tumors no longer respond to these therapies. Two of the most commonly used treatments for these patients are 5-fluorouiracil ("5-FU") or capecitabine (a prodrug of 5-FU) plus radiation (chemoradiation therapy). We believe that both treatments are only marginally effective in treating the tumor and both result in serious side effects. More recently, radiation treatment alone is being used at some cancer centers in the United States ("U.S.").

We believe that all of these treatments are only marginally effective in treating the tumor and all can result in serious side effects. Other treatments are being tried in an attempt to address this problem, but their success is far from certain. Therefore, we are developing a therapy comprised of Cell-in-a-Box® encapsulated live cells implanted near the pancreas tumor followed by the infusion of low doses of the cancer prodrug ifosfamide. We believe that our therapy can serve as a "consolidation therapy" that can be used with the current standards of care for LAPC and thus address this critical unmet medical need.

Subject to the FDA approval, we plan to commence a clinical trial involving patients with LAPC whose tumors have ceased to respond to either Abraxane® plus gemcitabine or FOLFIRINOX after 4-6 months. We had a Pre-Investigational New Drug Application meeting ("Pre-IND meeting") with the Center for Biologics Evaluation and Research of the FDA ("CBER") in January 2017. At that Pre-IND meeting, the FDA communicated its agreement with certain aspects of our clinical development plan, charged us with completing numerous tasks and provided us with the guidance on the tasks we believe we need to complete for a successful IND, although no assurance could be given whether the FDA will approve our IND once it is submitted. The trial would initially take place in the U.S. with possible study sites in Europe at a later date.

Preparation of the Investigational New Drug Application

Before we can begin our clinical trial, we must submit an IND to the FDA. The IND consists of a submission of all available preclinical information (e.g. animal toxicity studies), Chemistry, Manufacturing and Controls ("CMC") information and other pre-clinical information about our product candidate to treat LAPC, as well as clinical information and other information and documentation required by the FDA. Facet Life Sciences ("Facet") has been retained by us as our FDA regulatory affairs consultant and is leading the preparation of the IND.

During fiscal year 2019, we have focused our research and development ("R&D") efforts at completing Cell-in-a-Box® encapsulation engineering runs and production runs successfully using cells from our Master Cell Bank ("MCB") that contain the genetically transformed human cells that can activate the prodrug ifosfamide into its cancer killing form. The MCB encapsulated cells from the final manufacturing run will be used for our planned clinical trial in LAPC. Several tests and experiments have been completed this past year to optimize the growth properties of the cells in the capsules. The data from these tests and experiments will be included in our IND.

In addition to the MCB work, we have completed a series of tests and studies on cells from the MCB and the capsules into which they will be placed. These tests and studies are required by the FDA. The data from these tests and studies will be included in our IND. The tests and studies consist of the following:

Completed Tests:

Polymerase Chain Reaction ("PCR") Assay as Identity Test for Clinical Product: A PCR -based identity test as quality control of the 22P1G encapsulated cell product was developed by Austrianova. This assay was transferred from Austrianova to a certified service provider in Thailand who provided the assay to Austrianova Thailand.

Characterization Studies of the 22P1G Cell Line: These 22P1G studies consisted of pre-existing data and other data generated in experimental plans developed by Austrianova. These studies focused on: (i) the characterization of the 22P1G original cell line, including the subcloning, testing of PrestoBlue (cell viability) and resorufin (enzymatic) activities of the different clones and subclones, testing of PrestoBlue and resorufin activities of the different clones and subclones, southern blots and growth analysis of the subclones; (ii) adaption to serum free medium and testing of the best growth conditions prior to and after encapsulation; and (iii) genetic and phenotypic stability of the 22P1G cell line. The purpose of these studies is to document the key characteristics of the parental 22P1G cell line and the clones and subclones in order to demonstrate the stability of the 22P1G cell line before, during and after the encapsulation process. The data will be used in the IND submission to the FDA.

Cell Culture Medium Comparison Study: Due to availability concerns with the cell culture medium in which the 22P1G cells were developed, Austrianova undertook a cell culture medium comparison study. The study was undertaken in order to source and check a backup cell culture medium. The study concurrently tested a new serum free medium and the existing SFM4HEK293 (the medium in which the cell line was developed) in parallel under the same conditions to establish equivalency for supporting cell growth of the 22P1G cells in capsules.

Certificate of Analysis: The Certificate of Analysis ("COA") for the preparation of the MCB from Eurofins Lancaster Laboratories, Inc. ("Eurofins") has been accepted by Austrianova Singapore Pte Ltd ("Austrianova"), who will perform the Cell-in-a-Box® encapsulation in the manufacturing facility located Bangkok, Thailand and owned by Austrianova Thailand Pte Ltd ("Austrianova Thailand"). The COA was issued following a series of tests required before the cells could be accepted by Austrianova Thailand into its manufacturing facility.

Pig Study Report: This study report on the safety of instillation of the capsules in pigs has been completed and approved by Facet. The report is a summary of information and data from preclinical work completed by Dr. Matthias Löhr ("Dr. Löhr") in preparation for the first clinical trial using our therapy for pancreatic cancer.

Site of Integration Study: This FDA required study characterized the site of integration and the structure of the integrated CMV CYP2B1 plasmid (hence CYP therapeutic transgene) into the genome of the 22P1G cell line being used for our planned clinical trial. The cell line is referred to as 22P1GSF because it can be grown in serum-free cell culture medium. The goal of the study was to show that the site of integration is not near to a cancer-causing gene as well as to identify and characterize PCR primers that could be used as an identity test for release of the product.

Next Generation Sequencing ("NGS") followed by a robust and multi-faceted analysis of the data yielded could confirm that the cytochrome P450-2B1 transgene from the CMV-CYP plasmid transfection of HEK293 cells (to create the 22P1G cell line) resulted in the stable integration of plasmid sequences into a non-gene-coding region of human chromosome 9. Using the NGS sequence data, a Capture PCR protocol was tested in an attempt to fish-out products with identified chromosome 9 and plasmid sequences but this was not successful. Instead, a parallel strategy using PCR, designing of several rounds of primers and nested primers followed by primer walking sequencing was undertaken. After several progressive rounds of work, it was possible to obtain sequences confirming the integration site of the CMV-CYP plasmid in chromosome 9. The NGS data showed that all of the CMV-CYP plasmid sequences are present between positions 93,691,754 and 93,691,785 of chromosome 9 in the 22P1G genome but it was not possible to elucidate the entire structure (number and orientation of repeats) of the plasmid sequences in complete detail, most likely due to the plasmid being concatemerized in various orientations. Nevertheless, the CMV promotor region and the CYP2B1 gene was confirmed to be present at this location in chromosome 9 by the PCR work here and previous work by Austrianova with enzymatic assays and Southern blotting confirms this by also showing that the CYP gene is biologically functional.

Initial Two Testing of Alternative Methods and Reagents for Measuring Cell Numbers: This involved the required testing of various new assays, especially those directed at new DNA synthesis, to validate or modify Austrianova's existing cell number metabolic activity assays. This testing was done at the request of the FDA to demonstrate cell numbers in the capsules and to determine cell viability. This testing program focused on developing several assays as appropriate and quantitative assays that are effective even at high cell densities.

Bench Thawing Study. The purpose of this study was to assess the stability of encapsulated 22P1G cells after hand thawing and subsequent exposure to room temperature. It involves testing the metabolic activity of the cells in the capsules after hand-unfreezing and placement at room temperature for varying lengths of time.

Capsule Cell Count Study:

This study is part of a larger objective (which also included a previous PrestoBlue study) aimed at testing alternative methods and reagents for measuring cell division and determining the numbers of cells in capsules. This involved the testing of various new assays, especially those aimed at new DNA synthesis, to validate or modify existing metabolic activity assays which indirectly determines cell number. This study is a consequence of the request of the FDA to demonstrate cell number in capsules as well as cell viability. The program focused on developing the Celltox Green and Decapsulation Cell Count assays as appropriate quantitative assays.

After extensive investigations it was concluded that the best method of estimating cell numbers inside the capsule is the Decapsulation Cell Count. Several issues remain unresolved with the Celltox Green assay, such as: (i) the disparity in peak cell numbers when compared with the Direct Cell count method; (ii) the plateauing of total cell numbers and drop in live cell numbers; (iii) the high standard error due to the low signal window required to keep within the linear range of the cell standard; and (iv) the large day-by-day fluctuation inherent in the method.

In contrast, the direct cell count method provided stable, consistent results with comparatively low standard errors and fluctuation. It also has the advantage of being a direct visualization method, which gives more confidence in the interpretation of the raw input data than either Celltox Green or Prestoblue assays. As a result of this project, not only the best method to be used was determined but also simultaneously allowed the creation of a final and robust standard operating procedure ("SOP") which will now be transferred into an SOP for integration into the documentation system for use during the manufacturing procedure for quality control.

Final Testing of Alternative Methods and Reagents for Measuring Cell Numbers: A third testing alternative method and testing for reagents for measuring cell division were completed. This involved the testing of additional new assays directed at new DNA synthesis to validate or modify our existing cell number metabolic activity assays.

Manufacturing Process Testing: Following an initial manufacturing run, changes were made to parts of the manufacturing process being performed under current Good Manufacturing Practice ("cGMP") conditions at Austrianova's manufacturing facility in Bangkok, Thailand. The data obtained from the encapsulation parameters of the manufacturing process itself indicated that the encapsulation portion of the process is fault-free and reproducible, which is a fundamental requirement of the FDA.

Experiments to Optimize the Growth of the Encapsulated Cells from the MCB: The cells from the MCB produced by Eurofins showed slightly different growth properties when compared to the cells from our Research Cell Bank ("RCB") that were previously tested by Austrianova's laboratories, a finding that is not unusual when a new cell bank is established. Although minor in nature, these different growth characteristics of the MCB cells initially affected many of the steps required for the overall production process of our clinical trial material called "CypCaps™," necessitating counter-measures to re-align and restructure part of the production process. Several independent tests were conducted by Austrianova to test the effects of possible changes to the production process.

Experiments by Austrianova and Eurofins. Several experiments were conducted by Austrianova in its laboratory in Singapore. Based upon the results of those experiments, changes were incorporated into the manufacturing process at the manufacturing facility in Bangkok, Thailand. Those changes led to Austrianova's successful encapsulation and growth of the live cells from the MCB which will be used in our therapy for pancreatic cancer. The growth components of the experiments that were done to see what changes should be made to the pre-encapsulation portion of the production process were conducted by Eurofins as well.

Completion of Technology Transfer: All of the manufacturing technology developed by Austrianova was documented according to cGMP standards and successfully transferred to Austrianova's Thailand facility where the encapsulation of our clinical trial material will be done.

Encapsulation and Further Testing

We are in the process of conducting two additional and staggered manufacturing runs in order to maximize the chances for a successful IND submission, given the novelty and complexity of the manufacturing process. These runs are also required by cGMP Validation, Inc, the company who is taking responsibility for "releasing" the clinical trial material into the U.S.

Following the encapsulation process, numerous tests will be conducted by Austrianova to generate the data necessary to satisfy regulatory requirements for the IND. When Austrianova finishes its work, it will issue a COA for our encapsulated cell product that we believe will comply with the FDA requirements

Revised Trial Design

We have completed a redesign of our planned clinical trial from a registrational trial to a Phase 2b trial. To help with the redesign of our clinical trial in patients with LAPC we formed an Oncology Advisory Board ("Advisory Board") with leading oncologists in the U.S. Members include Dr. James Abbruzzese (Duke University Medical Center), Dr. Alok Khorana (The Cleveland Clinic Lerner College of Medicine), Dr. Eileen O'Reilly (Memorial Sloan Kettering Cancer Center), Dr. Vincent Picozzi (Virginia Mason Medical Center), Dr. Margaret Tempero (University of California, San Francisco), Dr. Syma Iqbal (USC Keck School of Medicine, Norris Cancer Center) and Dr. Robert McWilliams (The May Clinic Rochester). Dr. Manuel Hidalgo ("Dr. Hidalgo"), the Principal Investigator for the LAPC trial and a consultant to our company, led these individuals in working with us to finalize the new trial design

Study Synopsis and Schedule of Assessments

The Study Synopsis and Schedule of Assessments for the Phase 2b trial have been revised by our Clinical Trial Leadership Team ("CTLT"). The CTLT meets on a regular basis to advance our clinical development program for pancreatic cancer.

Members of the CTLT include Kenneth L. Waggoner ("Mr. Waggoner"), our Chief Executive Officer, President and General Counsel, Dr. Gerald W. Crabtree ('Dr. Crabtree"), our Chief Operating Officer, Dr. Linda Sher ("Dr. Sher"), our Chief Medical Officer, Dr. Löhr, the Chairman of our Medical and Scientific Advisory Board and a consultant to us, Dr. Hidalgo, a consultant to us and the Principal Investigator for the clinical trial in LAPC, Dr. Leonard Makowka, our Senior Strategic Advisor to the Chief Executive Officer and our Board of Directors ("Board"), Lisa Guttman of Practical Clinical (a company specializing in clinical trial planning and execution) who is our Director of Clinical Operations and Jason Mercer and then Maria Osaka, the Project Managers from Facet.

The purpose of the new study design is to investigate the efficacy and safety of CypCaps™ (genetically engineered human cells encapsulated using the Cell-in-a-Box® technology) in combination with low doses ($1g/m^2$) ifosfamide as compared to chemoradiation therapy with capecitabine plus external beam radiation therapy ("EBRT") or stereotactic body radiation therapy ("SBRT") alone. The study population has been finalized and will consist of approximately 100 patients with LAPC.

CRO Selection Process Completed

The CTLT concluded its selection process for a Contract Research Organization ("CRO") to conduct our clinical trial in LAPC. We selected Medpace, Inc. ("Medpace") as our CRO. Medpace is an established and highly regarded full-service CRO with expertise in numerous therapeutic areas focused on supporting the biotech sector. It is a scientifically-driven organization with a dedicated in-house study team supported by outstanding experts to lead the way. Medpace has an extensive portfolio of successfully completed clinical trials, including those involving pancreatic cancer. In 2018, Medpace was ranked among the top 10 CROs in the world.

Cannabinoids to Treat Cancer

Numerous studies have demonstrated the anti-cancer effects of certain cannabinoids (constituents of *Cannabis*). Two of the most widely studied cannabinoids in this regard are tetrahydrocannabinol ("THC") and cannabidiol ("CBD"). Cannabinoids are: (i) anti-proliferative (slow tumor growth); (ii) anti-metastatic (slow tumor spread); (iii) anti-angiogenic (slowing blood vessel development); and (iv) pro-apoptotic initiate programed cell death). In *in vitro* and *in vivo* models, the anti-cancer effects of cannabinoids are broad. They have been shown to apply to lung, brain, thyroid, lymphoma, liver, skin, pancreas, uterus breast and prostate cancers. In a review of 51 scientific studies, among other properties, it was observed that cannabinoids can regulate cellular signaling pathways critical for cell growth and survival. These properties indicate that cannabinoids could be useful in the treatment of cancer.

As of May 2019, 33 states and the District of Columbia have approved the use of *Cannabis* for medical purposes. A plethora of medical marijuana companies have emerged. Most of them are involved in the production and distribution of *Cannabis* in its various forms, such as liquid extracts and pills, and in *Cannabis* delivery systems, such as vapor pens. We believe we are one of the few companies that are focused on using cannabinoids for the treatment of specific diseases.

We have several competitors that are developing *Cannabis*-based treatments for cancer. GW Pharmaceuticals, PLC has an approved cannabinoid product for the treatment of multiple sclerosis spasticity and is developing a product portfolio to treat a variety of illnesses, including glioblastoma (brain cancer). Cannabis Science, Inc. is developing topical cannabinoid treatments for basal and squamous cell skin cancers and Kaposi's sarcoma, and is exploring pre-clinical development of cannabinoid-based anti-cancer drugs in a collaborative agreement with the Dana Farber/Harvard Cancer Center. OWC Pharmaceutical Research Corp. is developing *Cannabis*-based products targeting a variety of indications and has a collaborative agreement with an academic medical center in Israel to study the effects of cannabinoids on multiple myeloma (a cancer of plasma cells). Cannabis Pharmaceuticals, Inc. is developing personalized anti-cancer and palliative *Cannabis*-based treatments aimed mainly at improving the cachexia, anorexia syndrome and quality-of-life issues that are often characteristic of patients with devastating diseases like cancer.

In contrast to the work being done by these companies, we plan to focus on developing specific therapies based on carefully chosen molecules rather than using complex *Cannabis* extracts. Our therapy will use the Cell-in-a-Box® technology in combination with genetically modified cell lines designed to activate cannabinoid molecules for the treatment of diseases and their related symptoms. Our initial target will be glioblastoma – a very difficult-to treat form of brain cancer.

Cannabis-derived cannabinoids "prodrugs"

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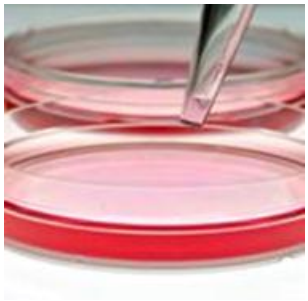

Bio-engineered cell line encapsulated using Cell-in-a-Box® produces activating enzyme

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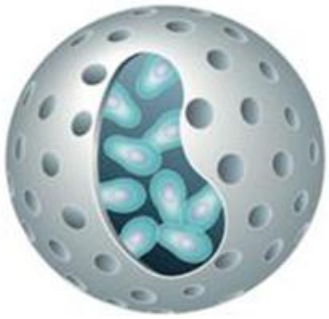
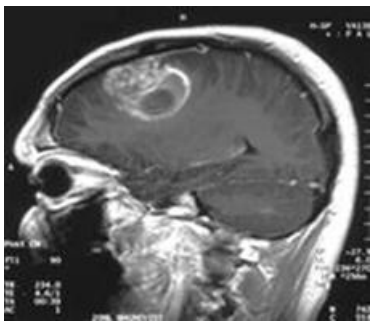


Targeted chemotherapy using activated cannabinoids ☐ ☐ ***cancer cell death***



In May 2014, we entered into a Research Agreement with the University of Northern Colorado ("UNC"). The goal of the ongoing research is to develop methods for the identification, separation and quantification of constituents of *Cannabis*, some of which are prodrugs, which may be used in combination with the Cell-in-a-Box® technology to treat cancer. Significant effort has been expended to establish accurate analytical methods to separate, identify and quantitate various cannabinoids; these methods have now been identified. Studies have also been undertaken using cannabinoids to identify the appropriate cell type that can best convert the selected cannabinoid prodrugs into metabolites with anticancer activity. Once identified, the genetically modified cells which are expected to produce the appropriate enzyme to convert that cannabinoid prodrug will be encapsulated using the Cell-in-a-Box® technology. The encapsulated cells and cannabinoid prodrugs identified by these studies will then be combined and used for future studies to evaluate their anticancer effectiveness.

In January 2017, we entered into a second Research Agreement with UNC. The goal of this ongoing research is to assess the synthesis of the patG gene and its incorporation into a vector, transfection of human embryonic kidney cells using this vector and assessment of cannabinoic acid decarboxylase activity.

During 2017, UNC identified an organism whose genome contains the genetic code for production of an enzyme capable of activating a cannabinoid prodrug into its active cancer-killing form. Our Cannabis Program now has two primary areas of focus. The first is confirming the anti-cancer activity of cannabinoids, such as THC and CBD, particularly in our main "target" tumor – glioblastoma. UNC's research has confirmed that a purified cannabinoid showed a potent dose-dependent decrease in cell viability for various cancers, suggesting that this cannabinoid exhibits significant anti-proliferative effects (stops the growth of cancer cells). This activity has been demonstrated in brain (glioblastoma), pancreas, breast, lung, colon and melanoma cancer cells. The second area of focus is in finding an enzyme capable of converting an inactive, side-effect-free, cannabinoid prodrug into its active cancer-killing form. The research team at UNC has screened numerous cell lines and numerous enzymes. As result of this extensive work, an organism has been identified that has been confirmed to produce an enzyme capable of catalyzing the desired cannabinoid-prodrug-activating reaction.

The next step is to test the efficiency of the transfected cells in converting cannabinoid prodrugs into their active cancer-fighting forms. If the cells are suitably active, they would then be propagated to the point that they can be encapsulated using the Cell-in-a-Box® technology. Also, we will continue our analysis of other genes of interest that could be used in a similar way.

Clinically, targeted cannabinoid-based chemotherapy would be accomplished by implanting the encapsulated bio-engineered cells near the site of a tumor, along with administration of a cannabinoid prodrug which would become activated at the site of the tumor by an enzyme produced by the encapsulated cells. The end goal is better efficacy than existing therapies with few, if any, treatment related side effects.

Malignant Ascites Fluid Therapy

We are studying the development of a possible therapy to delay the production and accumulation of malignant ascites fluid that results from many types of abdominal tumors. Malignant ascites fluid is secreted by an abdominal tumor into the abdomen after the tumor reaches a certain stage of growth. This fluid contains cancer cells that can seed and form new tumors throughout the abdomen. As this ascites fluid accumulates in the abdominal cavity, it can cause gross swelling of the abdomen, severe breathing difficulties and extreme pain.

Once an abdominal tumor reaches a certain stage of development, it secretes malignant ascites fluid into the abdominal cavity. When that occurs, malignant ascites fluid must be removed by paracentesis on a periodic basis. This procedure is painful and costly. We know of no available therapy that prevents or delays the production and accumulation of malignant ascites fluid. We have been involved in eight preclinical studies conducted by Translational Drug Development ("TD2"), an early stage CRO specializing in oncology, to determine if the combination of Cell-in-a-Box® encapsulated cells plus low doses of ifosfamide can delay the production and accumulation of malignant ascites fluid. The data from these eight studies indicated that the treatment might play a role in malignant ascites fluid production and accumulation, but the conclusions were difficult to interpret with certainty. As a result, we plan to conduct another preclinical study in Germany to determine if our conclusions from the TD2 studies are valid. If the ninth study is successful, we plan to seek approval from the FDA to conduct a Phase 1 clinical trial in the U.S.

Diabetes Therapy

Diabetes

Diabetes is caused by insufficient availability of, or resistance to, insulin. Insulin is produced by the beta islet cells of the pancreas. Its function is to assist in the transport of sugar (glucose) in the blood to the inside of most types of cells in the body where it is used as a source of energy for those cells. In Type 1 diabetes, the islet cells of the pancreas have been destroyed, usually by an autoimmune reaction. Type 1 diabetics require daily insulin administration through injection or by use of an insulin pump. In Type 2 diabetes, the body does not use properly insulin that is produced by the pancreas. This means the body has become resistant to insulin produced by the pancreas. Type 2 diabetes can generally be controlled by diet and exercise in its early stages. But as time goes by, it may be necessary to use antidiabetic drugs to control the disease. However, over time these too may lose their effectiveness. Thus, even Type 2 diabetics may become insulin-dependent.

Diabetes Epidemic

Diabetes is one of the largest health problems in the world. In its 2016 Global Report on Diabetes, the World Health Organization ("WHO") estimated that, by the end of 2014, 422 million people worldwide had the disease – 314 million more than in 1980. Approximately 8.5% of adults worldwide have diabetes. Approximately $825 billion is spent annually in the treatment of diabetes and related healthcare. Nearly 30 million people in the U.S. have diabetes. Diabetes and prediabetes cost the U.S. more than $32 billion per year. The worldwide market for diabetes treatment drugs alone is over $70 billion.

Efforts to Cure Diabetes

In an attempt to "cure" Type 1 diabetes, replacement of damaged pancreatic beta islet cells has been attempted. This involves transplantation of the entire pancreas or of its beta islet insulin-producing cells. In 2000, islet cells from human cadavers were transplanted into insulin-dependent diabetics in a clinical trial. In this clinical trial involving seven patients in Edmonton, Canada, each patient remained insulin-independent for one year. But high doses of immune-suppressive drugs were needed to accompany the transplantations to avoid rejection of the transplanted islet cells. Without immunosuppressive drugs, these patients would be at a high risk of infection by bacteria, viruses and fungi and open to the growth of cancerous tumors. Therefore, the administration of these immunosuppressive drugs was necessary throughout the remaining lifespan of the patients in the trial. Unfortunately, these drugs are not only expensive, but they are also associated with serious side effects that have required patients to cease long-term treatment with them. Worldwide, less than 1,000 people with Type 1 diabetes are known to have been transplanted with pancreatic islet cells from another human being.

To avoid the use of islet cells from human donors, encapsulated islet cells from pigs have been used. This type of interspecies transplantation is known as "xenotransplantation". Drug regulatory authorities have been reluctant to approve the use of such interspecies transplantations. Also, other challenges with this approach include the potential for the body's immune system to attack the transplanted cells. To protect the non-human cells from attack by the immune system of the human being, they have been encapsulated using forms of encapsulation technology that are different than the encapsulation technology we use. In those studies, the transplanted islet cells from pigs were surrounded by a porous capsule, typically made of alginate - a derivative of seaweed.

Efforts to translate this concept into a viable treatment for Type 1 diabetes have been plagued by poor survival of the transplanted islet cells. Furthermore, the integrity of capsules composed of alginate has been shown to degrade over time. This degradation allows for immune system cells to attack the transplanted pig islet cells and this, in turn, necessitates additional transplantations. Also, as the alginate "capsules" degrade, they themselves can elicit an immune response.

Different tubular and planar "chamber-type" immune-protective devices that contain islet cells are under development by several companies. Such devices are placed in the body where they can be retrieved and replaced if necessary. Tubular chambers have shown good biocompatibility, but they are subject to rupture, exposing the islets to immune system attack. They also require large numbers of islet cells. Planar chambers are more stable, but they can cause extensive foreign body reactions in the host resulting in fibrotic overgrowth of the chambers which can cause "death" of the encapsulated islet cells and thus overall transplant failure.

Among the most extensively researched immune-protective strategy is that which employs micro-capsules. They are relatively simple to manufacture, can be implanted into the body without major surgery and, depending on the nature of the encapsulation material, micro-encapsulated cells can be cryopreserved. Micro-encapsulated islet cells first appeared in 1994 when a diabetic patient, already receiving immunosuppressive drugs, was transplanted with these cells encapsulated in alginate and remained insulin-independent for nine months. However, 23 years and numerous clinical trials later, there are still no publicly reported cases of long-term insulin-independence in non-immune-suppressed diabetic patients receiving encapsulated pancreatic islet transplants.

A Bio-Artificial Pancreas for Diabetes

We are developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes based upon the encapsulation of a human liver cell line genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body. We are also considering an alternative route to bringing a biological treatment for diabetes into the clinic. We are exploring the possibility of encapsulating human insulin-producing stem cells and islet cells and then transplanting them into a diabetic patient.

All three types of cells will be encapsulated using the Cell-in-a-Box® encapsulation technology. After appropriate animal testing has been completed successfully, we will seek the FDA's approval to transplant encapsulated insulin-producing cells into diabetic patients. The goal for these approaches is to develop a bio-artificial pancreas for purposes of insulin production for diabetics who are insulin-dependent.

Austrianova has already successfully encapsulated live pig pancreas islet insulin-producing cells using the Cell-in-a-Box® technology. We understand that the encapsulated cells were then given to the University of Graz and implanted into diabetic rats. In this one-time experiment, it was reported in a poster presentation that the rats' blood glucose levels normalized by day seven and remained normal throughout the study period of approximately 150 days. However, when attempts were made at the University of Graz to repeat this study on its own (including the encapsulation process), those at the University of Graz were unsuccessful. It is believed that this lack of reproducibility was due to a lack of knowledge of Austrianova's encapsulation technology and trade secrets that reside with the Cell-in-a-Box® encapsulation technology.

We believe that encapsulating genetically engineered human cells, genetically engineered stem cells and beta islet cells using the Cell-in-a-Box® cellulose-based encapsulation technology has numerous advantages over encapsulation of cells with other materials, such as alginate. The Cell-in-a-Box® capsules are composed largely of cellulose, which is a bio-inert material in the human body. Also, these capsules are robust and do not trigger any sort of immune or inflammatory response from the body. This allows the capsules to remain intact for long periods of time in the body, all the while protecting the living cells inside them from immune system attack. In earlier clinical studies, these capsules and the cells inside them have not caused any immune or inflammatory responses like those seen with alginate-encapsulated cells, and any fibrotic overgrowth that occurs with the Cell-in-a-Box® capsules is minimal to none.

Our Diabetes Program began with two of the most critical components of a biological diabetes therapy - a line of human cells which release insulin in response to the blood glucose level in their environment and a technology to protect the cells from an attack by the immune system once they are transplanted into a patient's body to replace his or her own destroyed insulin-producing cells. This technology is the Cell-in-a-Box® encapsulation technology. The cells used are called Melligen cells. They are patent-protected and have been licensed to us by the University of Technology, Sydney ("UTS").

Melligen cells are no ordinary insulin-producing cells. They stand out from the array of cells used and newly created cells to serve as a replacement for insulin-producing cells in diabetics. We believe Melligen cells are much more robust than intrinsic insulin-producing cells and withstand an attack by cell-toxic molecules that typically lead to the destruction of insulin-producing cells.

Regulations for the use of living cells as a medical product require that the potential of the cells to grow and form a tumor in a patient be assessed. This so-called "tumorigenicity study" has been completed successfully by our International Diabetes Consortium. Melligen cells showed very low tumorigenicity – the level one would expect to pass regulatory scrutiny.

Putting Melligen cells and the Cell-in-a-Box® technology together, we conducted the first functional study in diabetic mice. The results did not meet our expectations. We discovered that, contrary to what we had expected and what we had read in published scientific papers on the Melligen cells published by UTS, the cells are not stable. With extensive testing and experiments, we discovered that the Melligen cells lose some of their specific beneficial properties over time.

Because of the advantages we felt the Melligen cells have over other competing therapies for diabetes, we made the decision to recreate the Melligen cells and to include a few needed improvements. To minimize the delay in the development of our Diabetes Program caused by the challenges encountered from the Melligen cells, we opened an additional, alternative route to bring a biological treatment for diabetes into the clinic. Concurrently with the recreation of functioning Melligen cells, we are exploring the possibility of encapsulating genetically modified stem cells and human insulin-producing pancreatic beta islet cells and then transplanting them into diabetic patients.

The first step in examining the feasibility of such an approach is an animal experiment using insulin-producing islet cells from one animal -- encapsulating them -- and then transplanting them into another animal. We plan to conduct preclinical studies at the University of Veterinary Medicine ("VetMed"), Vienna, Austria where Dr. Günzburg is a Professor. An encapsulation machine has been put into place at the VetMed, and the first live-cell encapsulation at the site was conducted successfully.

Recently we reached an agreement with UTS to enter into a new research agreement to create an advanced version of the Melligen cells for the treatment of diabetes. Under the new research agreement, which is in the process of being prepared, improvements will be made to the Melligen cells that we expect will increase their stability, increase their insulin production and increase the bioactivity of the produced insulin.

Prof. Ann Simpson, who created the Melligen cells, and her team of research scientists at UTS will be conducting this new research project. Dr. Eva Marie Brandtner ("Dr. Brandtner"), our Director of Diabetes Program Development, will also be involved in the research project.

International Diabetes Consortium

We have established an international Diabetes Consortium ("Consortium"). The Consortium consists of world-renowned physicians and scientists from several countries around the globe, all of whom share the same goal of developing a therapy for Type 1 and insulin-dependent Type 2 diabetes.

In addition to our Chief Executive Officer, Chief Operating Officer, Chief Medical Officer and Chief Scientific Officer, the Consortium is made up of well-known physicians and scientists from leading Universities in Munich, Germany, Mannheim, Germany, Vienna, Austria, Barcelona, Spain, Copenhagen, Denmark and Sydney, Australia. It also includes members from the Karolinska Institute in Stockholm, Sweden, the Vorarlberg Institute for Vascular Investigation and Treatment ("VIVIT") in Feldkirch, Austria and Austrianova in Singapore.

Dr. Brandtner, Head of the Bioencapsulation Unit at VIVIT, leads the Consortium and is our Director of Diabetes Program Development. Dr. Brandtner previously served as the Chief Scientist with Austrianova and is an expert in the use of the Cell-in-a-Box® encapsulation technology.

Relationship between PharmaCyte, S.G. Austria and Austrianova

The principal developers of the Cell-in-a-Box® technology are Prof. Dr. Walter H. Günzburg ("Prof. Günzburg") and Dr. Brian Salmons ("Dr. Salmons"). Both are officers of SG Austria Pte. Ltd. ("SG Austria") and its wholly-owned subsidiary Austrianova. The success of SG Austria and Austrianova, on the one hand, and our success, on the other hand, are co-dependent in almost every respect. SG Austria and Austrianova benefit from our success. If we sublicense our encapsulation technology for the development of therapies for cancer and diabetes, payments are owed by us to SG Austria or Austrianova. In turn, we are dependent upon SG Austria and Austrianova because of the knowledge and expertise of Prof. Günzburg and Dr. Salmons concerning the Cell-in-a-Box® technology and the actual process of cell encapsulation. This technology serves as the basis for all our efforts in developing treatments for both cancer and diabetes. In addition, we own a 14.5% equity interest in SG Austria and have contractual relationships, including license agreements, with SG Austria and Austrianova.

Key Consultants

Prof. Günzburg and Dr. Salmons are involved in numerous aspects of the scientific endeavors relating to our Cancer and Diabetes Programs, having initially commenced work for us as consultants at the beginning of 2014 under an oral agreement. They provide services to us as consultants through their consulting company, Vin-de-Bona Trading Company Pte Ltd ("Vin-de-Bona"). This arrangement was formalized in writing as of April 1, 2014, when we entered a Consulting Agreement with Vin-de-Bona ("Vin-de-Bona Consulting Agreement"). The Vin-de-Bona Consulting Agreement had an initial term of 12 months, with additional terms of 12 months automatically renewing unless either party terminates an additional term upon 30 days' prior written notice. The professional services rendered to us by Prof. Günzburg and Dr. Salmons are charged at a negotiated and confidential hourly rate.

The Vin-de-Bona Consulting Agreement requires that Prof. Günzburg and Dr. Salmons not disclose or use our confidential information for any purpose, other than performing services under the Consulting Agreement, without our prior written consent. Also, during the term of the Vin-de-Bona Consulting Agreement and for a period of twelve months after termination or expiration of the agreement, Dr. Günzburg and Dr. Salmons are prohibited from soliciting any of our customers, employees, suppliers or other persons with whom they had dealings during the tenure of their consultancy for us.

In September 2014, Dr. Günzburg was appointed as our Chief Scientific Officer. Dr. Günzburg is compensated for being our Chief Scientific Officer by us issuing Vin-de-Bona 500,000 restricted shares of our common stock. Dr. Günzburg is compensated in the same way and in the same amount for each succeeding year during which he serves as our Chief Scientific Officer.

Dr. Löhr, a noted European oncologist and gastroenterologist, also participates in the development of our Cancer Program. Dr. Löhr, currently with the Karolinska Institute in Stockholm, Sweden, served as Principal Investigator of the earlier Phase 1/2 and Phase 2 clinical trials (discussed below) of the combination of CapCell® with low-dose ifosfamide in patients with advanced, inoperable pancreatic cancer. CapCell® is now known as and hereinafter referred to as CypCaps™ denoting encapsulated cells using the Cell-in-a-Box® technology that will be used in our LAPC trial. Like Dr. Günzburg and Dr. Salmons, Dr. Löhr is involved in planning and overseeing much of our planned clinical trial in LAPC. Dr. Löhr is the Chairman of our Medical and Scientific Advisory Board and a consultant to us. Dr. Löhr received 500,000 shares of our restricted common stock to serve as the Chairman of our Medical and Scientific Advisory Board. Since April 15, 2014, Dr. Löhr also receives fees to provide professional consulting services to us through his consulting company based upon a confidential hourly rate.

History of the Business

We were incorporated in 1996. In 2013, we restructured our operations to focus on biotechnology, having been a nutraceutical products company before then. The restructuring occurred so we could develop a unique, effective and safe way to treat cancer and diabetes. On January 6, 2015, we changed our name from "Nuvilex, Inc." to "PharmaCyte Biotech, Inc." to reflect the nature of our business.

As mentioned above, we are now a clinical stage biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer and diabetes using our live cell encapsulation technology. This resulted from entering into the following agreements.

On May 26, 2011, we entered an Asset Purchase Agreement with SG Austria ("SG Austria APA") to purchase 100% of the assets and liabilities of SG Austria. Under the SG Austria APA, Austrianova and Bio Blue Bird AG ("Bio Blue Bird"), then wholly-owned subsidiaries of SG Austria, were to become wholly-owned subsidiaries of ours on the condition that we pay SG Austria $2.5 million and 100,000,000 shares of our common stock. We were to receive 100,000 shares of common stock of Austrianova and nine bearer shares of Bio Blue Bird representing 100% of the ownership of Bio Blue Bird.

Through two addenda to the SG Austria APA, the closing date of the SG Austria APA was extended twice by agreement between the parties.

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 the 14.5% equity interest of SG Austria. The transaction required SG Austria to return to us the 100,000,000 shares of our common stock held by SG Austria and for us to return to SG Austria the 100,000 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 June 2013, we acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® technology and trademark for the development of a therapy for Type 1 and insulin-dependent Type 2 diabetes ("Diabetes Licensing Agreement"). This allows us to develop a therapy to treat diabetes through encapsulation of a human cell line that has been genetically modified to produce, store and release insulin in response to the levels of blood sugar in the human body.

In October 2014, we entered into an exclusive, worldwide license agreement with the UTS ("Melligen Cell License Agreement") in Australia to use insulin-producing genetically engineered human liver cells developed by UTS to treat Type 1 diabetes and insulin-dependent Type 2 diabetes. These cells, named "Melligen", were tested by UTS in mice and shown to produce insulin in direct proportion to the amount of glucose in their surroundings. In those studies, when Melligen cells were transplanted into immunosuppressed diabetic mice, the blood glucose levels of the mice became normal. In other words, the Melligen cells reportedly reversed the diabetic condition.

In December 2014, we acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® technology and trademark in combination with genetically modified non-stem cell lines which are designed to activate cannabinoid prodrug molecules for development of therapies for diseases and their related symptoms using of the Cell-in-a-Box® technology and trademark ("Cannabis Licensing Agreement"). This allows us to develop a therapy to treat cancer and other diseases and symptoms through encapsulation of genetically modified cells designed to convert cannabinoids to their active form using the Cell-in-a-Box® technology and trademark.

In July 2016, we entered into a Binding Memorandum of Understanding with Austrianova ("Austrianova MOU"). Pursuant to the Austrianova MOU, Austrianova will actively work with us to seek an investment partner or partners who will finance clinical trials and further develop products for our therapy for cancer, in exchange for which we, Austrianova and any future investment partner will each receive a portion of the net revenue from the sale of cancer products.

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

In August 2017, we entered into a Binding Term Sheet ("Binding Term Sheet") with SG Austria and Austrianova pursuant to which the parties reached an agreement to amend certain provisions in the SG Austria APA, the Diabetes Licensing Agreement, the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement.

In May 2018, the Company entered into the amendments contemplated by the Binding Term Sheet ("Binding Term Sheet Amendments"). The Binding Term Sheet Amendments provide that our obligation to make milestone payments to Austrianova is eliminated in their entirety under the: (i) Cannabis License Agreement; and (ii) the Diabetes License Agreement, as amended. The Binding Term Sheet Amendments also provide that our obligation to make milestone payments to SG Austria pursuant to the SG Austria APA, as amended and clarified, is eliminated in their entirety. One of the Binding Term Sheet Amendments also provides that the scope of the Diabetes License Agreement is expanded to include all cell types and cell lines of any kind or description now or later identified, including, but not limited to, primary cells, mortal cells, immortal cells and stem cells at all stages of differentiation and from any source specifically designed to produce insulin for the treatment of diabetes.

In addition, one of the Binding Term Sheet Amendments provides that we will have a 5-year right of first refusal from August 30, 2017 in the event that Austrianova chooses to sell, transfer or assign at any time during this period the Cell-in-a-Box® technology, tradename and Associated Technologies (defined below), intellectual property, trade secrets and know-how, which includes the right to purchase any manufacturing facility used for the Cell-in-a-Box® encapsulation process and a non-exclusive license to use the special cellulose sulfate utilized with the Cell-in-a-Box® encapsulation process (collectively, "Associated Technologies"); provided, however, that the Associated Technologies subject to the right of first refusal do not include Bac-in-a-Box®. Additionally, for a period of one year from August 30, 2017 one of the Binding Term Sheet Amendments provides that Austrianova will not solicit, negotiate or entertain any inquiry regarding the potential acquisition of the Cell-in-a-Box® and its Associated Technologies.

The Binding Term Sheet Amendments further provide that: (i) the royalty payments on gross sales as specified in the SG Austria APA, the Cannabis License Agreement and the Diabetes License Agreement are changed to 4%; and (ii) the royalty payments on amounts received by us from sublicensees on sublicensees' gross sales under the same agreements are changed to 20% of the amount received us from our sublicensees, provided, however, that in the event the amounts received by us from sublicensees is 4% or less of sublicensees' gross sales, Austrianova will receive 50% of what we receive (up to 2%) and then additionally 20% of any amount we receive over that 4%.

One of the Binding Term Sheet Amendments requires that we pay $900,000 to Austrianova ratably over a nine-month period in the amount of two $50,000 payments each month during the nine-month period on the days of the month to be agreed upon between the parties, with a cure period of 20 calendar days after receipt by us of written notice from Austrianova that we have failed to pay timely a monthly payment. As of April 30, 2019, the $900,000 amount has been paid in full.

The Binding Term Sheet Amendments also provide that Austrianova receives 50% of any other financial and non-financial consideration received from our sublicensees of the Cell-in-a-Box® technology.

Finally, one of the Binding Term Sheet Amendments provides that Dr. Günzburg will not receive any cash compensation from us for services rendered as our Chief Scientific Officer under the Vin-de-Bona Consulting Agreement for a period of six months beginning September 1, 2017.

Goal and Strategies to Implement

Our goal is to become an industry-leading biotechnology company using the Cell-in-a-Box® technology as a platform upon which therapies for cancer and diabetes are developed and obtain marketing approval for these therapies from regulatory agencies in the U.S., the European Union ("E.U."), Australia and Canada.

Our strategies to implement our goal consist of the following:

- Submission of our IND to the FDA and for the FDA to allow us to commence a clinical trial for LAPC;
- Completion of preclinical studies and clinical trials that demonstrate the effectiveness of our cancer therapy in reducing the production and accumulation of malignant ascites fluid in the abdomen that is characteristic of pancreas and other abdominal cancers;
- Completion of preclinical studies and clinical trials that involve the encapsulation of the Melligen cells, genetically modified stem cells and beta islet or islet-like cells using the Cell-in-a-Box® technology to develop a therapy for Type 1 and insulin-dependent Type 2 diabetes;
- Enhancement of our ability to expand into the biotechnology arena through further research and partnering agreements with one or more third parties involved in the development of cancer and diabetes therapies;
- Acquisition of contracts that generate revenue or provide research and development capital utilizing our sublicensing rights;
- Further development of uses of the Cell-in-a-Box® technology platform through contracts, licensing agreements and joint ventures with other companies; and
- Completion of testing, expansion and marketing of existing and newly derived product candidates.

Cell Therapy Product Development

In our efforts to bring potential treatments to bear on pancreatic and other solid tumor cancers, we acquired Bio Blue Bird. This subsidiary holds our exclusive license, as amended, to a certain type of genetically modified cell line we use with the Cell-in-a-Box® live cell encapsulation technology for use in oncology. We have also entered into license agreements (discussed above and below) to use Cell-in-a-Box® technology to develop a therapy for Type 1 and insulin-dependent Type 2 diabetes, as well as cancer therapies where the Cell-in-a-Box® technology is combined with certain cannabinoids.

Our focus is currently placed on the preparations for our planned Phase 2b clinical trial in LAPC. These preparations include the live cell encapsulation of cancer prodrug-activating cells – the cells that convert the prodrug ifosfamide into its cancer-killing form. For our trial, as in the earlier Phase 1/2 and Phase 2 clinical trials that were done using live cell encapsulation plus ifosfamide, live cells expressing a cytochrome P450 isozyme will be encapsulated using the Cell-in-a-Box® technology. These capsulated cells will be implanted as close to the patient's tumor as possible. Once implanted, ifosfamide, a chemotherapy drug that is normally activated in the liver, will be given intravenously at approximately one-third (1 g/m^2) of the normal dose. The ifosfamide will be carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide flows through the porous capsules with the live cells inside, they act as a "bio-artificial liver" and convert the inactive form of the chemotherapy prodrug ifosfamide to its active form at or near the cancerous tumor. The results of this "targeted chemotherapy" are discussed in more detail above and below.

The Cell-in-a-Box® encapsulation technology potentially enables genetically engineered live human cells to be used as miniature factories. The technology results in the formation of pin-head sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In the laboratory setting, which involves the large-scale amplification and production of useful biotech products outside the body of a person or animal, the proprietary live cell encapsulation technology has been shown to create a micro-environment in which these encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors, passage through catheters and needles, etc., enabling greater growth and production of the end-product. The capsules are largely composed of cellulose (cotton) and are bio-inert.

Our encapsulation technology has the potential to enable live cells to survive in the human host and function like any other living cell in the body. The capsules contain small pores. The pores are big enough to allow nutrients in and waste products out of the capsules and small enough to keep the cells inside. Small molecules (such as ifosfamide, nutrients, oxygen and waste products) can pass through the pores of the capsules easily. The cells of the human's immune system cannot. The live cells inside the capsules do not protrude through the pores of the capsules, for if they did so, they would be subject to immune system attack. The encapsulated cells live in the body and behave like a miniature organ of the body without any inflammatory response or rejection. Furthermore, the cellulose-based capsules do not appear to irritate or inflame nearby tissues. Nor do they cause fibrous overgrowth in the area where the capsules are implanted.

Market Opportunity and the Competitive Landscape

The two areas we are currently developing for live cell encapsulation-based therapies are cancer and diabetes.

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. For example, the Cell-in-a-Box® capsules have remained intact for approximately two years in humans and for several months in animals during clinical trials and preclinical studies, respectively. 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

Studies have also shown that 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 90% 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 significant new advantages and 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 drug to be given to a patient, significantly reducing or even eliminating side effects from the chemotherapy;
- Encapsulating genetically modified live cells has the potential for the treatment of systemic diseases of various types, including diabetes;
- Multi-layered patent and 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
- Safety and effectiveness of the Cell-in-a-Box® technology and the cells used with our technology have already been shown in both human clinical trials and animal studies.

The field of diabetes cell therapy development is competitive. There are numerous companies developing cell-based therapies for diabetes. These competitors include companies such as Viacyte, Inc. ("Viacyte") in collaboration with Gore, Semma Therapeutics, Inc. in collaboration with Defymed, SAS, Diabetes Research Institute Foundation, Beta-O2 Technologies Ltd., Diatranz Otsuka Ltd., Sernova Corp. and BetaCell NV. All these entities are developing some form of encapsulation-based disease therapies. Although such competition exists, we believe these other companies are developing encapsulation-based therapies using encapsulation materials and methodologies that produce capsules or devices that are far less robust than ours or that are associated with other problems, such as extremely short shelf-life of the product and/or fibrotic overgrowth of their encapsulation products when implanted in the body. These properties are not characteristic of the Cell-in-a-Box® capsules.

Pancreatic cancer is increasing in most industrialized countries. The American Cancer Society estimates that in 2019 there will be 56,770 people in the U.S. diagnosed with pancreatic cancer. It estimates 45,750 patients with pancreatic cancer will die in 2019.

The International Agency for Research on Cancer ("IARC") released new global cancer statistics in September 2018. Of the 18 million cancer diagnoses predicted worldwide in 2018, nearly half 500,000 will be pancreatic cancer. The World Pancreatic Cancer Coalition ("WPCC") predicts that more than 430,000 pancreatic cancer deaths worldwide will occur in 2018. A diagnosis of pancreatic cancer is associated with poor prognosis due to early micrometastatic spread. The five-year survival rate for metastatic pancreatic cancer is approximately 7% according to the American Cancer Society.

Even with the best available therapy, patients with advanced pancreatic cancer can only expect median survival times of about 8.5 months. The percentage of one-year survivors is in the order of approximately 20%. The disease is operable in about only 10% of patients after being diagnosed. This is largely because pancreatic cancer shows no symptoms until it is at an advanced stage (stage 3 or 4) of development. However, over the past few years, radiologic techniques have advanced to the point where some pancreatic cancers may be detectable somewhat sooner. A new definition of "borderline operable" has been coined, and a greater number of pancreatic cancers are now being detected when they are "locally advanced" rather than after they have metastasized and spread to other organs in the body.

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 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. In addition to commercial entities such as Halozyme, Inc., OncoMed Pharmaceuticals, Inc., and Boston Biomedical, Inc., to name a few of the smaller companies, several academic institutions and cancer centers are 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 more recently in the U.S., the 4-drug combination known as 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 ("EMA") for our pancreatic cancer therapy, our trade secrets, the patents we are seeking and the licensing agreements we have that are described in this Report. 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.

We believe our therapy for pancreatic cancer has already shown promise through the completion of a Phase 1/2 and a Phase 2 clinical trial in advanced, inoperable pancreatic cancer. Our therapy for diabetes has also shown promise. Completed research studies have resulted in positive responses in animal models using the Melligen cells. We believe we are in a strong competitive position considering our unique encapsulation technology and the genetically modified cells that we have the exclusive worldwide license to use in most industrialized countries.

As discussed above in the section on cannabinoids, PharmaCyte has several major competitors developing*Cannabis*-based therapies for cancer.

Previous Clinical Trials Using Our Encapsulation Technology

Two previous clinical trials using what is now our encapsulation technology were carried out in Europe in 1998-1999 and 2000, respectively. Both employed the combination of the cellulose-based live cell encapsulation technology with low doses of the anticancer drug ifosfamide. The results of the two clinical trials have appeared in the peer-reviewed scientific literature and are summarized as follows:

Phase 1/2 Clinical Trial

Dates of Trial and Location: This clinical trial was opened on July 28, 1998 and closed on September 20, 1999. It was carried out at the Division of Gastroenterology, University of Rostock, Germany.

Identity of Trial Sponsors: The clinical trial was sponsored by Bavarian Nordic.

Trial Design: The clinical trial was an open-label, prospective, single-arm and single center trial.

Patient Information: A total of 17 patients were enrolled in the clinical trial (51 were screened). A total of 14 patients were treated because two of the original 17 patients developed severe infections before the start of the clinical trial and had to be treated by other means. For the other patient, angiography was not successful, causing the patient to be disqualified from participating in the clinical trial.

Trial Criteria: Criteria for enrolling in the clinical trial included inoperable pancreatic adenocarcinoma Stage 3-4 (according to IUCC criteria) as determined by histology and measured by computerized tomography ("CT") scan and the patients must not have had any prior chemotherapy for their disease.

Duration of Treatment and Dosage Information: On day 0, celiac angiography was performed and 300 (in 13 patients, 250 in one) of the capsules containing the ifosfamide-activating cells were placed by supraselective catheterization of an artery leading to the tumor. Each capsule (~0.7 mm in diameter) contained about 20,000 cells. The cells overexpressed CYP2B1 (a cytochrome P450 isoform), which catalyzed the conversion of the anticancer prodrug ifosfamide into its "cancer-killing" form.

On day 1, patients were monitored for evidence of any clinically relevant adverse reactions, e.g. allergy and/or pancreatitis. On days 2-4, each patient received low-dose (1 g/m^2 body surface area) ifosfamide in 250 ml of normal saline administered systemically as a 1-hour infusion. This was accompanied by a 60% dose equivalent of the uroprotective drug Mesna, which is used to reduce the side effects of ifosfamide chemotherapy, given as three intravenous injections. This regimen was repeated on days 23-25 for all but two patients who received only one round of ifosfamide. A total of only two cycles of ifosfamide were given to the remainder of the patients.

Specific Clinical Endpoints: Median survival time from the time of diagnosis, the percentage of patients who survived one year or more and the quality of life of each patient were examined in the clinical trial.

Observational Metrics Utilized and Actual Results Observed: Standard National Cancer Institute ("NCI") criteria for evaluating tumor growth were used to assess results:

- stable disease (tumors 50-125% of initial size) ("SD");
- partial remission (more than 50% reduction in tumor volume) ("PR"); and
- minor response (tumor reduction of between 25% and 50%) ("MR").

Effects of the treatment on tumor size were measured by CT scans. Control CT scans were scheduled for weeks 10 and 20, respectively. During the final visit a control angiography was performed. On the initial CT scan, the scan demonstrating the largest diameter of the primary tumor was identified and the area measured. Using appropriate landmarks, an identical scan was used for comparison. CT scans were evaluated by two unrelated radiologists, one of whom was not involved in the clinical trial. After formally finishing the clinical trial, patients were followed on an ambulatory basis with visits once every three months.

Toxicity was measured based on WHO/NCI guidelines on common toxicity criteria. The WHO and the NCI use standardized classifications of the adverse events associated with the use of cancer drugs. In cancer clinical trials, these are used to determine if a drug or treatment causes unwanted side effects ("Adverse Events") when used under specific conditions. For example, the most commonly used classification is known as the "Common Terminology Criteria for Adverse Events" developed by the NCI in the U.S. Most clinical trials carried out in the U.S. and the United Kingdom code their Adverse Event. This system consists of five grades. These are: 1 = mild; 2 = moderate; 3 = severe; 4 = life-threatening; 5 = death. In the studies reported for Cell-in-a-Box® plus low-dose ifosfamide combination in pancreatic cancer patients, the study investigators noted 11 Serious Adverse Events ("SAEs") in 7 patients, none of which were believed to be treatment-related.

Each patient's need for pain medication and the quality of life ("QOL") was monitored using a questionnaire established for diseases of the pancreas. A QOL questionnaire for cancer patients, QLQ-C30, had been validated in several languages, but the module for pancreatic cancer *per se* was still under development at the time of the study with respect to reliability, sensibility against changes and multicultural validation. Accordingly, a version of the core questionnaire and a German QOL scale (published in 1995) for pancreatic cancer patients was used. QOL data were documented independently from safety and efficacy data by having patients complete an independent questionnaire. Assessment of QOL data did not interfere with routine documentation of Adverse Events reported by the patients. QOL questionnaires were analyzed according to the criteria developed by the European Organization for Research and Treatment of Cancer ("EORTC"). As used in the description of the QOL results discussed in the published report of the Phase 1/2 trial of the Cell-in-a-Box® plus low-dose ifosfamide combination in pancreatic cancer patients, the questionnaire was used to assess the QOL of patients undergoing treatment. The QOL was analyzed in a similar manner to the way that a QOL questionnaire developed by the EORTC is usually analyzed. This latter questionnaire is known as EORTC QLQ-C30. QOL data were available from the baseline evaluation for 14 patients and for analysis of change for 8 patients.

A clinical benefit score based on variables, including the "Karnofsky Score" and body weight, was determined. Pain and analgesic consumption were calculated from the QOL questionnaires. The Karnofsky Score is a scale that is used to attempt to quantify a cancer patient's general well-being and activities of daily life. It is often used to judge the suitability of patients for inclusion into clinical trials. As a clinical trial progresses, a patient's Karnofsky Score can change. It is also used to assess a patient's QOL as a clinical trial progresses. The scale starts at 100 (normal, no complaints, no evidence of disease) and decreases in decrements of 10 down through 50 (requires considerable assistance and frequent medical care) all the way to 10 (moribund, fatal processes progressing rapidly) and finally to 0 (deceased). Pain intensity was measured on a visual analog scale ranging from 0 (no pain) to 100 (the most intensive pain imaginable) in increments of 10. Analgesic consumption was assessed using a separate scale in which 0 indicated no regular consumption of analgesics and 25, 50 and 100 indicated administration of non-steroidal anti-inflammatory drugs or opiates several times per year, per month or per week, respectively.

The primary tumor did not grow in any of the 14 patients. Two patients had a PR; 12 patients exhibited SD; and two patients showed an MR.

Median survival time of patients in this clinical trial was 39 weeks. The one-year survival rate was 36%.

Within the 20-week study period, three patients died from disease progression (on days 9, 85 and 132). Upon postmortem examination, the patient who died on day 9 from recurrent pulmonary embolism was found to have extensive tumor necrosis.

The chemotherapy regimen was well tolerated. No toxicity beyond Grade 2 (moderate adverse effect) was detected in any of the 14 patients.

Eleven SAEs were seen in 7 patients during the study period. None of them were treatment-related (due to capsule implantation or ifosfamide administration). These SAEs were attributed to underlying disease and/or the effects associated with the disease.

Implanting the capsules did not result in any obvious allergic or inflammatory response, and no patients developed pancreatitis during the trial. Some patients exhibited elevated amylase levels, presumably due to tumor infiltration of the pancreas and limited obstructive chronic pancreatitis. However, no further increase in amylase levels was seen after angiography and capsule implantation.

In accordance with the report of the study, only one Adverse Event (increased lipase activity on day 15 after installation of the capsules), which was a Grade 1 Adverse Event, "may" have been linked to implanting the capsules.

Ten of 14 patients experienced a "clinical benefit" which means either no increase or a decrease in pain intensity. For 7 of the patients, this was confirmed by their analgesic consumption. None of these "benefited" patients registered an increased analgesic usage either in terms of dosage or WHO levels.

None of the patients showed an increased Karnofsky Score after treatment. However, 7 of the 14 patients had stable Karnofsky Scores at the week 10 assessment. For 4 of these patients, their indices were still stable at the week 20 assessment.

One patient's body weight increased at both weeks 10 and 20 and another patient showed increased weight at week 10 (this patient withdrew from the clinical trial and no week 20 weight was obtained). Two patients showed stable body weights at week 10, one of whom dropped out of the clinical trial and the other showed weight loss at week 20.

Two scenarios were used to establish the overall integrative clinical benefit response, where each patient was given a +2 score for an improved value, a +1 score for a stable value and a -1 score for a worsened value for each of four criteria (pain, analgesic consumption, Karnofsky Score and body weight) as compared to the relevant week 0 values.

The "worst case scenario" required a pain relief score of 20 points or more to be judged an improvement and a decrease in the Karnofsky Score of 10 points or more to indicate worsening. Using this scenario, 50% or 7 of the treated patients experienced clinical benefit; 21.4% or 3 patients were neutral (benefits were offset by impairments); and 28.6% or 4 patients had no clinical benefit. The latter included those passing away before the median survival time.

In the "best case scenario," a pain relief score of 10 points or more was an improvement. A decrease in Karnofsky Score of 20 points or more was considered a worsening. In this scenario, 71.4% or 10 patients had clinical benefit, 14.2% of patients showed neither benefit nor deterioration and 14.3% patients had no benefit.

Standard of Care: At the time this clinical trial was conducted, only one FDA-approved treatment for advanced, inoperable pancreatic cancer was available. That was the drug gemcitabine, first approved by the FDA in 1996.

An examination of the prescribing information for gemcitabine reflects that the median survival seen in the Phase 3 pancreatic cancer clinical trial for gemcitabine was approximately 23 weeks (5.7 months). The percentage of one-year survivors was approximately 18%. In a Phase 3 clinical trial of Celgene's Abraxane® plus gemcitabine combination that was approved by the FDA in September 2013, the median survival time for patients was about 8.5 months and the percentage of one-year survivors was approximately 35%.

The treatment with gemcitabine of patients with pancreatic cancer is often associated with severe side effects. According to the prescribing information for gemcitabine, for use to treat pancreatic cancer the recommended dose is 1000 mg/m^2 given intravenously over 30 minutes. The schedule of administration is: weeks 1-8, weekly dosing for 7 weeks followed by one-week rest and then after week 8, weekly dosing on days 1, 8 and 15 of 28-day cycles.

Reductions in the doses of gemcitabine are necessitated by the occurrence of myelosuppression. Permanent discontinuation of gemcitabine is necessary for any of the following:

- unexplained dyspnea or other evidence of severe pulmonary toxicity;
- severe hepatotoxicity;
- hemolytic-uremic syndrome;
- capillary leak syndrome; and
- posterior reversible encephalopathy syndrome.

Gemcitabine should be withheld, or its dose reduced by 50% for other severe (Grade 3 or 4) non-hematologic toxicity until that toxicity is resolved.

Conclusions: In the opinion of the trial's investigators, in this Phase 1/2 clinical trial the use of the combination of Cell-in-a-Box® capsules plus low-dose ifosfamide was both safe and effective. This assessment was not based on the opinion of any drug regulatory authority and does not guarantee that that this assessment will be maintained in any late-phase clinical trial or that any drug regulatory authority will ultimately determine that the Cell-in-a-Box® plus low-dose ifosfamide combination is safe and effective for the purposes of granting marketing approval.

In the Phase 1/2 clinical trial only a small number of patients were evaluated. Statistical parameters were not used in the published reports of the Phase 1/2 trial to validate the anticancer efficacy of the Cell-in-a-Box® plus low-dose ifosfamide combination in patients with advanced, inoperable pancreatic cancer. In the opinion of the investigators, the results indicate a trend towards efficacy; accordingly, the results should not be viewed as absolute numbers. It should be noted, however, that because the results were not statistically significant, any observations of efficacy must be weighed against the possibility that the results were due to chance alone. The purpose of the clinical trial was not to obtain data so that marketing approval could be obtained from regulatory authorities. Rather, the clinical trial allowed the investigators to determine whether the Cell-in-a- Box® capsules plus low-dose ifosfamide combination holds promise as a therapy for advanced pancreatic cancer. In the cancer arena, Phase 1/2 clinical trials are used to: (i) establish the safety of the drug or treatment being investigated; and (ii) determine if a trend towards efficacy exists. In accordance with FDA guidance, as well as similar guidance from other regulatory authorities in countries other than the U.S., we realize that a large, multicenter, randomized, comparative study needs to be conducted and the results from such a trial would have to confirm the results from this previous Phase 1/2 trial before an application for marketing approval could be filed with the FDA or EMA. We are currently engaged in preparing an IND for submission to the FDA to conduct a new clinical trial.

If our cancer therapy is approved by the regulatory agencies, we believe it could provide a significant benefit to those with this devastating and deadly disease, not only in terms of life-span but also in terms of increased quality of life. Also, we believe that success of the live cell encapsulation technology in the pancreatic cancer setting may lead to its successful use in developing therapies for other forms of solid cancerous tumors after preclinical studies and clinical trials have been completed.

Phase 2 Clinical Trial

Location of Trial: The clinical trial was opened on November 16, 1999 and closed on December 1, 2000. This clinical trial was carried out at four centers in two countries in Europe. These were in Berne, Switzerland, and in Rostock, Munich and Berlin, Germany.

Trial Sponsor: The clinical trial was sponsored by Bavarian Nordic.

Trial Design: This was an open-label, prospective, single-arm multi-site study.

Patient Information: All 13 patients enrolled in the trial were treated. Twelve patients exhibited Stage 4 disease. The remaining patient had Stage 3 disease. Ten of the 13 patients exhibited metastases.

Duration of Treatment and Dosage Information: The number of capsules implanted varied from 221 to 300 with a mean of 244. On day 1, patients were monitored for any allergic reactions to capsule implantation and/or pancreatitis. The administration schedule of the treatment was the same as in the earlier Phase 1/2 trial, except that in this Phase 2 trial the dose of ifosfamide was doubled to 2 g/m^2. In the Phase1/2 trial, it was $1g/m^2$. On days 2-4, patients received 2 g/m^2 in normal saline as a one-hour infusion. The urinary tract protector Mesna was also given as 3 intravenous injections. This regimen was repeated on days 23-25.

Specific Clinical Endpoints: The primary endpoint of the trial was to determine response rate as defined by SD, PR and MR as well as the clinical benefit (Karnofsky score) of the treatment. The timing of the tumor size measurements and determination of tumor sizes by CT scans were done by independent radiologists. A secondary endpoint was to determine time to progression, tumor response, duration of partial or complete remission, length of symptom-free survival, survival time and quality of life. Another secondary endpoint was to evaluate the safety and tolerability of the treatment regimen, with attention being paid to the appearance of pancreatitis or immediate allergic reactions.

Safety Analysis of Angiography, Capsule Implantation and Chemotherapy: On average, angiography took approximately 40 minutes. For 5 of the patients in this clinical trial, more than one blood vessel had to be used for placement of the capsules. The administration of the capsules was well tolerated. There were no signs of allergic reactions or hemorrhagic cystitis after implantation of the capsules. Two patients had increased levels of serum lipase at baseline. After additional measurements, these were not considered to be clinically relevant. The dose of ifosfamide (2 g/m^2) used was found to be toxic in most patients. This resulted in one patient having to reduce the ifosfamide dose in the second of the two cycles of treatment with the drug. The most common toxic effects were nausea, vomiting, malaise, anorexia and mild hematuria.

Serious Adverse Events: A total of 16 SAEs were documented in eight patients, including 3 SAEs leading to death. None of these SAEs were attributed to placement of the encapsulated cells. One patient experienced neurological impairment (drowsiness, nocturnal enuresis, mild somnolence) which was attributed to treatment with the 2 g/m^2 dose of ifosfamide. All patients experienced between 5 and 19 SAEs. Six SAEs were rated as life-threatening; 10.2% were rated as severe; 28.7% were rated as moderate; and 53.7% were rated as mild. None of the SAEs was thought to be related to placement of the encapsulated cells, but 44% were related to the administration of ifosfamide at the elevated dose given. Most frequent SAEs were alopecia, anemia, leucopenia, nausea and vomiting or encephalopathy. Other SAEs were new or worse symptoms of the patients' underlying disease. A total of 65 events met the NCI's common toxicity criteria. Of these, 46.2% had Grade 1, 40% had Grade 2, 9.2% had Grade 3 and 4.6% had Grade 4 toxicities.

Tumor Reductions and Patient Survival Results: The size of the primary tumor was measured before starting the live cell encapsulation plus ifosfamide therapy and at weeks 10 and 20 post-treatment. No PRs were observed, but 4 patients exhibited tumor size reductions, 4 patients showed tumor growth and the remaining 5 patients had SD over the "follow-up" period after chemotherapy.

The median survival of patients was 40 weeks. Most the survival benefit was shown early during the entire observation period. However, as time progressed, these patients succumbed at the same rate as historical controls. This observation suggested to the investigators that prolongation of the survival benefit might be achieved if additional courses of ifosfamide chemotherapy were given. The one-year survival rate was 23%. It was thought that this may be attributable to the higher dose of ifosfamide used in this clinical trial.

Quality of Life: An assessment of the quality of life of the patients was performed in this clinical trial. Quality of life data were available for all the patients. According to this quality of life assessment, although pain during the night decreased, patients felt themselves to be less attractive and lost interest in sex. No additional improvements in patients' quality of life were observed.

Conclusions: The opinions of the investigators were as follows: (i) the lack of "problems" associated with the implanted encapsulated cells was noted as in the Phase 1/2 trial; (ii) administering more than two courses of treatment with ifosfamide might have beneficial effects on survival; and (iii) since doubling the dose of ifosfamide from that used in the Phase 1/2 trial had no beneficial antitumor or survival effect but was associated with increased side effects from the treatment, the dose of ifosfamide to be used in combination with the encapsulated cells for all future trials should be 1 g/m^2.

Manufacturing

We are outsourcing all cell growth, processing and encapsulation services needed for our future clinical trials of the encapsulated cell-based cancer and diabetes therapies. The Cell-in-a-Box® encapsulation will be done by Austrianova at its cGMP-compliant manufacturing facility in Bangkok, Thailand.

We initially engaged ViruSure GmbH ("ViruSure"), a professional cell growing and adventitious agent testing company that has had extensive experience with the CYP2B1-expressing cancer prodrug-activating cells that will be needed for our pancreatic cancer therapy. We did so to recover them from frozen stocks of similar cells developed by Bavarian Nordic and regenerate new stocks for use by us in our preclinical studies and clinical trials. ViruSure cloned new cells from one selected clone. We planned to use the clones to populate a Master Cell Bank ("MCB") and a Working Cell Bank ("WCB") for our future clinical trials.

In March 2014, we entered a Manufacturing Framework Agreement with Austrianova ("Manufacturing Framework Agreement") pursuant to which Austrianova will encapsulate the genetically engineered live cells that will be used for our cancer therapy. We have also contracted with Austrianova to provide encapsulated insulin-producing cells for our preclinical studies in diabetes. At the appropriate time, we intend to enter into a similar manufacturing framework agreement with Austrianova for the encapsulated cells we will need for our diabetes therapy.

In April 2014, we entered an agreement with ViruSure pursuant to which ViruSure agreed to clone cells from the 22P1G cell line (the cells that express the CYP2B1 isoform of cytochrome P450 that converts ifosfamide into its cancer-killing form). In August 2014, we entered into a revised proposal with ViruSure pursuant to which ViruSure modified certain testing recommendations and cell banking procedures. ViruSure was engaged in the process of cloning cells for some time and conducted various tests of the cells it had grown for us.

In June 2017, we entered into an agreement with Eurofins for the preparation and characterization of a cGMP quality MCB for use in our therapy for pancreatic cancer. The agreement includes pre-bank testing, MCB preparation, MCB characterization, Working Cell Bank ("WCB") preparation, WCB characterization, end of production characterization and related analyses, as well as optional testing. The MCB was initially planned to be used as a "safe" repository of the cloned cells that we would use in our cancer therapy. The WCB was planned to be used to supply the large numbers of cells needed for our preclinical studies, clinical trials and other purposes related to the development of our therapy for LAPC and other forms of solid tumor cancers.

In January 2018, we modified our agreement with Eurofins to exclude the WCB preparation and characterization, as well as the end of production characterization and related analysis. We did so to expedite the availability of the cells needed for encapsulation by Austrianova to conduct our planned clinical trial in LAPC and to save the costs.

Pursuant to the terms of the Austrianova MOU, Austrianova and we have agreed to negotiate a new Manufacturing Framework Agreement pursuant to which Austrianova will provide us with Phase 3 clinical material utilizing the genetically engineered cells designed to activate ifosfamide that have been encapsulated using the Cell-in-a-Box® technology to conduct a late phase clinical trial in the U.S. with possible study sites in Europe.

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 and promotion 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. Generally, 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 appropriate 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 into 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 problems with 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 ("PHSA"). Pharmaceutical products and biologics are also subject to other federal, state and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or by an Institutional Review Board ("IRB") of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of 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;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product candidate is produced to assess compliance with cGMP and proof that the facilities, methods and controls are adequate;
- 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 federal regulations and with Good Clinical Practices ("GCPs") standards to establish 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 such as the therapies we are developing;
- 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 biologic product may be given to humans, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate's chemical and biological activities and animal studies to assess potential safety and efficacy in humans. The results of these studies must be submitted to the FDA as part of an IND which must be reviewed by the FDA for safety and other considerations before even an initial (Phase 1) clinical trial in humans can begin.

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 of any new drug or biologic product 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. If the FDA has neither commented on nor questioned the IND within this 30-day period after submission of the IND, the clinical trial proposed in the IND may begin. A clinical trial involves the administration of the investigational product candidate to patients under the supervision of qualified investigators following GCP standards. These international standards 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 protocols that detail the parameters to be used in monitoring safety, 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.

We devote significant resources to research and development programs to discover and develop potential future product candidates. The product candidates in our pipeline are at various stages of preclinical and clinical development. The path to regulatory approval includes three phases of clinical trials in which we collect data to support an application to regulatory agencies to allow us to ultimately market a product for treatment of a specified disease. There are many difficulties and uncertainties inherent in research and development of new products, and these can conceivably result in a high rate of failure. To bring a drug from the discovery phase to regulatory approval, and ultimately to market, takes years and the costs to do so are significant. Failure can occur at any point in the process, including after the product is approved, based on post-marketing factors. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, reimbursement challenges, difficulty or excessive costs of manufacture, alternative therapies or infringement of the patents or intellectual property rights of others. Uncertainties in the approval process of the regulatory agencies can result in delays in product launches and lost market opportunities. Consequently, it is very difficult to predict which products will ultimately be submitted for approval, which have the highest likelihood of obtaining approval and which will be commercially viable and generate profits. Successful results in preclinical or clinical studies may not be an accurate predictor of the ultimate safety or effectiveness of a product candidate.

Phase 1 Clinical Trial: A Phase 1 clinical trial begins when a regulatory agency, such as the FDA, allows initiation of the clinical investigation of a new product candidate. The clinical trial studies a product candidate's safety profile and may include a preliminary determination of a product candidate's safe dosage range. The Phase 1 clinical trial can also determine how a drug is absorbed, distributed, metabolized and excreted by the body and, therefore, the potential duration of its action.

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. An initial evaluation of the product candidate's effectiveness on patients is performed. Additional information on the product candidate's safety and dosage range is obtained. For many diseases, a Phase 2 clinical trial can include up to several hundred patients.

Phase 3 Clinical Trial: A Phase 3 clinical trial is typically rigorously controlled, conducted in multiple centers and involves a larger target patient population that can consist of from several hundred to thousands of patients (depending on the disease being studied) to ensure that study results are statistically significant. During a Phase 3 clinical trial, physicians monitor patients to determine efficacy and to gather further information on safety. A Phase 3 clinical trial is designed to generate all the clinical data necessary to apply for marketing approval to a regulatory agency.

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 a company 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. In some cases, a clinical trial is overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board. This group provides authorization for whether a trial may move forward at designated checkpoints. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of a clinical trial if it is determined that the patients are being exposed to an unacceptable health risk. There are also requirements for the registration of an ongoing clinical trial of a product candidate on public registries and the disclosure of certain information pertaining to the trial, as well as clinical trial results after completion.

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 clinical trial protocol design and 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 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, and there is no guarantee that a study 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.

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 indications.

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 the proposed labeling for the product, 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. There may be some instances in which the user fee is waived. 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. 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. During a normal review cycle, a product is given an FDA action or Prescription Drug User Fee Act ("PDUFA") date within 12 months of the submission, if the submission is accepted. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA may also issue a complete response, which may delay approval for several months or even years. 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 that includes clinicians and other experts for review, evaluation and 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 a NDA or a BLA, the FDA will 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 follow cGMP requirements and are adequate to assure consistent production of the product within required specifications. Also, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGMP standards. Manufacturers of human cellular or tissue-based biologics also must comply with the FDA's Good Tissue Practices ("GTPs"), as applicable, and with the general biological product standards. After the FDA evaluates the NDA or BLA and the sponsor company's manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If, or 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.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require risk evaluation and mitigation strategies ("REMS") to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA/BLA or a NDA/BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data like that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

Disclosure of Clinical Trial Information

A sponsor of a clinical trial of certain FDA-regulated products, including prescription drugs and biologics, is required to register and disclose certain clinical trial information on a public website. Information related to the product, patient population, phase of investigation, study sites and investigator involved, and other aspects of the clinical trial are made public as part of the registration. A sponsor is also obligated to disclose the results of a clinical trial after completion. Disclosure of the results can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

Advertising and Promotion

The FDA and other federal regulatory agencies closely 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 product cannot be commercially promoted before it is approved. 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 permitted to prescribe drugs or biologics for "off-label" uses (uses not approved by the FDA and therefore not described in the drug's labeling) 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 off-label use, but may engage in non-promotional, balanced communication 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 Office of the Inspector General of Health & Human Services ("HHS") and state authorities. This could subject a company 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 drug products.

Post Approval Regulations

After regulatory approval of a drug or biologic is obtained, a company is required to comply with certain post-approval 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. Also, as a holder of an approved NDA or BLA, a company is required to: (i) report adverse reactions and production problems to the FDA; (ii) provide updated safety and efficacy information; and (iii) comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP standards after approval to assure and preserve the long-term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP standards, which imposes extensive procedural and substantive record keeping requirements. Also, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. 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. 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.

U.S. Patent Extension and Marketing Exclusivity

The Biologics Price Competition and Innovation Act ("BPCIA") amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its product as highly like an approved innovator biologic, among other requirements. The BPCIA bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval.

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 testing phase (the time between the IND submission becoming effective and the NDA, BLA or premarket approval ("PMA") submission) and all the review phase (the time between NDA, BLA or PMA submission and approval) 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.

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.

European and Other International Government Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U.S. have a similar process to that of the FDA in that such countries require the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and an IRB. Once the CTA is approved in accordance with a country's requirements, a clinical trial may proceed in that particular country.

To obtain regulatory approval to commercialize a new drug or biologic under the E.U. regulatory systems, we must submit a marketing authorization application ("MAA") with the EMA, the E.U.'s counterpart to the U.S. FDA. It is like the NDA or the BLA, except for, among other things, country-specific document requirements.

Outside of the E.U. the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with cGMP standards - applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

Regulatory Review

If a product candidate successfully completes a Phase 3 clinical trial and is submitted to regulatory agencies, such as the FDA in the U.S. and the EMA in Europe, the time to final marketing approval can vary from months to years, depending on several variables. These variables can include such things as the disease type, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas. In some cases, further studies beyond the three-phase clinical trial process described above are required as a condition for approval of a NDA, a MAA or a BLA. Each country-specific regulatory agency requires monitoring of all aspects of a clinical trial and reporting all adverse events in the trial. A regulatory agency may also require the conduct of pediatric studies for the product and indication either before or after submission of a NDA or a BLA.

Approval by Regulatory Agencies

The results of the preclinical testing, production parameters and a clinical trial are submitted to the regulatory agency as part of a NDA, a MAA or a BLA for evaluation to determine if there is substantial evidence that the product is sufficiently safe and effective to warrant approval. In responding to a NDA, a MAA or a BLA, the regulatory agency may grant market approval, deny approval or request additional information.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on a trial, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Special Regulatory Procedures

The FDA has developed distinct approaches to make new drugs and biologics available as rapidly as possible in cases where there is no available treatment or there are advantages over existing treatments. For example, the FDA may grant "Accelerated Approval" to products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. For Accelerated Approval, the product must influence a surrogate endpoint or an intermediate clinical endpoint that is considered reasonably likely to predict the clinical benefit of a product candidate, such as an effect on irreversible morbidity and mortality. When approval is based on surrogate endpoints or clinical endpoints, other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. These studies are known in as confirmatory trials. Accelerated Approval of a product may be withdrawn, or the labeled indication of the drug changed if these trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the product candidate.

The FDA may grant "Fast Track" status to products that treat serious diseases or conditions and fill an unmet medical need. Fast Track is a process designed to facilitate the development and expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan, more frequent written correspondence from the FDA about trial design, eligibility for Accelerated Approval if relevant criteria are met and rolling review, which allows submission of individually completed sections of a NDA or a BLA for regulatory agency review before the entire submission is completed. Fast Track status does not ensure that a product will be developed more quickly or receive regulatory agency approval.

The FDA's "Breakthrough Therapy" designation for a product candidate is designed to expedite the development and review of drugs and biologics that are intended to treat a serious condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over available therapies in terms of a clinically significant endpoint. For drugs and biologics that have been designated as Breakthrough Therapies, robust FDA-sponsor interaction and communication can help to identify the most efficient and expeditious path for clinical development while minimizing the number of patients placed in ineffective "control" regimens.

The FDA may grant "Priority Review" status to product candidates that, if approved, would provide significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions. Priority Review is intended to reduce the time it takes for the FDA to review a NDA or a BLA, with the goal to act on the application within six months.

Orphan Drug Status

In accordance with laws and regulations pertaining to regulatory agencies, a sponsor may request that the regulatory agencies designate a drug or biologic intended to treat a "Rare Disease or Condition" as an "Orphan Drug." For example, in the U.S., a "Rare Disease or Condition" is defined as one which affects less than 200,000 people in the U.S., or which affects more than 200,000 people but for which the cost of developing and making available the product is not expected to be recovered from sales of the product in the U.S. 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 7 years of exclusive marketing rights in the U.S. for the drug or 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 drug that has other labeled indications that are not under orphan or other exclusivities. An Orphan Drug may also be eligible for federal income tax credits for costs associated with the disease state, the strength and complexity of the data presented, the novelty of the target or compound, the risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas.

Priority Review and Accelerated Review

Based on results of a Phase 3 clinical trial submitted in a NDA or a BLA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from the FDA's decision on priority review application, or eight months from the NDA filing. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the standard FDA review period is ten months from the FDA's decision on priority review application, or 12 months from the NDA or BLA filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under a centralized procedure in the European Union, the maximum timeframe for the evaluation of a MAA 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 Committee for Medicinal Products for Human Use ("CHMP")). Accelerated evaluation might be granted by the CHMP in exceptional cases, for example, when a medicinal product is expected to be of a major public health interest, which takes into consideration: (i) the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; (ii) the absence or insufficiency of an appropriate alternative therapeutic approach; and (iii) anticipation of high therapeutic benefit. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

Healthcare Reform

In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "Affordable Care Act"). The Affordable Care Act substantially changes the way healthcare will be delivered and financed by both governmental and private insurers and significantly impacts the pharmaceutical and biotechnology industries. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the Affordable Care Act's provisions of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any covered entity engaged in manufacturing or importing certain branded prescription drugs and biological products, apportioned among such entities in accordance with their respective market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13.0% of the Average Manufacturer Price ("AMP"), for most branded and generic drugs, respectively;
- expansion of the scope of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a partial prescription drug benefit for Medicare recipients, or Medicare Part D, coverage gap discount program in which manufacturers must agree to offer 50.0% point of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133.0% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report annually specified financial arrangements with physicians and teaching hospitals, as defined in the Affordable Care Act and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals, and other healthcare providers and reporting any ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare and Medicaid Services ("CMS") required beginning March 31, 2014 and by the 90th day of each subsequent calendar year;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- a mandatory nondeductible payment for employers with 50 or more full time employees (or equivalents) who fail to provide certain minimum health insurance coverage for such employees and their dependents, beginning in 2015 (pursuant to relief enacted by the Treasury Department).

The Affordable Care Act also established an Independent Payment Advisory Board ("IPAB") to reduce the per capita rate of growth in Medicare spending. Beginning in 2014, the IPAB was mandated to propose changes in Medicare payments if it determines that the rate of growth of Medicare expenditures exceeds target growth rates. The IPAB has broad discretion to propose policies to reduce expenditures that may have a negative impact on payment rates for pharmaceutical and biologic products. A proposal made by the IPAB is required to be implemented by the CMS unless Congress adopts a proposal with savings greater than those proposed by the IPAB. The IPAB has not yet been called upon to act as the annual determinations by the CMS Office of the Actuary have not identified a savings target for implementation.

In addition, other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction ("Joint Select Committee") to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers, patients and third-party payors and, accordingly, our financial operations.

In January 2016, the CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revises the way the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Also, there has been significant negative publicity and increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. It is possible that there will be further legislation or regulation that could harm our business, products financial condition and results of operations.

We anticipate that the Affordable Care Act and other legislative reforms will result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business, though we are still unsure what its full impact will be. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect such challenges and amendments to continue in the future. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. At the same time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the "Tax Cuts and Jobs Act" ("Tax Act"), enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019.

The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. Newly enacted FDA regulations may require us to expend additional resources to obtain or maintain regulatory approval. For example, in August 2017 President Trump signed into law the Food & Drug Administration Reauthorization Act ("FDARA"). This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, the development of drugs and biological products for pediatric use. This legislation may result in new regulations, which may affect future options or timelines for regulatory approval.

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 in 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.

Existing federal law requires pharmaceutical manufacturers to pay rebates to state governments, based on a statutory formula, on covered outpatient drugs reimbursed by the Medicaid program as a condition of having their drugs paid for by AMP. AMP is determined by a statutory formula that is based on prices defined in the statute. AMP must be calculated for all products that are covered outpatient drugs under the Medicaid program and be the "best price." Best price must be calculated only for those covered outpatient drugs that are a single source drug or innovator multiple source drug, such as biologic products. Manufacturers are required to report AMP and best price for each of their covered outpatient drugs to the government on a regular basis. Additionally, some state Medicaid programs have imposed a requirement for supplemental rebates over and above the formula set forth in federal law as a condition for coverage. In addition to the Medicaid rebate program, federal law also requires that if a pharmaceutical manufacturer wishes to have its outpatient drugs covered under Medicaid as well as under Medicare Part B, it must sign a "Master Agreement" obligating it to provide a formulaic discount of approximately 24%, known as the federal ceiling price for drugs sold to the U.S. Departments of Defense, Veterans Affairs, the Public Health Service and the Coast Guard, and also provide discounts through a drug pricing agreement meeting the requirements of Section 340B of the PHSA for outpatient drugs sold to certain specified eligible healthcare organizations. The formula for determining the discounted purchase price under the 340B drug pricing program is defined by statute and is based on the AMP and rebate amount for a product as calculated under the Medicaid drug rebate program discussed above.

Different pricing and reimbursement schemes exist in other countries. In the E.U. 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, particularly prescription drugs, has become more intense.

Thus, increasingly high barriers are being erected to the entry of new products. The E.U. provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product 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 HHS and its Office of Inspector General, the Office for Civil Rights that has jurisdiction over matters relating to individuals' privacy and protected health information, the DOJ, individual U.S. Attorney offices within the DOJ and state and local governments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare 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 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 Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

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

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or 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. Through a modification made to the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved—and thus non-reimbursable—uses. The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have additional similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the type of payor.

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 relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," such as independent contractors or agents of covered entities that receive or obtain protected health information with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons. 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. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect - thus complicating compliance efforts.

The federal Physician Payments Sunshine Act under the Affordable Care Act and its implementing regulations also require that certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals. It also requires reporting annually certain ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners. Failure to submit timely, accurately and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period of August 1, 2013 to December 31, 2013, by March 31, 2014. They are also required to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. The CMS made all reported data publicly available starting on September 30, 2014. Certain states also mandate implementation of compliance programs, impose additional restrictions on pharmaceutical manufacturer marketing practices and/ or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

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

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. These include criminal and civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, 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 refusal to allow us to enter supply contracts and 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.

Controlled Substances Regulation

Our product candidates involving *Cannabis* contain controlled substances, as defined in the federal Controlled Substances Act of 1970 ("CSA"). The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the U.S. Drug Enforcement Administration ("DEA"). The DEA is the federal agency responsible for regulating controlled substances. It requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV or V—with varying qualifications for listing in each schedule. Schedule I substances have a high potential for abuse, have no currently accepted medical use in treatment in the U.S. and lack accepted safety for use under medical supervision. They may be used only in federally approved research programs and may not be marketed or sold for dispensing to patients in the U.S. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule I substances presenting the highest potential for abuse and physical or psychological dependence. Schedule V substances present the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations and cannot be refilled.

Following NDA approval of a drug containing a Schedule I controlled substance, that substance must be rescheduled as a Schedule II, III, IV or V substance before it can be marketed. On November 17, 2015, H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act, passed through both houses of Congress. On November 25, 2015, the bill was signed into law. The law removes uncertainty associated with timing of the DEA rescheduling process after NDA approval. Specifically, it requires DEA to issue an "interim final rule," pursuant to which a manufacturer may market its product within 90 days of FDA approval. The law also preserves the period of orphan marketing exclusivity for the full seven years such that this period only begins after DEA scheduling. This contrasts with the previous situation whereby the orphan "clock" began to tick upon FDA approval, even though the product could not be marketed until DEA scheduling was complete.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the location, activity and controlled substance schedule. For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer for a Schedule I or II substance must be published in the Federal Register and is open for 30 days to permit interested persons to submit comments, objections or requests for a hearing. A copy of the notice of the Federal Register publication is forwarded by DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances and other designated substances. Registrants must also report any controlled substance thefts or significant losses and must obtain authorization to destroy or dispose of controlled substances. As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the U.S. complies with its obligations under international drug control treaties.

For drugs manufactured in the U.S., the DEA establishes annually an aggregate quota for substances within Schedules I and II that may be manufactured or produced in the U.S. based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific research and industrial needs. This limited aggregate amount of *Cannabis* that the DEA allows to be produced in the U.S. each year is allocated among individual companies, which, in turn, must annually apply to the DEA for individual manufacturing and procurement quotas. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Patents, Intellectual Property and Trade Secrets

Intellectual property ("IP") 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 IP and trade secrets and those of Austrianova, we cannot guarantee we will be able to protect and enforce our IP or obtain international patent protection for our product candidates as needed. We license technology and trademarks relating to three 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; (ii) treatment of solid cancerous tumors and (ii) encapsulation of cells for producing retroviral particles for gene therapy. We also have exclusive worldwide licensing rights to patents, trademarks and know-how using Cell-in-a-Box® technology in the diabetes field and in the treatment of diseases and related conditions using cannabinoids.

Litigation may be required to protect our product candidates, IP rights and trade secrets or to determine the validity and scope of the proprietary rights of others. Maintenance of our IP utilizes financial and operational resources. In addition, the possibility exists that our IP could be discovered to be owned by others, be invalid or be unenforceable - potentially bringing unforeseen challenges to us.

Intellectual Property Agreements and Patent Applications

The following patents and agreements constitute our material IP:

- We are a party to the Bavarian Nordic/GSF License Agreement pursuant to which Bavarian Nordic/GSF are the licensors and Bio Blue Bird, our wholly owned subsidiary, is the licensee. The Bavarian Nordic/GSF License Agreement was signed in July 2005 and amended in December 2006. Pursuant to the Bavarian Nordic/GSF License, the licensee is granted an exclusive license to use Bavarian Nordic's clinical data and know-how for encapsulating genetically modified human cells to treat cancer. The licensors have rights to terminate the license if the annuity and upkeep fees are not paid to Bavarian Nordic, there is not proper reporting or there is not a clearly documented effort to commercialize this technology. The term of the Bavarian Nordic/GSF License Agreement expired on March 27, 2017.
- In October 2016, Bavarian Nordic/GSF and Bio Blue Bird amended the Bavarian Nordic License Agreement to include, among other things, the right to import within the scope of the license, reflect ownership and notification of improvements, clarify which provisions survive expiration or termination of the Bavarian Nordic License Agreement and provide rights to Bio Blue Bird to the clinical data and know-how after the expiration of the licensed patent rights.
- The Third Addendum and the Clarification Agreement provides us with an exclusive worldwide license, with a right to sublicense, to use Austrianova's Cell-in-a-Box® encapsulation technology and associated technologies for the development of treatments for cancer and use of Austrianova's Cell-in-a-Box® trademark and its associated technology using genetically modified HEK293 cells overexpressing the cytochrome P450 2B1 gene that are encapsulated using the licensed technology.
- The Diabetes Licensing Agreement provides us with an exclusive worldwide license, with a right to sublicense, to use the Cell-in-a-Box® trademark and its associated technology with genetically modified or non-modified non-stem cell lines and induced pluripotent stem ("iPS") cells designed to produce insulin or other critical components for the treatment of diabetes.
- The Cannabis Licensing Agreement provides us with an exclusive worldwide license, with a right to sublicense, to use the Cell-in-a-Box® trademark and its associated technology with genetically modified non-stem cell lines which are designed to convert cannabinoids to their active form to develop therapies for diseases and their related symptoms.
- We entered into a Binding Term Sheet ("Binding Term Sheet") with SG Austria and Austrianova pursuant to which the parties reached an agreement to amend certain provisions in the SG Austria APA, the Diabetes Licensing Agreement, the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement.

We entered into the amendments contemplated by the Binding Term Sheet ("Binding Term Sheet Amendments"). The Binding Term Sheet Amendments provide that our obligation to make milestone payments to Austrianova will be eliminated in their entirety under the: (i) Cannabis License Agreement; and (ii) the Diabetes License Agreement, as amended. The Binding Term Sheet Amendments also provides that our obligation to make milestone payments to SG Austria pursuant to the SG Austria APA, as amended and clarified, is eliminated in their entirety. One of the Binding Term Sheet Amendments also provides that the scope of the Diabetes License Agreement is expanded to include all cell types and cell lines of any kind or description now or later identified, including, but not limited to, primary cells, mortal cells, immortal cells and stem cells at all stages of differentiation and from any source specifically designed to produce insulin for the treatment of diabetes.

In addition, one of the Binding Term Sheet Amendments provides that we have a 5-year right of first refusal from August 30, 2017 in the event that Austrianova chooses to sell, transfer or assign at any time during this period the Cell-in-a-Box® technology, tradename and Associated Technologies; provided, however, that the Associated Technologies subject to the right of first refusal do not include Bac-in-a-Box

The Binding Term Sheet Amendments further provide that: (i) the royalty payments on gross sales as specified in the SG Austria APA, the Cannabis License Agreement and the Diabetes License Agreement are changed to 4%; and (ii) the royalty payments on amounts received by us from sublicensees on sublicensees' gross sales under the same agreements are changed to 20% of the amount received by us from our sublicensees, provided, however, that in the event the amounts received by us from sublicensees is 4% or less of sublicensees' gross sales, Austrianova will receive 50% of what we receive (up to 2%) and then additionally 20% of any amount we receive over that 4%.

The Binding Term Sheet Amendments also provide that Austrianova will receive 50% of any other financial and non-financial consideration received from our sublicensees of the Cell-in-a-Box® technology.

The Melligen Cell License Agreement provides us with an exclusive worldwide license, with a right to sublicense, to use genetically modified human cells that have been modified to comprise pancreas islet cell glucokinase for use in developing a therapy for diabetes. The Melligen cells are patent protected in the U.S. and Europe.

Patent Applications

On March 21, 2018, we filed a U.S. patent application and a Patent Cooperation Treaty ("PCT") application directed at methods of treating cancerous tumors, such as those of the pancreas, liver, breast and colon, using the live-cell encapsulation of genetically modified human cells that overexpress a form of the cytochrome P450 enzyme system normally found in the liver. The methods involve administering encapsulated cells expressing the cytochrome P450 enzyme system along with a prodrug, such as an oxazaphosphorine or ifosfamide, which gets converted to an active form by the cytochrome P450 enzyme system. These applications, if approved, will expire on March 21, 2038, subject to any applicable patent term adjustment or extension that may be available. We plan to prosecute both patent applications.

Details of Our Material Agreements

Third Addendum to the SG Austria APA

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

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

Pursuant to the Third Addendum, we agreed to and have entered a manufacturing agreement with SG Austria for the manufacture of the pancreatic cancer clinical trial material we will need. The Manufacturing Framework Agreement requires us to pay Austrianova a one-time manufacturing setup fee in the amount of $647,000, of which 50% is required to be paid on the effective date of the Manufacturing Framework Agreement and 50% is required to be paid three months later. We have paid the full amount of the manufacturing setup fee. The Manufacturing Framework Agreement also requires us to pay a fee for producing the final encapsulated cell product of $647 per vial of 300 capsules after production, with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product. The fees under the Manufacturing Framework Agreement are subject to annual increases according to the annual inflation rate in the country in which the encapsulated cell products are manufactured. We have placed an order to produce 400 vials for our pancreatic cancer studies and have paid Austrianova $172,533 of the total cost of $258,800 for the order.

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

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

On May 14, 2018, we entered into amendments to the Third Addendum. See "—Details of the Company's Material Agreements" discussed above.

Diabetes Licensing Agreement

Under the Diabetes Licensing Agreement, we are required to make a payment of $2,000,000 in two equal payments of $1,000,000 each. We made our first $1,000,000 payment on October 30, 2013. Our second payment of $1,000,000 was made on February 25, 2014.

The Diabetes Licensing Agreement requires us to pay Austrianova, pursuant to a manufacturing agreement to be entered between the parties, a one-time manufacturing setup fee in the amount of approximately $600,000, of which 50% is required to be paid on the signing of a manufacturing agreement for a product and 50% is required to be paid three months later. In addition, the Diabetes Licensing Agreement requires us to pay a manufacturing production fee, which is to be defined in the manufacturing agreement, for producing the final encapsulated cell product of approximately $600.00 per vial of 300 capsules after production, with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® encapsulation-based product. All costs for encapsulated cell products will be subject to an annual increase equal to the published rate of inflation in the country of manufacture of the vials.

The Diabetes Licensing Agreement requires us to make future royalty and milestone payments as follows:

- Ten percent royalty of gross sales of all products we sell;
- Twenty percent royalty of the amount received by us from a sub-licensee on its gross sales; and
- Milestone payments of $100,000 within 30 days of beginning the first pre-clinical experiments using the encapsulated cells; $500,000 within 30 days after enrollment of the first human patient in the first clinical trial; $800,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial; and $1,000,000 within 90 days after having a NDA or a BLA approved by the FDA or a MAA approved by the EMA in Europe or its equivalent based on the country in which it is accepted for each product.

The license under the Diabetes Licensing Agreement, as amended, may be terminated and all rights will revert to Austrianova if any of the following milestone events do not occur within the following timeframes, subject to all the necessary and required research having been successful and the relevant product being sufficiently prepared to enter a clinical trial:

- If we fail to enter a research program with the technology in the scope of the license providing a total funding equal to or greater than $400,000 within three years of June 25, 2013, the effective date of the Diabetes Licensing Agreement (we have met this requirement); or
- If we fail to enter a clinical trial or its equivalent for a product within seven years of the effective date of the Diabetes Licensing Agreement.

In May 2018, we entered into amendments to the Diabetes Licensing Agreement. See "—Details of the Company's Material Agreements" discussed above.

Cannabis Licensing Agreement

Pursuant to the Cannabis Licensing Agreement, we acquired from Austrianova an exclusive worldwide license to use the Cell-in-a-Box® trademark and its associated technology with genetically modified non-stem cell lines which are designed to activate cannabinoids to develop therapies involving *Cannabis* with a right to sublicense.

Under the Cannabis Licensing Agreement, we are required to pay Austrianova an initial upfront payment of $2,000,000 ("Upfront Payment"). We have the right to make periodic monthly partial payments of the Upfront Payment in amounts to be agreed upon between the parties prior to each such payment being made. Under the Cannabis Licensing Agreement, the Upfront Payment must be paid in full by no later than June 30, 2015. The parties amended the Cannabis Licensing Agreement twice pursuant to which the balance of the Upfront Payment is to be paid by June 30, 2016. We have paid the Upfront Payment of $2,000,000 in full.

The Cannabis Licensing Agreement requires us to pay Austrianova, pursuant to a manufacturing agreement to be entered between the parties, a one-time manufacturing setup fee in the amount of $800,000, of which 50% is required to be paid on the signing of a manufacturing agreement for a product and 50% is required to be paid three months later. In addition, the Cannabis Licensing Agreement requires us to pay a manufacturing production fee, which is to be defined in the manufacturing agreement, for producing the final encapsulated cell product of $800 per vial of 300 capsules after production with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product. All costs for encapsulated cell products, the manufacturing setup fee and the manufacturing production fee will be subject to annual increases, in accordance with the inflation rate in the country in which the encapsulated cell products are manufactured.

The Cannabis Licensing Agreement requires us to make future royalty and milestone payments as follows:

- Ten percent royalty of the gross sale of all products sold by us;
- Twenty percent royalty of the amount received by us from a sublicense on its gross sales; and
- Milestone payments of $100,000 within 30 days of beginning the first pre-clinical experiments using the encapsulated cells; $500,000 within 30 days after enrollment of the first human patient in the first clinical trial; $800,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial; and $1,000,000 within 90 days after having a NDA or a BLA approved by the FDA or a MAA approved by the EMA or its equivalent based on the country in which it is accepted for each product.

The license under the Cannabis Licensing Agreement, as amended, may be terminated and all rights will revert to Austrianova if any of the following milestone events do not occur within the following timeframes:

If we do not enter a research program involving the scope of the license within three years of December 1, 2014, the effective date of the Cannabis Licensing Agreement (we have met this requirement); or
If we do not enter a clinical trial or its equivalent for a product within 7 years of the effective date of the Cannabis Licensing Agreement

In May 2018, we entered into amendments to the Cannabis Licensing Agreement. See "—Details of the Company's Material Agreements" discussed above.

Melligen Cell License Agreement

The Melligen Cell License Agreement requires that we pay royalty, milestone and patent costs to UTS as follows:

- Six percent of gross exploitation revenue on product sales;
- Twenty-five percent of gross revenues if the product is sublicensed by us;
- Milestone payments of AU$ 50,000 at the successful conclusion of a preclinical study, AU$ 100,000 at the successful conclusion of a Phase 1 clinical trial, AU$ 450,000 at the successful conclusion of a Phase 2 clinical trial, and AU$ 3,000,000 at the successful conclusion of a Phase 3 clinical trial; and
- Patent costs of fifteen percent of the costs paid by UTS to prosecute and maintain patents related to the licensed intellectual property.

In the event of a default under the Melligen Cell License Agreement, the non-defaulting party may immediately terminate the agreement by notice in writing to the defaulting party if: (i) the default has continued for not less than 14 days or occurred more than 14 days earlier and has not been remedied; (ii) the non-defaulting party serves upon the defaulting party notice in writing requiring the default to be remedied within 30 days of such notice, or such greater number of days as the non-defaulting party may in its discretion allow, and (iii) the defaulting party has failed to comply with the notice referred to in (ii) above.

The Melligen Cell License Agreement was amended in April 2016 to change the name of the license to our current name and clarify certain ambiguities in the agreement. We are required to pay the Melligen cell patent prosecution costs and to pay to UTS a patent administration fee equal to 15% of all amounts paid by UTS to prosecute and maintain patents related to the Melligen cells.

In August 2017, we entered into the Binding Term Sheet pursuant to which the parties reached an agreement to amend certain provisions in the SG Austria APA, the Diabetes Licensing Agreement the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement.

In May 2018, we entered into agreements with SG Austria and Austrianova to amend certain provisions of the SG Austria APA, the Diabetes Licensing Agreement, the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement pursuant to the Binding Term Sheet. For a full description of these amendments , see Item 1. "History of the Business."

Sources and Availability of Raw Materials

The entire encapsulation process relating to the encapsulation of the cells for the oncology and diabetes-based therapies we are developing is to be carried out by Austrianova. 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. As mentioned above, we engaged ViruSure to clone new cells from a selected clone. Those cells have been grown by Eurofins to populate a MCB for our future clinical trials. See also "—Manufacturing" in this Item 1. "Business."

Employees

As of April 30, 2019, we had four full-time employees and eight consultants who devote substantial time to us. They function as our Chief Scientific Officer, Director of Diabetes Program Development, Director of Cannabis Program Development, Chairman of our Medical and Advisory Board, Members of our Medical and Scientific Advisory Board, a Senior Strategic Advisor to our Chief Executive Officer and the Board and a business development consultant. We use several other consulting scientists, physicians and academics for a great deal of our R&D.

Medical and Scientific Advisory Board

We regularly seek advice and input from the members of our Medical and Scientific Advisory Board on matters related to our R&D programs. The members of our Medical and Scientific Advisory Board consist of experts across a wide range of key disciplines relevant to our clinical development programs. We intend to continue to leverage the broad expertise of our advisors by seeking their counsel on important topics relating to our product development and clinical development programs. The members of our Medical and Scientific Advisory Board are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or other technologies. All the members of our Medical and Scientific Advisory Board are affiliated with other entities and devote only a portion of their time to us. The members of our Medical and Scientific Advisory Board are not officers or directors of our company. Our current advisors are:

- Dr. Matthias Löhr – Professor of Gastroenterology & Hepatology, Karolinska Institute, Stockholm, Sweden
- Dr. Manuel Hidalgo – Chief of the Division of Hematology and Medical Oncology at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center in New York, New York.
- Prof. Dr. Hans-Peter Hammes – Professor of Internal Medicine and Endocrinology, Faculty of Clinical Medicine Mannheim of Heidelberg University and Section Leader for Endocrinology and Diabetology, Mannheim, Germany
- Dr. Brian Salmons – Chief Executive Officer and President of Austrianova Pte Ltd and Co-Developer of Cell-in-a-Box® and its Associated Technologies.
- Dr. Mark L. Rabe – Chief Executive Officer of Rabe Medical Solutions, San Diego, California
- David A. Judd - cellular biologist of 35 years and a long-term employee of the Grand Island Biological Company with experience in culturing various types of human cells, including the cells that were transfected with the gene that activates the prodrug ifosfamide and that are encapsulated for our LAPC clinical trial.

Financial Information Concerning Geographic Areas

We had no revenues in the fiscal years ended April 30, 2019 and 2018, including no revenues from foreign countries. We have long-lived assets, other than financial instruments, located in the following geographical areas:

	FY 2019	FY 2018
United States:	$ 5,128,992	$ 5,128,992
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; 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. For additional information, see “Cautionary Note Regarding Forward-Looking Statements.”

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

We have a short operating history, a relatively new business model and have not produced any revenues in our current business model. This makes it difficult to evaluate our prospects and increases the risk that we will not be successful.

We have a short operating history with our current business model. Our current operations have produced no revenues and may not produce revenues in the near term or at all, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. If we create revenues in the future, we will derive most of these revenues from the sale of product candidates. You must consider our business and prospects considering the risks and difficulties we will encounter as an early-stage biotech company in a new and rapidly evolving biotech sector. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a clinical stage biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer and diabetes 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. We have generated significant operating losses since our inception. Our net losses for the years ended April 30, 2019 and 2018 were approximately $4.1 million and $6.8 million, respectively. As of April 30, 2019, we had an accumulated deficit of approximately $100 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 the research and development of, and 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. If either any of our product candidates fail in clinical trials or do not gain regulatory approval, or even if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

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 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 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 will need additional capital to continue our business plans.

We will need additional capital to continue our operations. As of April 30, 2019, we had approximately $515,000 in our bank accounts. There can be no assurance that we will obtain sufficient capital on acceptable terms, if at all. Failure to obtain such capital would have an adverse impact on our financial position, operations and ability to continue as a going concern. Our operating and capital requirements during the next fiscal year and thereafter will vary based on several factors, including whether the FDA approves our IND when submitted allowing us to commence our clinical trial, how quickly enrollment of patients in our planned clinical trial in LAPC 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. There can be no assurance that additional private or public financing, including debt or equity financing, will be available as needed or if available, on terms favorable to us. Additionally, any future equity financing may be dilutive to stockholders' present ownership levels. It may also have rights, preferences, or privileges that are senior to those of our existing common stock.

Furthermore, debt financing, if available, may require payment of interest and potentially involve restrictive covenants that could impose limitations on our flexibility to operate. Any difficulty or failure to successfully obtain additional funding may jeopardize our ability to continue the business and our operations.

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; and (viii) general economic conditions.

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 the same as or are like our approach, and others are based on entirely different approaches. 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 and diabetes, 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.

Risks Related to FDA Approval of Our Planned Clinical Trial, Approval of Our Product Candidates and Other Legal Compliance Matters

If the FDA does not approve our IND to begin a trial in LAPC once we submit it to the FDA or places us on clinical hold, we will not be able to commence a Phase 2b clinical trial for LAPC in the U.S. which would likely have a material adverse effect on us.

Subject to FDA approval, we plan to commence a Phase 2b clinical trial in LAPC. A Pre-IND meeting with CBER was held on January 17, 2017, at which the FDA provided us with guidance to complete the IND process and communicated its agreement with certain aspects of our clinical development plan. We have been delayed in submitting our IND to the FDA, due to guidance provided by the FDA and due to delays in preparing the materials necessary to submit our IND. No assurance can be given whether the FDA will approve our IND once we submit it to the FDA. The FDA may put us on a clinical hold until we satisfy its requirements to commence our clinical trial involving LAPC, which may never occur. We cannot provide assurance as to the timing of our IND submission to the FDA and the FDA's reaction to it. In the event the FDA does not approve our IND, we will not be able to commence our clinical trial in LAPC which would likely have a material adverse effect on us.

Our plan to first pursue a Phase 2b 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 we can submit an IND, and that IND is approved, we have determined that the data contained in previous clinical trial reports using the Cell-in-a-Box® and its Associated Technologies are not enough to advance the program next to a Phase 3 pivotal trial. Therefore, we are designing a Phase 2b 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 Phase 2b 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.

Our ability to timely submit an IND to the FDA may depend on circumstances outside of our control.

Our ability to execute our current plan for the completion of all activities and submission of an IND to the FDA depends on a variety of factors, some of which are outside of our control, such as the manufacturing of our clinical trial product for our plan clinical trial for LAPC. We must submit the results of various preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol to the FDA as part of the IND. Preclinical tests include laboratory evaluations of product chemistry and formulation, as well as other studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements. The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. The preparation of the IND will also involve considerable work from our employees and advisors. Should our employees and advisors not be able to complete the preparation of the IND in a timely manner, the submission of the IND to the FDA could be delayed.

If we are unable to obtain, or if there are delays in obtaining, required approval from the 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 and other regulatory agencies. 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 several 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.

Clinical drug development 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 is in 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, 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 severe or medically or commercially unacceptable 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 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 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 outcome of preclinical studies and early and mid-phase clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict overall results. Many companies in the pharmaceutical and biotechnology sectors have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier stages of development, and we cannot be certain that we will not face similar setbacks.

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 initial 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 and safety necessary to obtain regulatory approval to market our product candidates.

We intend to seek 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.

We intend to seek FDA acceptance of an IND to commence a Phase 2b clinical trial in LAPC using genetically engineered live human cells encapsulated using our Cell-in-a-Box® technology in combination with ifosfamide. A Phase 1/2 clinical trial and a Phase 2 clinical trial were 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. 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 Phase 2b 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.

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.

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 regulatory agencies outside of the U.S. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the population in the country in which the clinical trial is being conducted. The data must be applicable to the U.S. population and medical practice in the U.S. in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the U.S. must be representative of the population for whom we intend to seek approval in the U.S.

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.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the regulatory agencies, we may incur additional costs or experience delays in completing or be unable to complete the development and commercialization of these product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the U.S. without obtaining marketing approval from the FDA. Comparable regulatory agencies outside of the U.S., such as the EMA in the European Union, impose similar restrictions. We may never receive such approvals. We may be required to complete additional preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted an NDA, a BLA or a MAA to regulatory agencies for any of our product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if: (i) we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate; (ii) we are unable to successfully complete our planned clinical trials of our product candidates or other testing; (iii) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable; or (iv) there are unacceptable safety concerns associated with our product candidates, we, in addition to incurring additional costs, may:

- Be delayed in obtaining marketing approval for our product candidates;

- Not obtain marketing approval at all;

- Obtain approval for indications or patient populations that are not as broad as we intended or desired;
- Obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including "black-box" warnings;
- Be subject to additional post-marketing testing or other requirements; or
- Be required to remove the product from the market after obtaining marketing approval.

Promising 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.

Positive 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 Phase 2b clinical trial in LAPC. 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. 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 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.

If we experience any unforeseen events in the clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during our clinical trials that could delay or prevent marketing approval of our product candidates, including:

- Clinical trials of our product candidates may produce unfavorable or inconclusive results;
- We may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs or candidates;
- The number of patients required for clinical trials of our product candidates may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- Regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- We may experience delays in reaching or may fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- Patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- We may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of a product candidate;

- Regulatory agencies or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their respective standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;

- Regulatory agencies may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials;

- Regulatory agencies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter agreements for clinical and commercial supplies;

- The supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate, delayed, or not available at an acceptable cost, or we may experience interruptions in supply; and

- The approval policies or regulations of the regulatory agencies may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals. We may also be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of any of 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. 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;
- The design of the clinical trial;
- Efforts to facilitate timely enrollment;
- 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. 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. The regulatory agencies may not grant priority review for any of our product candidates. Moreover, even if the regulatory agencies designated such products for priority review, that designation may not lead to a faster regulatory review or approval process and, in any event, may not assure approval by the regulatory agencies.

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 or provide a treatment where no adequate therapy exists. A priority review designation means that the time required for the regulatory agencies to review an application is less than the standard review period. The regulatory agencies have 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, the regulatory agencies may decide not to grant it. Thus, while the regulatory agencies have granted priority review to other oncology and diabetes products, our product candidates, should we determine to seek priority review of them, may not receive similar designation. Moreover, even if one of our product candidates is designated for priority review, such a designation does not necessarily mean a faster overall regulatory review process or necessarily confer any advantage with respect to approval compared to conventional procedures of the regulatory agencies. 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 the regulatory agencies 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. Under the accelerated approval provisions or their implementing regulations of the regulatory agencies, they may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product influences a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. Regulatory agencies consider a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. 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. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, regulatory agencies may withdraw their approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the regulatory agencies and will otherwise evaluate our ability to seek and receive such accelerated approval. 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, a BLA or an MAA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from regulatory agencies that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, 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. Regulatory agencies could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any of our product candidates that we determine to seek accelerated approval 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 may seek Orphan Drug designation for some of our product candidates, and we may be unsuccessful.

Regulatory agencies may designate drugs for relatively small patient populations as Orphan Drugs. Under the standards and requirements of regulatory agencies, they may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition. In the U.S., this is generally defined as a disease with a patient population of fewer than 200,000 individuals. If a product with an Orphan Drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or FDA from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

We have been granted Orphan Drug designation for our pancreatic cancer therapy in the U.S. and European Union. 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 condition. Even after an Orphan Drug is approved, the regulatory agency can subsequently approve a different drug for the same condition if they conclude that the later drug 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 successful. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation by the FDA or similar designation by another regulatory agency. Regulatory agencies have broad discretion whether to grant this designation by the FDA or similar designation by another regulatory agency. Even if we believe a product candidate is eligible for this designation, we cannot assure you that a 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 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.

A Breakthrough Therapy or similar designation is within the discretion of the FDA and other 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 make 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 assure their 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.

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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, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive 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 closely regulate the post-approval marketing and promotion of drugs to ensure drugs 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 our product candidates 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 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, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Restrictions on such products, 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;
- Warning or untitled letters;
- 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;
- Refusal to permit the import or export of our product candidates;
- Product seizure; or
- Injunctions 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 the Europe's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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.

Healthcare providers, physicians 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, including civil whistleblower or *qui tam* actions, 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. Federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, which includes data collection and reporting obligations. The information is to be 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.

In the U.S. and some foreign jurisdictions, there have been a several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In March 2010, former President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- An annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- Expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- A new Medicare Part D coverage gap discount program in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- Extension of manufacturers' Medicaid rebate liability;
- Expansion of eligibility criteria for Medicaid programs;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- New requirements to report financial arrangements with physicians and teaching hospitals;
- A new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. At the same time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future.

Newly enacted FDA regulations may require us to expend additional resources to obtain or maintain regulatory approval. For example, in August 2017 President Trump signed into law the FDARA. This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, the development of drugs and biological products for pediatric use. This legislation may result in new regulations, which may affect future options or timelines for regulatory approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of FDA's approval process may significantly delay or prevent marketing approval in the U.S., as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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 compounds 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 compound.

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 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 proves 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 are conducted in carefully defined subsets of patients who have agreed to enter a clinical trial. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. 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 adverse events 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 and expect to continue to rely heavily on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies and trials.

We currently rely on third parties to conduct the planning for our clinical trials. We expect to continue to rely heavily on third parties, such as a CRO, a clinical data management organization, a medical institution, a clinical investigator 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. If we are required to enter alternative arrangements because of any such termination, the introduction of our product candidates to market could be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we 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 cGMP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. 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. 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.

We expect to rely on third parties to store and distribute our product candidates for our clinical trials. Any performance failure on the part of such third parties could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product candidate revenue. Our existing collaboration with universities and institutions is important to our business. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We rely on the University of Veterinary Medicine Vienna, UTS, the University of Barcelona, University of Copenhagen, Ludwig Maximilian University, Heidelberg University, VIVIT, Austrianova, Vin-de-Bona and University of Northern Colorado for a substantial portion of our research and development, including reliance on their employees whom we fund to conduct preclinical development of 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 universities and institutions 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.

Furthermore, if any of these universities or institutions 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 Dr. Günzburg, Dr. Salmons and Dr. Löhr 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.

Dr. Günzburg, Dr. Salmons and Dr. Löhr 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 to be conducted in the U.S. and elsewhere on our behalf. In addition, they will be assisting us in the development of a treatment for diabetes. Dr. Günzburg, Dr. Salmons and Dr. Löhr are fulfilling prominent roles in our Diabetes Consortium. They 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 a 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.

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or 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 clinical quantities of our encapsulated live cell and ifosfamide product for pancreatic cancer and other encapsulated product candidates and have limited personnel with manufacturing experience. We currently rely on and expect to continue to rely on third party contract manufacturers to manufacture supplies of our product candidates for preclinical studies and clinical trials, 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 and ifosfamide product and our other 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.

Our agreements with our third-party manufacturers can be terminated by us or such manufacturers on short notice. If any of our manufacturers should become unavailable to us for any reason, we may incur additional cost or delay in identifying or qualifying replacements. 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 or any other product candidate or may be delayed in doing so.

Even if we can establish such arrangements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

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

Third-party manufacturers 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 manufacturers, to comply with these practices or requirements could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, 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 for us.

In addition, we expect to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. 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 our manufacturers 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 and WCB. 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. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial 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 Eurofins, Austrianova or 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 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.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology and products, 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 commercialize successfully 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. These patents expired on March 27, 2017. We exclusively license from UTS patented Melligen cells, which cover our product candidate for the treatment of diabetes. Currently, we do not have any issued patents in any countries covering our product candidate for the treatment of cancer, and we only have one pending U.S. provisional application, one patent application and one PCT application relating to our product candidate for the treatment of cancer.

We filed a provisional patent application with the USPTO on March 21, 2017 to protect our therapy to treat cancer. The application is designed to cover the same countries in which Bavarian Nordic obtained patent protection, with a relation back date of March 21, 2017. On March 21, 2018, we filed a U.S. patent application and a PCT application to protect our therapy to treat cancer. We do not know if any of the claims set forth in our patent applications will be granted patent protection by the USPTO or by any other regulatory authority in other countries in which we seek patent protection.

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 in 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. 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 agreement, 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.

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 and invention or patent assignment 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 it, 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.

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 formulations or 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.

Additional 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.

Our success depends on additional states legalizing medical Cannabis.

Continued development of the medical *Cannabis* market is dependent upon continued legislative authorization of *Cannabis* at the state level for medical purposes. Any number of factors could slow or halt the progress. Further, progress, while encouraging, is not assured and the process normally encounters set-backs before achieving success. While there may be ample public support for legislative proposal, key support must be created in the legislative committee or a bill may never advance to a vote. Numerous factors impact the legislative process. Any one of these factors could slow or halt the progress and adoption of *Cannabis* for medical purposes, which would limit the market for our product candidates that are based on *Cannabis* constituents and negatively impact our business in this area.

Medicinal Cannabis faces strong opposition.

Certain well-funded and significant businesses may have a strong economic opposition to the medical *Cannabis* industry. Lobbying by groups within the pharmaceutical industry or changes in the regulation of *Cannabis*-based therapies could affect our ability to develop and market cannabinoid-based cancer therapies.

Our product candidates involving Cannabis will be subject to controlled substance laws and regulations. Failure to receive necessary approvals may delay the launch of our products and failure to comply with these laws and regulations may adversely affect the results of our business operations.

Our product candidates involving *Cannabis* contain controlled substances as defined in the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While *Cannabis* is a Schedule I controlled substance, products approved for medical use in the U.S. that contain *Cannabis* or *Cannabis* extracts must be placed in Schedules II - V, since approval by the FDA satisfies the "accepted medical use" requirement. If we receive FDA approval for a product candidate involving *Cannabis*, the DEA will make a scheduling determination and place it in a schedule other than Schedule I for it to be prescribed to patients in the U.S. If approved by the FDA, we expect the product candidates to be listed by the DEA as a Schedule II or III controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. The scheduling process may take one or more years beyond FDA approval, thereby significantly delaying the launch of our product candidates involving *Cannabis*. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that our product candidates involving *Cannabis* may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of such products.

Because one or more of our product candidates contain active ingredients of *Cannabis*, which are Schedule I substances, to conduct preclinical studies and clinical trials with these product candidates in the U.S. prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our product candidates and to obtain the product from our manufacturer. If the DEA delays or denies the grant of a research registration to one or more research sites, the preclinical studies or clinical trials could be significantly delayed, and we could lose and be required to replace clinical trial sites, resulting in additional costs.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates involving *Cannabis* as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Because of these risks, no assurance can be given that our Cannabis therapy under development will be successful.

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 product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates 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 product candidates, 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 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.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

In the U.S., there have been numerous legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval. The Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. A significant number of provisions are not yet, or have only recently become effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. At the same time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future.

Newly enacted FDA regulations may require us to expend additional resources to obtain or maintain regulatory approval. For example, in August 2017 President Trump signed into law the Food & Drug Administration Reauthorization Act. This legislation imposes significant new requirements for clinical trial sponsors which will affect, among other things, the development of drugs and biological products for pediatric use. This legislation may result in new regulations, which may affect future options or timelines for regulatory approval.

If we ever obtain regulatory approval and successfully commercialize any of our product candidates, these laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our future customers, patients and third-party payors and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize 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 health care 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 as we commence a clinical trial or if we commence commercialization of our product candidates. 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

We cannot predict the extent to which a trading market for our common stock will develop or how liquid that market might become.

Our common stock is currently traded on the OTC Link™ quotation platform of OTC Markets Group, Inc. We cannot predict the extent to which a trading market will develop or how liquid that market might become. Accordingly, holders of our common stock may be required to retain their shares for an indefinite period.

The OTC Link™ quotation system provides significantly less liquidity than national stock exchanges. Quotes for stocks included on the OTC Link™ quotation system are not listed in the financial sections of newspapers, as are those for the national stock exchanges. Therefore, prices for securities traded solely on the OTC Link™ quotation system may be difficult to obtain, and holders of our common stock may be unable to resell their shares at or near their original acquisition price or at any price. 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.

Our ability to access the capital markets is limited by inability to use a short form registration statement on Form S-3.

A Registration Statement on Form S-3 permits an eligible company to incorporate by reference in the registration statement its prior and subsequent filings and reports made under the Exchange Act. In addition, Form S-3 enables eligible companies to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act of 1933, as amended ("Securities Act"). The shelf registration process under Form S-3 combined with the ability to incorporate information on a prospective basis allows eligible companies to avoid additional delays and interruptions in the offering process that would be associated with the filing of a registration statement and review by the staff of the Commission and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard "long form" offering on Form S-1. Thus, our ability to raise, and the cost of raising, future capital could be adversely affected by any inability to use a short form registration statement on Form S-3.

To be eligible to use Form S-3 for a registered offering of our securities to investors, either: (i) the aggregate market value of our common stock held by non-affiliates must exceed $75 million; or (ii) our common stock must be listed and registered on a national securities exchange. We do not currently meet either of these eligibility requirements and are therefore precluded from conducting a registered offering of our securities to investors by means of filing a Form S-3 or effecting a "shelf" offering until we meet one of these requirements.

Penny stock rules may have an adverse effect on us.

Our securities sold as part of financing provided to us are currently subject to "penny stock rules" that impose additional sales requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors, the latter of which are generally people with assets more than $1,000,000 or annual income exceeding $200,000 (individually) or $300,000 (jointly with a spouse). For transactions covered by these rules, we and/or broker-dealers must make a special suitability determination for the purchase of such securities and have received the purchaser's written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the "penny stock rules" require the delivery, prior to the transaction, of a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer must also disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. Consequently, the "penny stock rules" may restrict the ability of broker-dealers to sell our securities. The foregoing required penny stock restrictions will not apply to our common stock if such securities maintain a market price of $5.00 or greater. Therefore, the challenge for us is that the market price of our common stock may not reach or remain at such a level.

Shareholders should be aware that, according to the Commission, the market for penny stocks continues to suffer from patterns of fraud and abuse. Such patterns include, but are not limited to:

- Control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- Manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases and paid promotions;
- "Boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- The wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, leaving investors with losses.

Our executive officers are aware of these abuses that have occurred historically in the penny stock market. Although we are in no position to dictate the behavior of the market or of broker-dealers or others that may engage in such abuses, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our common stock.

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

We experience 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. 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, that 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.

Our investors may suffer future dilution due to issuances of additional shares of our common stock in the future for various reasons.

There may be substantial dilution to our shareholders because of future decisions of our Board to issue shares for cash transactions, services rendered, acquisitions, payment of debt, sale of shares under our Form S-3 Registration Statement, if we are eligible to use Form S-3 or other public or private offerings of our securities and other permissible reasons. We can give investors no assurance that they will be able to sell their shares of our commons stock at or near the prices they ask or at all if they need money or otherwise desire to liquidate their shares.

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

We have a limited number of employees and are highly dependent on our Chief Executive Officer, Chief Operating 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 clinical development company with a limited operating history. As of April 30, 2019, we had four full-time employees and eight key consultants. We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical teams, specifically, on our Chief Executive Officer, Chief Operating 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 Chief Executive Officer, Chief Operating Officer and Chief Financial Officer or other key employees or consultants could severely impede the achievement of our research, development 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 products. 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.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws.

If it is determined that we have in the past experienced an ownership change, or if we experience one or more ownership changes because of this offering or future transactions in our stock, we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any such limitations on the ability to use our net operating loss carryforwards and other tax assets could potentially result in increased future tax liability to us.

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could adversely impact our business.

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

Despite the implementation of security measures, our internal computer systems and those of our third-party service providers on whom we rely 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.

The comprehensive tax reform law could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the final version of the Tax Act. The Tax Act significantly reforms the Internal Revenue Code of 1986, as amended, with many of its provisions effective for tax years beginning on or after January 1, 2018. The Tax Act, among other things, contains significant changes to corporate taxation, including a permanent reduction of the corporate income tax rate, a partial limitation on the deductibility of business interest expense, a limitation of the deduction for net operating loss carryforwards to 80% of current year taxable income, an indefinite net operating loss carryforward and the elimination of the two-year net operating loss carryback, temporary, immediate expensing for certain new investments and the modification or repeal of many business deductions and credits. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this reform on our stockholders is uncertain. Stockholders should consult with their tax advisors regarding the effect of the Tax Act and other potential changes to the U.S. Federal tax laws on them.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located at 20156 Avenida de la Carlota, Suite 600, Laguna Hills, California 92653. The offices we lease ("Leased Premises") consist of approximately 600 square feet plus the use of certain shared facilities, such as a lobby, conference rooms, a kitchen and open work spaces. The term of our current lease agreement expires on August 31, 2019. On May 29, 2019, we entered into a new lease agreement at our current location for an additional twelve-month term, expiring on August 31, 2020. The Leased Premises will consist of approximately 400 square feet plus the use of the same shared facilities and areas.

ITEM 3. LEGAL PROCEEDINGS

There is no material litigation currently pending against us or any of our subsidiaries or to which any of our or our subsidiaries' property is subject. To our knowledge, there is no 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.

Shares of our common stock are quoted and traded on the OTC Link™ quotation platform of OTC Markets Group, Inc. ("OTCQB") as a fully reporting Over-The-Counter Bulletin Board company under the classification of OTCQB utilizing the trading symbol "PMCB."

The following table sets forth the high and low bid quotations reported on the OTCQB for our shares for each quarter during the two fiscal years ("FYs") ended April 30, 2019 and 2018. The prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Date	Bid Price	
FY 2019	HIGH	LOW
First Quarter	$ 0.11	0.05
Second Quarter	$ 0.07	0.05
Third Quarter	$ 0.06	0.04
Fourth Quarter	$ 0.07	0.04
FY 2018		
First Quarter	$ 0.10	0.05
Second Quarter	$ 0.08	0.05
Third Quarter	$ 0.08	0.03
Fourth Quarter	$ 0.08	0.05

As of April 30, 2019, there were 1,161,004,505 issued and outstanding shares of common stock. We are informed these shares are held by approximately 1,300 shareholders of record.

Dividend Policy

We have not paid and do not plan to pay cash dividends now. Our Board will decide any future payment of dividends, depending on the results of operations, financial condition, capital requirements and other relevant factors.

Issuer Purchases of Equity Securities

We did not repurchase any of our securities registered under Section 12 of the Exchange Act during our fiscal year ended April 30, 2019.

Recent Issuance of Unregistered Securities

We issued Common Stock Purchase Warrants ("Warrants") to Aeon (defined below) in connection with our Block Trades (defined below). We issued Warrants to purchase the number of shares of our restricted common stock listed below.

The Warrants have a five-year term and represent 5% of the number of shares of common stock sold at an exercise price equal to the price per share at which the shares were sold in the Block Trade. They are exercisable by the Holder at any time and from time to time from the Sale Date through and including the expiration date set forth in the Warrant. Each Warrant has a specified Exercise Price as set forth below.

Sale Date	Warrants Issued	Exercise Price
May 24, 2017	833,333	$0.03
July 26, 2017	2,000,000	$0.025
February 27, 2018	1,666,667	$0.03
May 30, 2018	1,388,889	$0.018
June 28, 2018	1,923,077	$0.026
November 1, 2018	2,272,727	$0.011
March 26, 2019	1,250,000	$0.01
March 26, 2019	1,250,000	$0.01

In addition to issuances of unregistered securities by us to our officers and directors previously disclosed in our Quarterly Reports on Form 10-Q, our Form 8-Ks and this Report, on April 11, April 18 and April 21, 2019 we issued an aggregate of 2.5 million shares of restricted common stock to consultants for services provided to us. The non-cash expense for these share issuances total $151,425.

All such shares were issued without registration under the Securities Act in reliance upon the exemption afforded by Section 4(a)(2) of that Act based on the limited number of investors, the sophistication of the individuals involved and the use of restrictive legends on the share certificates issued to prevent a public distribution of the relevant securities. No underwriters were involved in any of these issuances.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company. Therefore, we are not required to include information called for by this Item 6.

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 clinical stage biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer and diabetes 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 the oncology and diabetes arenas.

We are now actively engaged with Austrianova and other entities in preparation for a Phase 2b clinical trial in LAPC using encapsulated live cells like those used in the previous Phase 1/2 and Phase 2 clinical trials discussed above. A Pre-IND meeting with CBER of the FDA was held on January 17, 2017, at which the FDA communicated its agreement with certain aspects of our development plan, charged us with completing numerous tasks and provided us with the guidance we need to complete what we expect will be a successful IND process. However, no assurance can be given that the FDA will approve our IND once it is submitted.

We are also conducting research relating to the use of constituents of*Cannabis*, known as cannabinoids, in treating cancer and its symptoms.

In addition, we have been involved in preclinical studies to determine if our cancer therapy can slow the production or accumulation of malignant ascites fluid in the abdomen that accompanies the growth of several types of abdominal cancers. In regard to the latter, one final study remains to be completed.

Finally, we are developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes based upon the encapsulation of a human liver cell line genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body. We are also exploring the possibility of encapsulating human insulin-producing stem cells and islet cells and then transplanting them into a diabetic patient. All three types of cells will be encapsulated using the Cell-in-a-Box® encapsulation technology. Each approach is designed to function as a bio-artificial pancreas for purposes of insulin production.

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 Phase 2b 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; and (vi) ensure completion of the production of encapsulated cells according to cGMP regulations to use in our planned clinical trial.

There are numerous items required to be completed successfully to ensure our final product candidates are ready for use in our planned clinical trial in LAPC and preclinical studies. 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

Our Consolidated Financial statements and related Notes have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Therefore, the Consolidated Financial Statements do not include any adjustments that might be necessary should we be unable to continue in existence. We have not generated any revenues and have not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. Also, development activities, preclinical studies, clinical trials and commercialization of our product candidates will require significant additional financing. Our deficit accumulated through April 30, 2019 was $100,031,371. We expect to incur substantial and increasing losses in future periods. Our total cash was $515,253 and $1,059,798 as of April 30, 2019 and 2018, respectively. Our net loss was $4,067,228 and $6,828,841 for the years ended April 30, 2019 and 2018, respectively. Cash flows from investing activities were $0 for the years ended April 30, 2019 and 2018. Net cash provided by financing activities was $2,342,500 and $2,681,409 for the years ended April 30, 2019 and 2018, respectively. For more information, see the discussion under the caption "—Discussion of Operating, Investing and Financing Activities" in this Item 7.

Our ability to successfully pursue our business is subject to certain risks and uncertainties, including, among other things, uncertainty of product development, uncertainty regarding the timing of our submission of our IND to the FDA, uncertainty of FDA approval of our IND once it is submitted to the FDA, need to raise capital to fund our various studies and FDA submissions, competition from third parties, uncertainty of capital availability, in particular, if we lost the ability to utilize our S-3 registration statement, uncertainty in our ability to enter agreements with collaborative partners, dependence on third parties and dependence on key personnel. We plan to finance future operations with a combination of proceeds from the issuance of equity, debt, licensing fees and revenues from future product sales, if any. We have not generated positive cash flows from operations. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our product candidates.

We do not believe there are trends, events or uncertainties that have, or are reasonably likely to have, a material effect on our short-term or long-term liquidity. Our research and development activities are scalable. This means that we can increase or decrease the expenses associated with our planned preclinical studies and clinical trials based on our available cash. We have no contractual obligations to perform preclinical studies or clinical trials. For the time being, the principal source of our cash is the sale of our common stock in registered offerings and private placements. However, there are no assurances that such sales will be sufficient to fund our planned clinical trial and other research and development costs.

The Statement of Cash Flow is the focal point for our liquidity, although the exercising of warrants and/or options at appropriate times by our investors, consultants, officers and directors will have potentially important positive effects on our liquidity. We also believe that the relationship between changes in operating results may induce changes in liquidity. For example, we may experience material changes in working capital components due to the acquisition of new capital through the "at-the-market" facility described below and the conversion of warrants and/or options by our investors, consultants, officers and directors. We rely solely on working capital as our liquidity indicator, since we do not presently have any open credit lines; however, we may try to obtain credit lines or other credit facility in the future. Further, as has often been a part of our mechanism to maintain overall liquidity, internal sources of liquidity from others associated with us may be utilized when needed.

We do not utilize any advanced methodology of cash management beyond paying our normal expenses.

On May 28, 2014, we entered a financial advisory offering and an at the market offering engagement agreement ("Chardan Agreement") with Chardan Capital Markets, LLC ("Chardan") pursuant to which Chardan agreed to use its reasonable best efforts to act as our sales agent for the sale of our common stock in "at-the-market" or privately negotiated transactions of up to $50,000,000, depending upon market conditions and at our discretion. In such transactions we agreed to pay to Chardan: (i) a cash fee of 3% of the gross proceeds from the sale of any shares of common stock sold in an "at-the-market" offering; and (ii) a cash fee of 7% of the aggregate sales price of any distinct blocks of common stock sold under the Chardan Agreement, plus five-year warrants representing 5% of the number of shares of common stock sold. We also agreed to reimburse certain expenses of Chardan in an amount not to exceed $15,000.

The Chardan Agreement was amended December 15, 2016. The amendment provides for the termination of the Engagement Agreement for any reason, with or without cause on five days' written notice by either party. The amendment also provides that Chardan will be entitled to collect transaction fees for common stock or other securities offered by us and sold to any parties introduced to us by Chardan within nine months following expiration or termination of the Engagement Agreement.

On January 26, 2018, we and Chardan entered into a Mutual Termination Agreement terminating the Chardan Agreement. We are not subject to any termination penalties related to the mutual termination of the Chardan Agreement. We do not owe any further fees to Chardan under any provision of the Chardan Agreement.

We raised approximately $13 million through our initial Registration Statement on Form S-3 filed on October 17, 2014 ("First S-3") pursuant to which Chardan was our exclusive placement agent.

On February 22, 2018, we entered into a financial advisory, offering and an "at the market offering" engagement agreement ("Aeon Agreement") with Aeon Capital, Inc. ("Aeon") pursuant to which Aeon agreed to use its reasonable best efforts to act as our agent for the sale of up to $25,000,000 of our common stock in "at-the-market," or privately negotiated transactions, or transactions structured as a public offering of a distinct block or blocks of the Shares ("Block Trades"). In connection with a transaction deemed to be an "at the market offering", we agreed to pay Aeon a cash fee of 3% of the aggregate sales price from the sale of shares of our common stock. In connection with a transaction structured as a Block Trade, we agreed to pay Aeon a cash fee of 7% of the aggregate sales price of any distinct blocks of common stock sold under the Aeon Agreement unless the Company introduced the investor to Aeon, in which event the fee shall be 4%, plus five-year warrants representing 5% of the number of shares of common stock sold at an exercise price equal to the price per share at which the shares were sold in the Block Trade. We also agreed to reimburse certain expenses of Aeon in an amount not to exceed $10,000. In addition, we agreed to provide Aeon with customary indemnification rights. The offering of the shares of our common stock will terminate upon the earliest to occur of: (i) the sale of all of the shares to be sold; or (ii) the termination of the Aeon Agreement by us or Aeon upon thirty days written notice prior to the effective date of the termination.

Sales of our common stock will be made, if we are eligible under applicable law, under our second Registration Statement on Form S-3 filed on September 13, 2017 ("Second S-3") allowing for offerings of up to $50,000,000 in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act or transactions structured as a public offering of a distinct block or blocks of the shares of our common stock.

From February 26, 2018 to April 30, 2019, the Company sold 195,027,194 shares of our common stock structured as a Block Trade. The issuance of these shares resulted in gross proceeds of $3.5 million. Pursuant to the Aeon Agreement, we incurred fees to Aeon of 7% ($245,000) and provided warrant coverage of 5% of the number of shares sold with a five-year term of approximately 9.75 million warrant shares.

We require substantial additional capital to finance our planned business operations and expect to incur operating losses in the future due to the expenses related to our core businesses. We have not realized material revenue since we commenced doing business as a biotechnology company, and there can be no assurance that we will be successful in generating revenues in the future in this sector.

Our current cash expenditures are approximately $240,000 per month. As of April 30, 2019, we had approximately $515,000 in cash in our bank account.

We believe our cash on hand at April 30, 2019, sales of shares of our common stock using the Second S-3, assuming we remain eligible to use the Second S-3, sales of unregistered shares of our common stock and any public offerings of common stock in which we may engage in will provide sufficient capital to meet our capital requirements and to fund our operations through July 31, 2020.

We will continue to be dependent on outside capital to fund our research and operating expenditures for the foreseeable future. If we fail to generate positive cash flows or fail to obtain additional capital when required, we may need to modify, delay or abandon some or all our business plans.

Year ended April 30, 2019 compared to year ended April 30, 2018

Revenue

We had no revenues in the fiscal years ended April 30, 2019 and 2018.

Operating Expenses

The total operating expenses during the year ended April 30, 2019 decreased by $2,880,800 to $4,100,629 from $6,981,420 in the year ended April 30, 2018. The decrease is mainly attributable to a decrease in R&D costs, compensation expense and in consulting expense as we awarded less stock-based consulting fees and compensation in 2019 than in 2018.

Operating expenses:	Year ended April 30, 2019	Change - Increase (Decrease) and Percent	Year ended April 30, 2018
R&D	$ 460,052	$ (1,537,759) (77%)	$ 1,997,811
Compensation expense	$ 1,555,258	$ (665,539) (30%)	$ 2,220,797
Director fees	$ 406,812	$ 80,272 25%	$ 326,540
General and administrative, legal and professional	$ 1,378,544	$ (440,379) (24%)	$ 1,818,923

Loss from Operations

Loss from operations during the year ended April 30, 2019 decreased by $2,880,800 to $4,100,629 from $_6,981,429 in the year ended April 30, 2018. The decrease is mainly attributable to a decrease in R&D costs, compensation expense and in consulting expense as we awarded less stock-based consulting fees in 2019.

Other Income (Expenses), Net

Other income for the year ended April 30, 2019 was $33,401 as compared to other expense, net of $152,588 in the year ended April 30, 2018. Other income for the year ended April 30, 2019, is attributable to the Australian research and development credit and the Goods and Services Tax ("GST") refund. The Australian research and development credits relate to qualified research and development expenditures incurred in Australia. An annual tax incentive schedule is filed with the Australian Taxation Office to apply for the credit. A GST refund request form is submitted to the Australian Taxation Office for the return of qualifying GST amounts paid in Australia.

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, 2019 and 2018.

	Year Ended April 30, 2019	Year Ended April 30, 2018
Net cash used in operating activities:	$ (2,877,912)	$ (5,079,395)
Net cash used in investing activities:	$ –	$ –
Net cash provided by financing activities:	$ 2,342,500	$ 2,681,409
Effect of currency rate exchange	$ (9,133)	$ (6,445)
Increase (decrease) in cash	$ (544,545)	$ (2,404,431)

Operating Activities:

The cash used in operating activities for the years ended April 30, 2019 and 2018 are a result of our net losses offset by securities issued for services and compensation, changes to prepaid expenses, accounts payable and accrued expenses.

Investing Activities: We had no investing activities for the years ended April 30, 2019 and 2018.

Financing Activities:

The cash provided from financing activities for the years ended April 30, 2019 and 2018 is mainly attributable to the proceeds from the sale of our common stock.

Off-Balance Sheet Arrangements

Except as described below, we have no 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.

On May 14, 2018, we entered into amendments to all of the material agreements with SG. Austria and Austrianova. See "Details of the Company's Material Agreements" above for a description of these amendments.

Critical Accounting Estimates and Policies

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.

Research and Development Expenses

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, that are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in our product candidates is expensed as incurred until technological feasibility has been established.

Stock-Based Compensation

Our stock-based compensation plans are described in Note 4 and 5 of the Notes of the Consolidated Financial Statements to this Report. We follow the provisions of ASC 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees. Effective August 1, 2018, we adopted early ASU 2018-07 *Compensation - Stock Compensation (Topic 718): - Improvements to Nonemployee Share-Based Payment Accounting,* which simplified the guidance for accounting for nonemployee share-based payment transactions for acquiring goods and services from nonemployees.

Net Income (Loss) Per Share

Basic net income (loss) per common share is computed using the weighted-average number of common shares outstanding. Diluted net income (loss) per common share is computed using the weighted-average number of common shares and common share equivalents outstanding. Potentially dilutive stock options and warrants to purchase 149,527,797 and 129,243,104 shares at April 30, 2019 and 2018, respectively, were excluded from the computation of diluted net income (loss) per share because the effect would be anti-dilutive.

New Accounting Pronouncements

For a discussion of all recently adopted and recently issued but not yet adopted accounting pronouncements, see "Recent Accounting Pronouncements" in Note 2 of our Notes to our consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data" of this Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Balance Sheets, as of April 30, 2019 and 2018, and our Consolidated Statements of Operations, Comprehensive Loss, Stockholders Equity and Cash Flows for each of the two years in the period ended April 30, 2019 and associated Notes and Schedules, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-26 of this Report and are incorporated by reference herein.

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

Our principal independent public accountant is Armanino LLP ("Armanino"). During our fiscal year ended April 30, 2019 and 2018, there have been no disagreements with Armanino on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure which, if not resolved to Armanino's satisfaction, would have caused Armanino to refer to the subject matter in its report on our Consolidated Financial Statements for such periods.

During our fiscal year ended April 30, 2019 and 2018, there were no "reportable events" requiring disclosure pursuant to Item 304(a)(1)(v) of Regulation S-K. As used herein, the term "reportable event" means any of the items listed in paragraphs (a)(1)(v)(A) - (D) of Item 304 of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer, President and General Counsel, 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, 2019, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting.

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.

Management's Evaluation of 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.

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, 2019 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 procedures and control documentation to implement control procedures including lack of contract review. We have developed procedures to provide ample review time of financial information, including contract review by qualified accounting and finance personnel as well as management. We have implemented these procedures, determined they are still insufficient and will continue to review these procedures to determine ways to further improve them.
- 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.
- Insufficient information technology controls and documentation. We currently use accounting software which we have determined is inadequate to provide the level of controls required by COSO. We are in the process of initiating a review process to fully evaluate the deficiencies in our technology controls and documentation. Based upon the results of this review process, we intend to implement the required remediation measures.

Because of these material weaknesses, our Chief Executive Officer and our Chief Financial Officer concluded that, as of April 30, 2019, our internal controls over financial reporting were not effective based on the COSO criteria.

We are in the process of investigating new procedures and controls for fiscal year 2020. 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 these material weaknesses, 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 in our internal controls over financial reporting during the most recent fiscal quarter 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors, executive officers and significant consultants, as of August 12, 2019, are:

	Age	Position
Kenneth L. Waggoner, JD	71	Chairman of the Board, Chief Executive Officer, President and General Counsel
Gerald W. Crabtree, PhD.	78	Director and Chief Operating Officer
Carlos A. Trujillo, CPA	61	Director and Chief Financial Officer
Thomas Liquard	46	Director
Thomas C. K. Yuen	67	Director
Michael M. Abecassis, MD	61	Director
Raymond C.F. Tong, MD.	60	Director
Walter H. Günzburg, PhD	60	Chief Scientific Officer and Consultant
Linda S. Sher, MD	63	Chief Medical Officer and Consultant

Kenneth L. Waggoner, JD

He became our Chief Executive Officer and President in November 2013. Shortly thereafter, Mr. Waggoner assumed the additional position of General Counsel. In April 2014, Mr. Waggoner became a full-time employee as the Chief Executive Officer, President and General Counsel of both PharmaCyte and Viridis Biotech, a wholly owned subsidiary of PharmaCyte. Mr. Waggoner has been a member of the Board since September 2014. Mr. Waggoner has over forty-five years of experience in management, business, operations and the practice of law. It was his education, training, experience and leadership skills that led us to elect him to the Board and appoint him Chairman.

Mr. Waggoner began his professional career as an attorney in private practice. From 1986 to 2003, he was a senior partner with Brobeck, Phleger and Harrison ("Brobeck"), where he was the Managing Partner of Brobeck's Los Angeles office. While at Brobeck, Mr. Waggoner served as a member of the Executive Committee and on the Policy Committee. Mr. Waggoner was the co-Chairman of Brobeck's worldwide Environmental Law Group.

Mr. Waggoner's career included leadership and legal positions with Fortune 100 companies most of his professional career. From 2003 to 2005, Mr. Waggoner served as the Vice President and General Counsel of Chevron's global downstream operations where he was responsible for the overall management of legal services to the North American, Latin American, European and Asian Products Companies. While at Chevron, Mr. Waggoner led the successful restructuring of Chevron's global Legal Department following Chevron's acquisition of Texaco.

From 2005 until September 2013, Mr. Waggoner was the principal of the Law Offices of Kenneth L. Waggoner & Associates. During that time, he held leadership and legal positions with several start-up companies and provided legal counsel and business advice to his clients.

Mr. Waggoner received his Juris Doctorate with honors from Loyola University School of Law in Los Angeles in 1973.

Gerald W. Crabtree, PhD

Dr. Crabtree has served as our Chief Operating Officer since February 2011 and has been a member of the Board since February 2013. Given the major importance to developing treatments for cancer and diabetes coupled with Dr. Crabtree's education, training and experience, Dr. Crabtree was appointed to the Board.

Dr. Crabtree's background in the biomedical sciences has been substantial, having been involved with various biopharmaceutical companies where he has alternatively supervised and coordinated the development of multiple drug candidates, prepared clinical protocols, investigator brochures, monographs, and research and review articles.

Dr. Crabtree has over 50 years of experience in the biomedical sciences sector with the majority of that being in the cancer area. Dr. Crabtree served as the Director of Project Planning and Management (Oncology and Immunology) at Bristol-Myers Squibb ("BMS") from 1990 to 1997. While at BMS, Dr. Crabtree established and directed the department that coordinated the development of all oncologic and immunologic drugs from initial discovery through regulatory approval. He also served as Project Manager for the development of the major anticancer agent, Taxol. Taxol ultimately became a multi-billion-dollar drug for BMS and is still widely used to treat a variety of cancers. From 1985 to 1990, Dr. Crabtree was the Director of Pharmacology at Viratek, a subsidiary of ICN Pharmaceuticals, in Costa Mesa, California, where he worked on the development of anticancer drugs first developed at the Nucleic Acid Research Institute, a joint venture between Eastman Kodak and ICN Pharmaceuticals. He also helped coordinate the development of ribavirin, Viratek's landmark antiviral drug. From 1970 through 1985, Dr. Crabtree was a member of the faculty of Brown University where he was involved in both basic and clinical cancer research.

Dr. Crabtree received his Ph.D. in Biochemistry from the University of Alberta, Edmonton, Alberta, Canada, and has published over 80 articles in peer-reviewed journals. He was a National Cancer Institute of Canada Research Fellow, is currently a member of the American Society of Clinical Oncology and was a member of the American Association for Cancer Research from the early 1990s until recently and has served on research grant review committees for the National Institutes of Health and the American Cancer Society.

Carlos A. Trujillo, CPA

Carlos A. Trujillo 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 been a member of the Board since March 2017. Mr. Trujillo has over three decades of experience in management, business, operations and financial accounting. It was his education, experience and leadership skills that led us to elect him to the Board.

Mr. Trujillo is a Certified Public Accountant with an active license from the State of California. He has 36 years of experience in finance, accounting and management. Mr. Trujillo started his career in public accounting and was the manager of an audit department a large 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 thirteen 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 extensive 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.

Thomas Liquard

Thomas Liquard has been a member of the Board since April 2015. Mr. Liquard has more than a decade of experience in the pharmaceutical industry, having held various commercialization, product development and leadership roles with large pharmaceutical and biotechnology companies. It was his education, experience and leadership skills that led us to elect him to the Board.

Mr. Liquard currently serves as an independent consultant to the biopharmaceutical industry. From August 2015 to August 2017, Mr. Liquard was the Chief Executive Officer of Immuron, a Melbourne, Australia-based pharmaceutical company. Prior to Immuron, Mr. Liquard served as the Chief Executive Officer and Chief Operating Officer of Alchemia, a major Australian pharmaceutical company. Mr. Liquard worked for Alchemia from October 2013 to November 2014. Mr. Liquard spent the previous seven years with Pfizer, Inc. based in New York, where he held various senior commercial positions. His last was as Senior Director, Portfolio Development Leader and Emerging Markets for the Established Products portfolio. In that role, Mr. Liquard drove business development (M&A, licensing, partnerships) and internal product development initiatives.

Mr. Liquard was appointed to the Board because of his experience and expertise in leading positions with life science-oriented biotech and pharmaceutical companies. We believed that his seven-year tenure with Pfizer, one of the world's leading pharmaceutical companies, where he played leading roles in the development of that company's portfolio development, was a needed asset to us. Mr. Liquard received his Master of Business Administration in Finance and Strategy from the Columbia Business School and a Bachelor of Science degree from the University of Southern California.

Thomas C. K. Yuen

Thomas C. K. Yuen was appointed to the Board in May 2017. Mr. Yuen has more than three decades of experience in entrepreneurship and business leadership, including in the biotech industry. It was his stellar career in business, leadership skills and business acumen and experience that led us to elect him to the Board.

Mr. Yuen's career is exemplified by his global entrepreneurial experience. He co-founded Irvine-based AST Research, Inc. ("AST") in 1981. AST was an early pioneer of the computer industry, and the company has been referred to as "the flagship of innovation in the PC era." Mr. Yuen served as AST's Co-Chairman and Chief Operating Officer from August 1987 to June 1992. Under his leadership, AST became a Fortune 500 company in 1991, and its stock was named the "Best Performing NASDAQ Stock" of that year.

Mr. Yuen left AST in 1992 and focused his efforts on investing in new projects. Mr. Yuen served in various engineering and project management positions with Hughes Aircraft Company, Sperry Univac and Computer Automation. Later in his career, Mr. Yuen became Chairman and CEO of SRS Labs, a world leader in audio and voice technology. Currently, Mr. Yuen is Chairman and Chief Executive Officer of PrimeGen Biotech, LLC, a private cell therapy company he founded in 2002.

Mr. Yuen has held numerous director positions. He served as a Director of AST from 1981 to June 1992. He served as a Director of Valence Technology, Inc., an energy storage company, from March 1998 to March 2000 and a Director of DTS, Inc., an audio technology company, from April 2012 to July 2013. Mr. Yuen has served as a Director of SRS Labs since January 1994. He is also an Honorary Professor of China Nationality University in Beijing.

In 1988 and 1991, the Computer Reseller News Magazine named Mr. Yuen one of the top 25 executives of the computer industry. In 1997, he received the Director of the Year Award from the Orange County Foundation of Corporate Directors. Mr. Yuen is the recipient of several awards from the University of California, Irvine ("UCI"), including the UCI Medal in 1990, the Outstanding Engineering Alumni Award in 1987 and the Distinguished Alumnus Award in 1986. Also, Mr. Yuen has received the prestigious UCI Extraordinarious Award for his exemplary career in business and his philanthropic and volunteer activities.

Mr. Yuen received his Bachelor of Science degree in Electrical Engineering from the University of California, Irvine.

Michael M. Abecassis, MD

Dr. Abecassis is a transplantation surgeon at the Northwestern University Feinberg School of Medicine who has demonstrated leadership qualities in academia, in the clinic and throughout his career in medicine – a career that spans over 30 years. Dr. Abecassis was appointed Board in July 2017 because of these attributes and his extensive experience in the medical field that translates directly to the work being undertaken by us in the cancer arena.

Dr. Abecassis is the Director of the Comprehensive Transplant Center of the Feinberg School of Medicine. He is also the Chief of Transplant Surgery in the Department of Surgery at Feinberg and a *James Roscoe Miller Distinguished Professor of Medicine* at Feinberg.

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. After his postgraduate tenure in Toronto, Dr. Abecassis began his clinical career as Assistant Professor of Surgery and Director of Liver Transplantation and Hepatobiliary Surgery at the University of Iowa. In 1993, 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. He became Founding Director of the Comprehensive Transplant Center at Northwestern in 2009 and was appointed Dean for Clinical Affairs at the Feinberg School of Medicine in 2008, serving until 2011.

Dr. Abecassis has received continuous funding from the National Institutes of Health ("NIH") for the past 16 years. He is the principal investigator in research that includes both laboratory and clinical studies. He is also the principal investigator of the clinical core of the NIH Genomics of Transplantation Cooperative Research Program. Dr. Abecassis has trained numerous clinical and research fellows.

Dr. Abecassis is a member of the Society of University Surgeons and the American Surgical Association and was President of the American Society of Transplant Surgeons 2010-2011. He has served and continues to serve on the Editorial Boards of major scientific journals (Hepatology, Surgery, Transplantation and Liver Transplantation) and is a reviewer for all major journals related to surgery and transplantation. He has served as a member of NIH grant study sections and special emphasis panels relating to both transplantation and virology. He is 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 since 2010 and was course director 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.

Raymond C.K Tong, MD

Dr. Tong serves as Chief Executive Officer of Harmony Medical Inc., an Asian investment group active in the introduction and distribution of medical and healthcare products and services in China and throughout Asia. He is also Chairman of the Business Development Committee of Shanghai Kedu Healthcare Group, the largest medical equipment third-party service provider in China, representing products from GE, Philips, Siemens, Kodak and other multi-nationals as well as local companies. He was appointed to the Board in October 2017 It was his stellar career in the medical field, as well as his significant connections to the investment community throughout Asia, leadership skills and business acumen and experience that caused us to elect him to the Board.

Dr. Tong has been a Director of Medifocus Inc. since January 27, 2015. He was also a Director of Shanghai CP Guojian Pharmaceutical, one of the first and largest bio-pharmaceutical manufacturers in China. In addition, Dr. Tong is the founding Director and Chief Executive Officer of VetCell Therapeutics Asia, a cell therapy company focused on providing cell-based treatments for use in veterinary medicine in Asia.

Dr. Tong's earlier career includes senior management positions in China with Pfizer and Ball Corporation. He was also responsible for the Healthcare Investment Division of CITIC in Hong Kong. CITIC is the largest conglomerate in China and an established global player, with businesses covering healthcare, financial services, resources, energy, manufacturing, engineering and many others.

Dr. Tong received his medical degree from the University of Toronto in Ontario, Canada in 1983. He also received a Ph.D. degree in neurophysiology and an M.B.A. degree. After receiving his medical degree, Dr. Tong founded a chain of medical clinics in the Province of Ontario where he served as Medical Director and Chief Physician. During this period, he also served as a consultant and an investigator in several clinical trials. In 1989, Dr. Tong returned to Hong Kong, where he was born and resided before medical school, and spent the next 19 years in prominent corporate appointments with several multinational medical and pharmaceutical companies discussed above.

Walter H. Günzburg, PhD

Dr. Walter H. Günzburg is our Chief Scientific Officer and has been consulting for us since September 2014. Prof. Günzburg is the founder of Austrianova and serves as its Chairman and Chief Technology Officer. Prof. Günzburg is a co-founder of SG Austria and serves as its Chairman. Prof. Günzburg has more than 35 years of experience in virology and over 25 years of experience in cell therapy and bio-encapsulation. Prof. Günzburg serves as a Member of the Supervisory Board of ViruSure, a virus and prion testing company in Vienna that he co-founded. He also serves as Professor of Virology at the University of Veterinary Medicine, Vienna. He has been Scientific Advisor to Bavarian Nordic (from 1994 to 2001), Director of the Christian Doppler Laboratory for Gene Therapeutic Vector Development in Vienna (2003 to 2011) and Scientific Advisor to Paktis and Liponova AG, biotech companies based in Germany, as well as to Tocagen Inc., a U.S.-based biotech company.

In 1984, Dr. Günzburg received a Ph.D. in gene regulation in conjunction with the Imperial Cancer Research Fund Laboratories in London. After a postdoc in Switzerland at the Ludwig Institute for Cancer Research and a research fellow position in the U.S., he joined the German National Research Centre in Munich as the Group Leader on Cell and Gene Therapy in 1988 and became a senior lecturer (Privatdozent) at the University of Munich. In 1996, Dr. Günzburg moved to Vienna to become Professor of Virology at the University of Veterinary Medicine, Vienna and Chair of the Department of Virology. Prof. Gunzburg served as an Adjunct Professor of Virology at the National University of Singapore from 2008-2010. He has been actively involved in European ethics and regulatory affairs in the fields of cell and gene therapy, as well as xenotransplantation, for many years.

Linda S. Sher, MD

Dr. Sher is a Professor of Clinical Surgery in the Division of Hepatobiliary/Pancreatic Surgery and Abdominal Organ Transplantation in the Department of Surgery at the University of Southern California's Keck School of Medicine ("USC"). Dr. Sher is also the Chief of the Division of Clinical Research for the Department of Surgery at USC where she oversees the implementation and conduct of clinical trials for the entire department, overseeing between 50 to 70 studies at a time. In addition, Dr. Sher is the Vice Chair of the USC Institutional Review Board. Dr. Sher oversees the structure, conduct and reporting of our clinical trials and represents us in our interactions with the company's clinical trial investigators, regulatory agencies, key opinion leaders, the investment, medical and regulatory communities, as well as pharmaceutical and biotechnology sector collaborators and potential partners.

After completing her medical school education and surgical residency at Mount Sinai School of Medicine in New York, Dr. Sher had fellowship training at the University of Pittsburgh in Liver and Kidney Transplantation. Following completion of her fellowship program in 1988, Dr. Sher was involved in the establishment of two liver transplant programs in Los Angeles before joining the USC program in 2001.

Dr. Sher has participated in the surgery and management of patients with end stage liver disease, hepatobiliary and pancreatic disease and liver transplant recipients for more than 30 years. She has been the Principal or Co-Principal Investigator for more than 50 clinical trials and has mentored young faculty at USC in the conduct of clinical trials. Dr. Sher is active in the clinical and basic science research components of the Abdominal Organ Transplantation Program at USC. She has authored or co-authored articles on immunosuppression, chronic rejection, disease recurrence, infection, hepatobiliary surgery and transplant outcomes. Dr. Sher is one of the original editors of Current Opinion in Organ Transplantation, which provides the reader with an up to date overview of the entire field of organ transplantation.

Compliance with Section 16(a) of the Exchange Act

We do not have a class of securities registered pursuant to Section 12 of the Exchange Act. Accordingly, our executive officers and directors and our investors who own more than 10% of their equity securities are not subject to the beneficial ownership reporting requirements of Section 16(a) of the Exchange Act.

Family Relationships

There are no family relationships among our executive officers, directors and significant employees. As of April 30, 2019, our personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the Rules and Regulations of the Commission.

Corporate Governance and Committees

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 Form 10-K.

Board Leadership and Structure

The Chairperson of the Board presides at all meetings of the Board. Mr. Waggoner serves as the Chairperson of the Board and as our Chief Executive Officer, President and General Counsel.

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 Dr. Michael Abecassis, Dr. Tong, Mr. Yuen and Mr. Thomas. The Chairperson of the Audit Committee is Dr. Abecassis. 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, Dr. Abecassis, is an "audit committee financial expert," as that term is defined in Item 407(d) of Regulation S-K under the Exchange Act.

Our Audit Committee charter can be viewed and downloaded from the "Governance" dropdown menu of our website under the "Company" tab.

Compensation Committee

The Compensation Committee is currently comprised of Mr. Liquard, Mr. Waggoner and Mr. Yuen. The Chairperson of the Compensation Committee is Mr. Liquard. 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 a majority of independent directors, provides overall guidance for our executive compensation policies and determines the value and elements of compensation for our executive officers.

Our Compensation Committee charter can be viewed and downloaded from the "Governance" dropdown menu of our website under the "Company" tab.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is currently comprised of Dr. Crabtree, Dr. Tong and Mr. Liquard. The Chairperson of the Nominating and Corporate Governance Committee is Dr. Crabtree.

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 SEC 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, taking into account 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.

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. Since September 2013, we have not held an annual meeting of stockholders.

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 our address set forth at the beginning of this Report. These communications will be reviewed by our Chief Executive Officer and Chief Financial Officer. They will determine whether the communications should be presented to our Board. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications.

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, 2019, our Named Executive Officers and their positions were as follows:

- Kenneth L. Waggoner, JD, Chief Executive Officer, President, General Counsel and Chairman of the Board;
- Gerald W. Crabtree, PhD, Chief Operating Officer and Director; and
- Carlos A. Trujillo, CPA, Chief Financial Officer and Director.

The following tables provide information about all compensation earned during our fiscal years ended April 30, 2019 and 2018 by our Named Executive Officers and directors, respectively.

Summary Compensation Table

Name	Principal Position	Fiscal Year	Salary ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Kenneth L. Waggoner, JD(2)	Chief Executive Officer, President and General Counsel	2019	$ 375,000	$ 178,200	$ 121,698	$ 674,898
		2018	$ 375,000	$ 316,500	$ 312,800	$ 1,004,360
Gerald W. Crabtree, PhD(2)	Chief Operating Officer	2019	$ 138,000	$ 29,700	$ 40,566	$ 208,266
		2018	$ 138,000	$ 52,760	$ 104,266	$ 295,026
Carlos A. Trujillo, CPA (2)	Chief Financial Officer	2019	$ 275,000	$ 118,800	$ 81,132	$ 474,932
		2018	$ 275,000	$ 211,040	$ 208,534	$ 694,574

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

(2) We did not pay or accrue any other compensation, in the form of bonuses, incentive plan compensation or nonqualified deferred compensation earnings to any Named Executive officer for services as an executive officer during the fiscal years ended April 30, 2019 and 2018; neither were there any perquisites or other personal benefits or compensation for a Named Executive Officer's services as a director. On October 15, 2018, we adopted a retirement plan for eligible employees named the PharmaCyte Biotech, Inc 401(k) Plan ("Plan"). The Plan is a safe harbor plan that allows eligible employees to contribute a portion of their salaries into the Plan. We are not required to and do not contribute to the highly compensated employees accounts and we do not match the contributions of the Named Executive Officers.

Outstanding Equity Awards at Fiscal Year End

	Option Awards				Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(1)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Kenneth L. Waggoner	10,000,000	–	$ 0.110	03/10/2020	–	$ –	–	$ –
	2,400,000	–	$ 0.110	03/10/2020	–	$ –	–	$ –
	6,000,000	–	$ 0.063	12/31/2020	–	$ –	–	$ –
	4,500,000	–	$ 0.104	03/09/2022	–	$ –	–	$ –
	4,500,000	–	$ 0.054	12/31/2023	–	$ –	–	$ –
	375,000	4,125,000	$ 0.0495	03/20/2024	–	$ –	–	$ –
	–	–	$ –	–	3,300,000	$ 135,300	–	$ –
Gerald W. Crabtree	10,000,000	–	$ 0.110	03/10/2020	–	$ –	–	$ –
	2,400,000	–	$ 0.110	03/10/2020	–	$ –	–	$ –
	4,800,000	–	$ 0.063	12/31/2020	–	$ –	–	$ –
	1,500,000	–	$ 0.104	03/09/2022	–	$ –	–	$ –
	1,500,000	–	$ 0.054	12/31/2023	–	$ –	–	$ –
	125,000	1,375,000	$ 0.0495	03/20/2024	–	$ –	–	$ –
	–	–	$ –	–	550,000	$ 22,550	–	$ –
Carlos A. Trujillo	2,400,000	–	$ 0.110	03/10/2020	–	$ –	–	$ –
	4,800,000	–	$ 0.063	12/31/2020	–	$ –	–	$ –
	3,000,000	–	$ 0.104	03/09/2022	–	$ –	–	$ –
	3,000,000	–	$ 0.054	12/31/2023	–	$ –	–	$ –
	250,000	2,750,000	$ 0.0495	03/20/2024	–	$ –	–	$ –
	–	–	$ –	–	2,200,000	$ 90,200	–	$ –

(1) Subject to the Named Executive Officer's continued employment, 1/12th of the grant vests monthly after the grant date.

(2) The market value is based on the closing stock price of $0.041 on April 30, 2019, the last day of trading in this fiscal year.

Employment Arrangements

Kenneth L. Waggoner, JD

We have entered into an Executive Compensation Agreement with Mr. Waggoner ("Waggoner Compensation Agreement"). The term of the Waggoner Compensation Agreement extends until December 31, 2018 with annual extensions at the end of the term or any extension of the term, unless we or Mr. Waggoner provide 90-days written notice of termination. The Waggoner Compensation Agreement provides that Mr. Waggoner will be employed as a member of our Board, as our Chief Executive Officer, President and General Counsel and as the Chief Executive Officer and General Counsel of our subsidiary Viridis Biotech. Under this agreement, Mr. Waggoner is paid a base salary of $375,000 subject to annual increases in the discretion of our Compensation Committee. The Waggoner Compensation Agreement also provides that, during his continued employment, Mr. Waggoner receives an annual stock grant of 3,600,000 shares of restricted common stock, vesting at the rate of 300,000 shares per month, and an annual stock option grant to purchase 4,500,000 shares of common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, vesting at the rate of 375,000 option shares per month.

If Mr. Waggoner's employment is terminated by us without "Cause" or by him for "Good Reason" (as such terms are defined in the Waggoner Compensation Agreement), then subject to his execution of a timely release, he is entitled to: (i) base salary continuation for 2 years, (ii) payment of the annual bonus, if any, earned by Mr. Waggoner 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. Waggoner and his family and life insurance coverage for Mr. Waggoner, if any, for 12 months at the Company's expense.

Notwithstanding the foregoing, if Mr. Waggoner's employment is terminated by us without Cause or by him for Good Reason because of a "Change in Control" (as such term is defined in the Waggoner Compensation Agreement), then the base salary and bonus, if any, component of severance would be paid in lump sum. Also, Mr. Waggoner 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. Waggoner's employment is terminated due to death, his designated beneficiary or estate would receive the severance benefits set forth above, excluding the base salary and bonus continuation and life insurance premium continuation, however, his estate would receive the proceeds, if any, from any life insurance.

If Mr. Waggoner's employment is terminated due to "Disability" (as such term is defined in the Waggoner Compensation Agreement) he would receive continued health coverage and life insurance coverage, if any, for 12 months at our expense.

Additionally, Mr. Waggoner is bound by confidentiality and non-disparagement provisions as well as non-solicitation and non-competition covenants that prohibit him from such action during the term of his employment and for twenty-four months after termination of his employment.

Assuming one of the following events occurred on April 30, 2019, Mr. Waggoner's payments and benefits have an estimated value of:

	Base Salary Severance Payment ($)	Bonus Severance Payment ($)	Health/Life Insurance Continuation ($)	Other ($)	Value of Options Subject to Acceleration ($)(1)	Value of Restricted Stock Subject to Acceleration ($) (2)	Total ($)
Death	–	–	32,457 (4)	–	–	135,300	167,757
Disability	–	–	32,457 (4)	–	–	135,300	167,757
Without Cause or for Good Reason	750,000 (5)	– (3)	32,457 (4)	–	–	135,300	917,757
Without Cause or for Good Reason in connection with a Change in Control	750,000 (6)	– (3)	32,457 (4)	– (7)	–	135,300	917,757
Change in Control (without termination)	–	–	–	–	–	–	–

(1) This amount represents the value of an option to purchase 4,125,000 otherwise unvested shares of our common stock, based on $0.041, the closing price of our common stock on April 30, 2019 and the exercise price of such option at $0.0495 per share. No value has been attributed to stock option acceleration as the closing price for the Company's stock was below the strike price of Mr. Waggoner's unvested option.

(2) This amount represents the value of 3,300,000 shares of otherwise unvested shares of our common stock, based on $0.041, the closing price of our common stock on April 30, 2019.

(3) There was no bonus payable to Mr. Waggoner in the 2019 fiscal year; nor did he have a target bonus for the 2019 fiscal year; accordingly, no severance would be payable under the Waggoner Compensation Agreement with respect to any bonus.

(4) This amount represents 12 months of Company paid health insurance continuation premiums for Mr. Waggoner and Mr. Waggoner's dependent. There was no life insurance policy for Mr. Waggoner in the 2019 fiscal year; accordingly, no life insurance benefits would be payable under the Waggoner Compensation Agreement.

(5) This amount is equal to 24 months of Mr. Waggoner's monthly base salary and is paid as base salary continuation for the 24 months following such termination of employment.

(6) This amount is equal to 24 months of Mr. Waggoner's monthly base salary and is paid in a lump sum.

(7) If Mr. Waggoner was subject to an excise under Section 280G of the Code, he would be entitled to receive a full excise tax gross-up, pursuant to the Waggoner Compensation Agreement. However, based on current estimates, we do not believe that Mr. Waggoner would have been subject to a 280G excise tax based on the benefits he would have received upon a change in control that occurred on April 30, 2019. Accordingly, no gross-up would need to have been made.

Gerald W. Crabtree, PhD

We have entered into an Executive Compensation Agreement with Dr. Crabtree ("Crabtree Compensation Agreement"). The term of the Crabtree Compensation Agreement extends until December 31, 2018 with annual extensions at the end of the term or any extension of the term unless we or Dr. Crabtree provide 90-days written notice of termination. The Crabtree Compensation Agreement provides that Dr. Crabtree will be employed as a member of our Board, as our Chief Operating Officer and as the Chief Operating Officer of our subsidiary Viridis Biotech. Dr. Crabtree is paid a base salary of $138,000 subject to annual increases in the discretion of our Compensation Committee. The Crabtree Compensation Agreement also provides that, during his continued employment, Dr. Crabtree will receive annual stock grants of 600,000 shares of restricted common stock, vesting at the rate of 50,000 shares per month, and an annual stock option grant to purchase 1,500,000 shares of common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, vesting at the rate of 125,000 option shares per month.

If Dr. Crabtree's employment is terminated by us without "Cause" or by him for "Good Reason" (as such terms are defined in the Crabtree Compensation Agreement), then subject to his execution of a timely release, he is entitled to: (i) base salary continuation for 2 years, (ii) payment of the annual bonus, if any, earned by Dr. Crabtree 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 the any unvested stock or option awards and (iv) continued health coverage for Dr. Crabtree and his family and life insurance coverage for Dr. Crabtree, if any, for 12 months at the Company's expense.

Notwithstanding the foregoing, if Dr. Crabtree's employment is terminated by us without Cause or by him for Good Reason because of a "Change in Control" (as such term is defined in the Crabtree Compensation Agreement), then the base salary and bonus, if any, component of severance would be paid in lump sum. Also, Dr. Crabtree 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 Dr. Crabtree's employment is terminated due to death, his designated beneficiary or estate would receive the severance benefits set forth above, excluding the base salary continuation and life insurance premium continuation, however, he would receive the proceeds, if any, from any life insurance.

If Dr. Crabtree's employment is terminated due to "Disability" (as such term is defined in the Crabtree Compensation Agreement) he would receive continued health coverage and continued life insurance coverage, if any, for 12 months at our expense.

Also, Dr. Crabtree is bound by confidentiality and non-disparagement provisions as well as non-solicitation and non-competition covenants that prohibit him from such action during the term of his employment and for twenty-four months after termination of employment.

Assuming one of the following events occurred on April 30, 2019, Dr. Crabtree's payments and benefits have an estimated value of:

	Base Salary Severance Payment ($)	Bonus Severance Payment ($)	Health/Life Insurance Continuation ($)	Other ($)	Value of Options Subject to Acceleration ($)(1)	Value of Restricted Stock Subject to Acceleration ($) (2)	Total ($)
Death	–	–	– (4)	–	–	22,550	22,550
Disability	–	–	– (4)	–	–	22,550	22,550
Without Cause or for Good Reason	276,000 (5)	– (3)	– (4)	–	–	22,550	298,550
Without Cause or for Good Reason in connection with a Change in Control	276,000 (6)	– (3)	– (4)	– (7)	–	22,550	298,550
Change in Control (without termination)	–	–	–	–	–	–	–

(1) This amount represents the value of an option to purchase 1,375,000 otherwise unvested shares of our common stock, based on $0.041, the closing price of our common Stock on April 30, 2019 and the exercise price of such option at $0.0495 per share. No value has been attributed to stock option acceleration as the closing price for the Company's stock was below the strike price of Dr. Crabtree's unvested option.

(2) This amount represents the value of 550,000 shares of otherwise unvested shares of our common stock, based on $0.041, the closing price of our common Stock on April 30, 2019.

(3) There was no bonus payable to Dr. Crabtree in the 2019 fiscal year, nor did he have a target bonus for the 2019 fiscal year; accordingly, no severance would be payable under the Crabtree Compensation Agreement with respect to his bonus.

(4) There was no health insurance policy for Dr. Crabtree as he did not participate in the Company's provided health insurance coverage and there was no life insurance policy for Dr. Crabtree in the 2019 fiscal year; accordingly, no health insurance continuation premiums or life insurance benefits would be payable under the Crabtree Compensation Agreement.

(5) This amount is equal to 24 months of Dr. Crabtree's monthly base salary and is paid as base salary continuation for the 24 months following such termination of employment.

(6) This amount is equal to 24 months of Dr. Crabtree's monthly base salary and is paid in lump sum.

(7) If Dr. Crabtree was subject to an excise tax under Section 280G of the Code, he would be entitled to receive a full excise tax gross-up, pursuant to the Crabtree Compensation Agreement. However, based on current estimates, we do not believe that Dr. Crabtree would have been subject to a 280G excise tax based on the benefits he would have received upon a change in control that occurred on April 30, 2019. Accordingly, no gross-up would need to have been made.

Carlos A. Trujillo, CPA

We have entered into an Executive Compensation Agreement with Mr. Trujillo ("Trujillo Compensation Agreement"). The term of the Trujillo Compensation Agreement extends until December 31, 2018 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 provides that Mr. Trujillo will be employed as a member of our Board, as our Chief Financial Officer and as the Chief Financial Officer of our subsidiary Viridis Biotech. Mr. Trujillo is paid an annual base salary of $275,000, subject to annual increases at the discretion of the Compensation Committee. The Trujillo Compensation Agreement also provide that during his continued employment, Trujillo will receive annual grants of 2,400,000 shares of restricted common stock, vesting at the rate of 200,000 shares per month, and an annual stock option grant to purchase 3,000,000 shares of common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, vesting at the rate of 250,000 option shares per month.

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) base salary continuation for 2 years, (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 and life insurance coverage, if any, for 12 months at our expense.

Notwithstanding the foregoing, if Mr. Trujillo's employment is terminated by us without Cause or by him for Good Reason because of a "Change in Control" (as such term is defined in the Trujillo Compensation Agreement) then the base salary 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 is terminated due to death, his designated beneficiary or estate would receive the severance benefits set forth above, excluding the base salary continuation and life insurance premium continuation, however, he 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 continued life insurance coverage, if any, for 12 months at our expense.

Also, Mr. Trujillo is bound by confidentiality and non-disparagement provisions as well as non-solicitation and non-competition covenants that prohibit him from such action during the term of his employment and for twenty-four months after termination of employment.

Assuming one of the following events occurred on April 30, 2019, Mr. Trujillo's payments and benefits have an estimated value of:

	Base Salary Severance Payment ($)	**Bonus Severance Payment ($)**	**Health/Life Insurance Continuation ($)**	**Other ($)**	**Value of Options Subject to Acceleration ($)(1)**	**Value of Restricted Stock Subject to Acceleration ($) (2)**	**Total ($)**
Death	–	–	38,310 (4)	–	–	90,200	128,510
Disability	–	–	38,310 (4)	–	–	90,200	128,510
Without Cause or for Good Reason	550,000 (5)	– (3)	38,310 (4)	–	–	90,200	678,510
Without Cause or for Good Reason in connection with a Change in Control	550,000 (6)	– (3)	38,310 (4)	– (7)	–	90,200	678,510
Change in Control (without termination)	–	–	–	–	–	–	–

(1) This amount represents the value of an option to purchase 2,750,000 otherwise unvested shares of our common stock, based on $0.041, the closing price of our common Stock on April 30, 2019 and the exercise price of such option at $0.0495 per share. No value has been attributed to stock option acceleration as the closing price for the Company's stock was below the strike price of Mr. Trujillo's unvested option.

(2) This amount represents the value of 2,200,000 shares of otherwise unvested shares of our common stock, based on $0.041, the closing price of our common Stock on April 30, 2019.

(3) There was no bonus payable to Mr. Trujillo in the 2019 fiscal year, nor did he have a target bonus for the 2019 fiscal year; accordingly, no severance would be payable under the Trujillo Compensation Agreement with respect to his bonus.

(4) This amount represents 12 months of Company-paid health insurance continuation premiums for Mr. Trujillo and his dependents. There was no life insurance policy for Mr. Trujillo in the 2019 fiscal year; accordingly, no life insurance benefits would be payable under the Trujillo Compensation Agreement.

(5) This amount is equal to 24 months of Mr. Trujillo's monthly base salary and is paid as base salary continuation for the 24 months following such termination of employment.

(6) This amount is equal to 24 months of Mr. Trujillo's monthly base salary and is paid in lump sum.

(7) If Mr. Trujillo was subject to an excise tax under Section 280G of the Code, he would be entitled to receive a full excise tax gross-up, pursuant to the Trujillo Compensation Agreement. However, based on current estimates, we do not believe that Mr. Trujillo would have been subject to a 280G excise tax based on the benefits he would have received upon a change in control that occurred on April 30, 2019. Accordingly, no gross-up would need to have been made.

Directors

The following table sets forth information concerning compensation paid or to our directors, other than our Named Executive Officers who also serve as directors, during the year ended April 30, 2019.

Director Compensation

Directors:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Thomas Liquard	$ 50,000	26,950(2)	21,569 (2)	$ 98,519
Thomas C.K Yuen	$ 50,000	26,950(3)	23,129 (3)	$ 100,079
Michael M. Abecassis, MD	$ 50,000	34,150(4)	18,280 (4)	$ 102,430
Raymond C.K. Tong, MD	$ 50,000	32,450(5)	18,372 (5)	$ 100,822

(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, 2019, as computed in accordance with FASB ASC Topic 718 and the assumptions stated in Note 4 and Note 5 of the Consolidated Financial Statements to this Report.

(2) As of April 30, 2019, Mr. Liquard held unexercised options to purchase an aggregate of 1,250,000 shares.

(3) As of April 30, 2019, Mr. Yuen held unexercised options to purchase an aggregate of 1,000,000 shares.

(4) As of April 30, 2019, Dr. Abecassis held unexercised options to purchase an aggregate of 1,000,000 shares.

(5) As of April 30, 2019, Dr. Tong held unexercised options to purchase an aggregate of 1,000,000 shares.

Each non-employee director is party to an agreement to serve as a director and to receive $12,500 per quarter on a pro-rated basis for periods of less than a quarter. In addition, we will annually grant each non-employee director: (i) 500,000 shares of our restricted common stock; and (ii) a stock option to purchase 500,000 shares of our restricted common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, both of which will be fully vested at the time of grant.

Other than as described above, directors do not receive any additional compensation for participation in either Board or Committee meetings of the Board.

Compensation Committee Interlocks

None of our officers currently serves, or has served during the last completed year, on the board of directors, compensation committee or other committee serving an equivalent function, of any other entity that has one or more officers serving as a member of our Board or Compensation Committee.

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

The following table sets forth as of July 16, 2019, 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.

Name and Address	Amount and Nature of Beneficial Ownership (1)	Percentage of Common Stock (1)
Kenneth L. Waggoner, JD, Chairman of the Board, Chief Executive Officer, President and General Counsel	54,475,000	4.35%
Gerald W. Crabtree, PhD, Chief Operating Officer and Board Member	36,925,000	2.97%
Carlos A. Trujillo, CPA, Chief Financial Officer and Board Member	23,850,000	1.93%
Thomas Liquard, Board Member	2,250,000	*
Thomas C.K. Yuen, Board Member	2,000,000	*
Michael M. Abecassis, MD, Board Member	4,400,000	*
Raymond C.K. Tong, MD, Board Member	2,000,000	*
All directors and executive officers as a group (7 persons)	125,900,000	9.95%

* Indicates percentage is less than 1.0%.

(1) Percentages based on 1,221,732,283 shares of common stock issued and outstanding as of July 16, 2019. Percentages include the option to purchase shares that are unexercised, but which are exercisable within sixty days of July 16, 2019, presented as follows:

Kenneth L. Waggoner, JD	30,775,000
Gerald W. Crabtree, PhD	21,325,000
Carlos A. Trujillo, CPA	15,450,000
Thomas Liquard	1,250,000
Thomas C.K. Yuen	1,000,000
Michael M. Abecassis, MD	2,200,000
Raymond C.K. Tong, MD	1,000,000

The address of all beneficial owners is 23046 Avenida de la Carlota, Suite 600, Laguna Hills, California 92653. Each person has sole voting and investment power with respect to the shares of common stock.

We are not aware of any arrangement, the operation of which may, at a subsequent date, result in a change in control. There are no provisions in our governing instruments that could delay a change in control.

Securities Authorized for Issuance under Equity Compensation Plans

The information in the following table is as of April 30, 2019:

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	-	-	-
Equity compensation plans not approved by security holders	63,800,000	$0.09	-
Total	63,800,000	$0.09	-

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

We had the following related party transactions during the years ended April 30, 2019 and 2018, respectively.

We own 14.5% of the equity in SG Austria and 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 $168,000 and $1,389,000 in the years ended April 30, 2019 and 2018, respectively.

In April 2014, we entered a consulting agreement with Vin-de-Bona 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 our scientific endeavors relating to cancer and diabetes (Prof. Gunzburg 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, 2019 and 2018 were approximately $18,000 and $35,000, respectively. In addition, during the year ended April 30, 2019 we issued 2 million common shares to Dr. Günzburg and 500,000 common shares to Dr. Salmons. We recorded a noncash consulting expense of approximately $140,000 relating to these share issuances.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

A summary of the fees billed by our independent audit firm, Armanino for professional services rendered for the years ended April 30, 2019 and 2018 is set forth below.

Service	2019	2018
Audit Fees	$ 94,799	$ 71,310
Quarterly Review Fees	59,248	81,304
Tax Fees	–	–
All Other Fees	–	16,291
Total	$ 154,047	$ 168,905

During the years ended April 30, 2019 and 2018, we paid Armanino $94,799 and $71,310 in annual audit fees, respectively, and $59,248 and $81,304 in quarterly review fees, respectively. During the year ended April 30, 2018, we paid Armanino additional fees of $16,291 relating to the S-3 Registration Statement and Supplemental Prospectus (presented as All Other Fees).

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

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, 2019 and 2018, and for each of the two years in the period ended April 30, 2019, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-26 of this Report.

(2) Financial Statement Schedules.

Schedule II - Valuation and Qualifying Accounts for the Years Ended 2019 and 2018 are incorporated by reference to page F-26 of the financial statements included herewith. Exhibit 15(a)(2) is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in such filing.

(3) Exhibits.

Except as so indicated below and in Exhibit 32.1, the following exhibits are filed as part of, or incorporated by reference into, the Report.

Exhibit No.	Description	Location
2.1	Third Addendum, effective as of June 25, 2013, between the Company and SG Austria Private Limited.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 18, 2013.
2.2	Licensing Agreement, dated as of June 25, 2013, between the Company and Austrianova Singapore Pte. Ltd. ("Austrianova").	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 18, 2013.
3.1	Articles of Incorporation of DJH International, Inc. dated October 25, 1996.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.2	Certificate of Amendment of Articles of Incorporation of DJH International, Inc. dated October 20, 2000.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.3	Certificate of Amendment of Articles of Incorporation dated November 14, 2003.	Incorporated by reference from the Company's Form 10-Q filed with the SEC on September 17, 2009.
3.4	Certificate of Amendment of Articles of Incorporation dated June 30, 2008.	Incorporated by reference from the Company's Form 10-Q filed with the SEC on September 17, 2009.
3.5	Certificate of Amendment of Articles of Incorporation dated January 22, 2009.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on March 26, 2009.
3.6	Corporate Bylaws.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.7	Certificate of Designations, Preferences and Rights of Series E Convertible Preferred Stock dated December 20, 2007.	Incorporated by reference from the Company's Current Report on Form 10-K filed with the SEC on August 13, 2009.
3.8	Certificate of Designations, Preferences and Rights of Series E Convertible Preferred Stock, dated April 29, 2008.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 13, 2009.
3.9	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 SEC on September 25, 2014.
3.10	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 SEC on October 3, 2014.
3.11	Articles of Merger merging PharmaCyte Biotech, Inc. with and into Nuvilex, Inc., effective January 6, 2015.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 9, 2015.
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.	
4.2	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 SEC on August 20, 2001.

Exhibit No.	Description	Location
10.1	License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules between and among Bavarian Nordic A/S, GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH and Bio Blue Bird AG dated July 28, 2005.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.2	Amendment to License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules between and among Bavarian Nordic A/S, GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH and Bio Blue Bird AG dated December 20, 2006.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.3	Second Amendment to License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules between and among Bavarian Nordic A/S, Helmholtz Zentrum München/GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH and Bio Blue Bird AG effective as of October 1, 2016.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on December 2, 2016.
10.4	Manufacturing Framework Agreement between Austrianova and the Company dated March 20, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.5	Master Services Agreement between ViruSure GmbH and Registrant dated April 7, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.6	Licensing Agreement between the Company and Austrianova, dated as of June 25, 2013.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 18, 2013.
10.7	Consulting Agreement between Vin-de-Bona Trading Company Pte. Ltd. and the Company effective as of April 1, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.8	Master Consultancy Agreement between BB Biotech Consulting GmbH and the Company dated as of April 15, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.9	Financial Advisory, Offering and At the Market Offering Engagement Letter between Chardan Capital Markets, LLC and the Company dated May 28, 2014.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 29, 2014.
10.10	Collaborative Research Agreement between University of Veterinary Medicine Vienna and the Company effective as of July 1, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.11	License Agreement between University of Technology, Sydney and PharmaCyte Biotech Australia Pty Ltd (formerly, Nuvilex Australia Pty Ltd, "PharmaCyte Biotech Australia") effective as of October 13, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.12	Master Services Agreement between ViruSure GmbH and the Company effective as of August 23, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.13	Licensing Agreement, effective December 1, 2014, between Austrianova and the Company.	Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on December 15, 2014.

Exhibit No.	Description	Location
10.14†	Stock Option Agreement, dated September 29, 2014, between PharmaCyte Biotech, Inc. and Patricia Gruden.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.15†	Consulting Agreement, dated September 29, 2014, between PharmaCyte Biotech, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.16†	Stock Option Agreement, dated September 29, 2014, between PharmaCyte Biotech, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.17†	Consulting Agreement, dated September 29, 2014, between PharmaCyte Biotech, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.18†	Stock Option Agreement, dated September 29, 2014, between PharmaCyte Biotech, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.19†	Executive Compensation Agreement between the Company and Kenneth L. Waggoner dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.20†	First Stock Option Agreement between the Company and Kenneth L. Waggoner dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.21†	Second Stock Option Agreement between the Company and Kenneth L. Waggoner dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.22†	Executive Compensation Agreement between the Company and Gerald W. Crabtree dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.23†	Executive Compensation Agreement between the Company and Gerald W. Crabtree dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.24†	Second Stock Option Agreement between the Company and Gerald W. Crabtree dated March 10, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.25†	Letter agreement between the Company and Thomas Liquard dated April 20, 2015.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on April 29, 2015.
10.26	First Amendment to Licensing Agreement dated as of December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company, effective June 30, 2015.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.27	Second Amendment to Licensing Agreement dated as of December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company, effective October 19, 2015.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.28†	Amendment No. 1 to Executive Compensation Agreement between the Company and Gerald W. Crabtree, dated December 30, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.29†	Amendment No. 1 to Executive Compensation Agreement between the Company and Kenneth L. Waggoner, dated December 30, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.30†	Third Stock Option Agreement between the Company and Gerald W. Crabtree dated December 30, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.31†	Third Stock Option Agreement between the Company and Kenneth L. Waggoner, dated December 30, 2015.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.32	Variation to License Agreement dated as of October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia, effective April 20, 2016.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.33	First Amendment to Licensing Agreement dated as of June 25, 2013, between Austrianova and the Company, effective June 24, 2016.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.34	Binding Memorandum of Understanding dated as of July 28, 2016, between the Company and Austrianova Singapore Pte Ltd.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.35†	Amendment No. 2 to Executive Compensation Agreement dated March 10, 2017 between Kenneth L. Waggoner and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.36†	Amendment No. 2 to Executive Compensation Agreement dated March 10, 2017 between Carlos A. Trujillo and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.37†	Amendment No. 2 to Executive Compensation Agreement dated March 10, 2017 between Gerald W. Crabtree and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.38†	Fourth Stock Option Agreement dated as of March 10, 2017 between Kenneth L. Waggoner and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.39†	Third Stock Option Agreement dated as of March 10, 2017 between Carlos A. Trujillo and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.

Exhibit No.	Description	Location
10.40†	Fourth Stock Option Agreement dated as of March 10, 2017 between Gerald W. Crabtree and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.41†	Letter agreement dated March 10, 2017 between Thomas Liquard and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.42†	Letter agreement dated May 1, 2017 between Thomas C. K. Yuen and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 2, 2017
10.43†	Letter agreement dated June 29, 2017 between Michael Abecassis, M.D. and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 10, 2017
10.44	Binding Term Sheet dated August 30, 2017 among PharmaCyte Biotech, Inc., Austrianova Singapore Pte. Ltd. and SG Austria Pte. Ltd.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 6, 2017
10.45†	Letter agreement dated October 10, 2017 between Raymond C. F. Tong and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 9, 2017
10.46	Financial Advisory, Offering and At the Market Offering Letter Agreement dated February 22, 2018 between Aeon Capital, Inc. and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on February 22, 2018
10.47	Mutual Termination Agreement dated January 26, 2018 between Chardan Capital Markets, LLC and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on February 22, 2018
10.48	Fourth Addendum to Asset Purchase Agreement dated May 15, 2018 between SG Austria Pte. Ltd. and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 14, 2018
10.49	Third Amendment to Licensing Agreement dated May 15, 2018 between Austrianova Singapore Pte. Ltd and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 14, 2018
10.50	Second Amendment to the Licensing Agreement dated May 15, 2018 between Austrianova Singapore Pte. Ltd and PharmaCyte Biotech, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 14, 2018
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 SEC on September 25, 2014.
15(a)(2)	Schedule II - Valuation and Qualifying Accounts for the Years Ended April 30, 2019 and 2018.	Incorporated by reference to page F-26 of the financial statements included herewith.
21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of Armanino LLP	Filed herewith.
31.1	Certification of Chief Executive Officer (Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
31.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
32.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101	Interactive Data Files for PharmaCyte Biotech, Inc. Form 10-K for the period ended April 30, 2019.	Submitted herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Exhibit 15(a)(2) and Exhibit 32.1 are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in such filing.

Financial Statements Schedule:

The following financial statement schedule is set forth on page F-26 of this Report:

Schedule II — Valuation and Qualifying Accounts for the years ended April 30, 2019 and 2018.

All other schedules are omitted because they are not required, not applicable or the information is provided in the financial statements or notes thereto.

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 12, 2019

By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

August 12, 2019

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 12, 2019

By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer, Chairman of the Board and Director
(Principal Executive Officer)

August 12, 2019

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

August 12, 2019

By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, Director

August 12, 2019

By: /s/ Thomas Liquard
Thomas Liquard, Director

August 12, 2019

By: /s/ Thomas C.K. Yuen
Thomas C.K. Yuen, Director

August 12, 2019

By: /s/ Raymond C.F. Tong
Raymond C.F. Tong, Director

August 12, 2019

By: /s/ Michael M. Abecassis
Michael M. Abecassis, 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, 2019.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PHARMACYTE BIOTECH, INC.
CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and
Stockholders of PharmaCyte Biotech, Inc. and Subsidiaries
Laguna Hills, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PharmaCyte Biotech, Inc. and Subsidiaries (collectively the "Company") as of April 30, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended April 30, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of April 30, 2019 and 2018, and the related consolidated results of its operations and cash flows for each of the two years in the period ended April 30, 2019, in conformity with U.S. generally accepted accounting principles. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set form therein when read in conjunction with the related consolidated financial statements.

Basis for Opinion

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

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

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

We have served as the Company's auditor since 2015.

/s/ Armanino LLP

Armanino LLP
San Jose, California

August 12, 2019

PHARMACYTE BIOTECH, INC.
CONSOLIDATED BALANCE SHEETS

	April 30, 2019	April 30, 2018
ASSETS		
Current assets:		
Cash	$ 515,253	1,059,798
Prepaid expenses and other current assets	138,151	224,067
Total current assets	653,404	1,283,865
Other assets:		
Intangibles	3,549,427	3,549,427
Investment in SG Austria	1,572,193	1,572,193
Other assets	7,372	7,372
Total other assets	5,128,992	5,128,992
Total Assets	$ 5,782,396	6,412,857
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 121,885	352,621
Accrued expenses	620,966	291,547
Total current liabilities	742,851	644,168
Total Liabilities	742,851	644,168
Commitments and Contingencies (Notes 6 and 8)		
Stockholders' equity:		
Common stock, authorized: 1,490,000,000 shares, $0.0001 par value; 1,186,004,505 and 1,013,260,644 shares issued and outstanding as of April 30, 2019 and 2018, respectively	118,600	101,326
Additional paid-in capital	104,966,158	101,636,215
Accumulated deficit	(100,031,371)	(95,964,143)
Accumulated other comprehensive loss	(13,842)	(4,709)
Total stockholders' equity	5,039,545	5,768,689
Total Liabilities and Stockholders' Equity	$ 5,782,396	6,412,857

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30, 2019	2018
Revenue	$ –	$ –
Operating Expenses:		
Research and development costs	460,052	1,997,811
Compensation expense	1,555,258	2,220,797
Director fees	406,812	326,540
Legal and professional	299,963	617,358
General and administrative	1,378,544	1,818,923
Total operating expenses	4,100,629	6,981,429
Loss from operations	(4,100,629)	(6,981,429)
Other income:		
Other income	33,401	152,588
Total other income	33,401	152,588
Net loss	$ (4,067,228)	$ (6,828,841)
Basic and diluted loss per share	$ (0.00)	$ (0.01)
Weighted average shares outstanding basic and diluted	1,100,104,338	968,641,686

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended April 30,	
	2019	2018
Net loss	$ (4,067,228)	(6,828,841)
Other comprehensive loss:		
Foreign currency translation adjustments	(9,133)	(6,445)
Other comprehensive loss	(9,133)	(6,445)
Comprehensive loss	$ (4,076,361)	(6,835,286)

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED APRIL 30, 2019 AND 2018

	Common stock		Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance, April 30, 2017	**905,349,047**	**$ 90,534**	**$ 97,130,279**	**$ (89,135,302)**	$ 1,736	**$ 8,087,247**
Shares issued for compensation	6,600,000	660	579,700	–	–	580,360
Shares issued for services	5,950,000	595	309,286	–	–	309,881
Shares cancelled	(340,500)	(34)	34	–	–	–
Shares issued for cash, net of issuance costs of $175,000	95,702,097	9,571	2,671,838	–	–	2,681,409
Stock options granted	–	–	945,078	–	–	945,078
Foreign currency translation adjustment	–	–	–	–	(6,445)	(6,445)
Net loss	–	–	–	(6,828,841)	–	(6,828,841)
Balance, April 30, 2018	**1,013,260,644**	**101,326**	**101,636,215**	**(95,964,143)**	**(4,709)**	**5,768,689**
Shares issued for compensation	6,600,000	660	292,669	–	–	293,329
Shares issued for services	4,450,000	445	316,094	–	–	316,539
Shares issued for cash, net of issuance costs of $175,000	161,693,861	16,169	2,308,831	–	–	2,325,000
Stock options granted	–	–	412,349	–	–	412,349
Foreign currency translation adjustments	–	–	–	–	(9,133)	(9,133)
Net loss	–	–	–	(4,067,228)	–	(4,067,228)
Balance, April 30, 2019	**1,186,004,505**	**$ 118,600**	**$ 104,966,158**	**$ (100,031,371)**	**$ (13,842)**	**$ 5,039,545**

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (4,067,228)	$ (6,828,841)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	316,539	309,881
Stock issued for compensation	293,329	580,360
Stock based compensation - options	412,349	945,078
Change in operating assets and liabilities:		
(Increase) / decrease in prepaid expenses and other current assets	85,916	(149,793)
Decrease in accounts payable	(230,736)	(12,979)
Increase in accrued expenses	311,919	76,899
Net cash used in operating activities	(2,877,912)	(5,079,395)
Cash flows from investing activities:		
Net cash used in investing activities	–	–
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	2,342,500	2,681,409
Net cash provided by financing activities	2,342,500	2,681,409
Effect of currency rate exchange on cash	(9,133)	(6,445)
Net decrease in cash	(544,545)	(2,404,431)
Cash at beginning of the year	1,059,798	3,464,229
Cash at end of the year	$ 515,253	$ 1,059,798
Supplemental disclosure of cash flows information:		
Cash paid during the years for taxes	$ 800	$ 800
Supplemental schedule of noncash investing and financing activity:		
Issuance costs for shares issued	$ 17,500	$ –

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

NOTE 1 – NATURE OF BUSINESS

The Company is a clinical stage biotechnology company focused on developing and preparing to commercialize cellular therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." The Company intends to use the Cell-in-a-Box® technology as a platform upon which treatments for several types of cancer and diabetes will be developed.

The Company is developing therapies for solid tumor cancers involving the encapsulation of live cells placed in the body to enable the activation of cancer-killing drugs to the source of the cancer.

The Company is also examining ways to exploit the benefits of the Cell-in-a-Box® encapsulation technology to develop therapies for cancer based upon the constituents of the *Cannabis* plant, known as "cannabinoids."

In addition, the Company is involved in preclinical studies to determine if its cancer therapy can slow the production and/or accumulation of malignant ascites fluid in the abdomen that accompanies the growth of several types of abdominal cancers.

Finally, the Company is developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes based upon the encapsulation of a human liver cell line genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body using our Cell-in-a-Box® encapsulation technology. The Company is exploring the possibility of encapsulating human insulin-producing stem cells and islet cells and transplanting them into a diabetic patient. All three types of cells will be encapsulated using the Cell-in-a-Box® encapsulation technology. Each method is designed to function as a bio-artificial pancreas for purposes of insulin production.

Cancer Therapy

Targeted Chemotherapy

The Company is using the Cell-in-a-Box® encapsulation technology to develop a therapy for solid cancerous tumors through targeted chemotherapy. For pancreatic cancer, the Company is encapsulating genetically engineered live human cells that produce an enzyme designed to convert the prodrug ifosfamide into its cancer-killing form. The capsules containing these cells will be implanted in a patient in the blood supply as near as possible to the pancreas tumor. The cancer prodrug ifosfamide will then be given intravenously at one-third the normal dose. In this way, it is believed that the ifosfamide will be converted at the site of the tumor instead of in the liver where it is normally converted. The Company believes placement of the Cell-in-a-Box® capsules near the tumor enables the production of optimal concentrations of the "cancer-killing" form of ifosfamide at the site of the tumor. The cancer-killing metabolite of ifosfamide has a short half-life, which the Company believes will result in little to no collateral damage to other organs in the body.

Pancreatic Cancer Therapy

A critical unmet medical need exists for patients with LAPC whose pancreas tumors no longer respond to Abraxane® plus gemcitabine or FOLFIRINOX, the current standards of care, after 4-6 months of treatment with these combination therapies. These patients have no effective treatment alternative once their tumors no longer respond to these therapies. Two of the most commonly used treatments for such patients are 5-fluorouiracil ("5-FU") or capecitabine (a prodrug of 5-FU) plus radiation. Both treatments are only marginally effective in treating the tumor and result in serious side effects. The Company is developing a therapy comprised of Cell-in-a-Box® encapsulated live cells implanted near the pancreas tumor followed treatment with low doses of the cancer prodrug ifosfamide. The Company believes that its treatment can serve as a "consolidation therapy" with the current standards of care for patients with LAPC and thus address this critical unmet medical need.

Subject to FDA approval, the Company plans to commence a clinical trial involving patients with LAPC to test this hypothesis. The trial will take place initially in the U.S. with possible study sites in Europe at a later date.

Cannabinoid Therapy to Treat Cancer

The Company plans to use cannabinoids, constituents of the *Cannabis* plant, to develop therapies for cancer, with the initial target of brain cancer. The Company is focusing on developing specific therapies based on carefully chosen molecules rather than using complex *Cannabis* extracts. Targeted cannabinoid-based chemotherapy utilizing the Cell-in-a-Box® technology offers a "green" approach to treating solid-tumor malignancies.

To further its *Cannabis* therapy development plans, the Company entered a Research Agreement with the University of Northern Colorado. The initial goal of the ongoing research was to develop methods for the identification, separation and quantification of constituents of *Cannabis* (some of which are prodrugs) that may be used in combination with the Cell-in-a-Box® technology to treat cancer; this has been accomplished. Subsequent studies have been undertaken to identify the appropriate cell type that can convert the selected cannabinoid prodrugs into metabolites with anticancer activity. Once identified, the genetically modified cells that will produce the appropriate enzyme to convert that prodrug will be encapsulated using the Company's Cell-in-a-Box® technology. The encapsulated cells and cannabinoid prodrugs identified by these studies will then be combined and used for future studies to evaluate their anticancer effectiveness.

Malignant Ascites Fluid Therapy

The Company is also developing a therapy to delay the production and accumulation of malignant ascites fluid that results from many types of abdominal tumors. Malignant ascites fluid is secreted by abdominal tumors into the abdomen after the tumors have reached a certain stage of growth. This fluid contains cancer cells that can seed and form new tumors throughout the abdomen. This fluid accumulates in the abdominal cavity, causing swelling of the abdomen, severe breathing difficulties and extreme pain.

Once an abdominal tumor reaches a certain stage of development, it produces malignant ascites in the abdominal cavity. Malignant ascites fluid must be removed by paracentesis on a periodic basis. This procedure is painful and costly. There is no therapy that the Company is aware of that prevents or delays the production and accumulation of malignant ascites fluid. The Company has been involved in a series of preclinical studies conducted by TD2 to determine if the combination of Cell-in-a-Box® encapsulated cells plus ifosfamide can delay the production and accumulation of malignant ascites fluid. The Company plans to conduct another preclinical study in Germany to determine if its conclusions from the TD2 studies are valid. If the preclinical study is deemed successful and the Company receives approval to do so from the FDA, the Company plans to conduct a clinical trial in the U. S. to test its hypothesis.

Diabetes Therapy

Bio-Artificial Pancreas for Diabetes

The Company plans to develop a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. It is developing a therapy that involves encapsulation of human liver cells that have been genetically engineered to produce, store insulin and release insulin on demand at levels in proportion to the levels of blood sugar (glucose) in the human body. The encapsulation will be done using the Cell-in-a-Box® technology. The Company is also exploring the possibility of using genetically modified stem cells and natural, human insulin producing cells (beta islet cells) and protecting them with its Cell-in-a-Box® encapsulation technology. These encapsulated cells will then be transplanted into diabetic patients. The goal for the three approaches is to develop a bio-artificial pancreas for purposes of insulin production for diabetics who are insulin dependent.

Company Background and Material Agreements

The Company is a Nevada corporation incorporated in 1996. In 2013, the Company restructured its operations to focus on biotechnology. The restructuring resulted in the Company focusing all its efforts upon the development of a novel, effective and safe way to treat cancer and diabetes. On January 6, 2015, the Company changed its name from Nuvilex, Inc. to PharmaCyte Biotech, Inc. to reflect the nature of its business.

In 2011, the Company entered the SG Austria APA with SG Austria to purchase 100% of the assets and liabilities of SG Austria. Austrianova and Bio Blue Bird, then wholly-owned subsidiaries of SG Austria, were to become wholly-owned subsidiaries of the Company on the condition that the Company pay SG Austria $2.5 million and 100,000,000 shares of the common stock of the Company's common stock. The Company was to receive 100,000 shares of common stock of Austrianova and nine bearer shares of Bio Blue Bird representing 100% of the ownership of Bio Blue Bird.

Through two addenda to the SG Austria APA, the closing date of the SG Austria APA was extended twice by agreement between the parties.

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

Effective as of the same date of the Third Addendum, the parties entered the 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 the Company an exclusive, worldwide license to use, with a right to sublicense, the Cell-in-a-Box® encapsulation technology for the development of treatments for cancer and use of Austrianova's Cell-in-a-Box® trademark and its associated technology.

With respect to Bio Blue Bird, Bavarian Nordic/GSF and Bio Blue Bird entered into the 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 second pancreatic cancer clinical trial which contained proprietary information from the 1st Interim Analysis of the trial 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.

Bavarian Nordic/GSF and Bio Blue Bird amended the Bavarian Nordic License Agreement in December 2006 to reflect: (i) the license granted was exclusive; (ii) the royalty rate increased from 3% to 4.5%; (iii) Bio Blue Bird assumed the patent prosecution expenses; and (iv) it was made 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 June 2013, the Company entered into the Diabetes Licensing Agreement pursuant to which the Company is provided an exclusive, worldwide license to use the Cell-in-a-Box® encapsulation technology and trademark for the development of a therapy for Type 1 and insulin-dependent Type 2 diabetes.

In October 2014, the Company entered the Melligen Cell License Agreement. The Company plans to develop a therapy for diabetes by encapsulating the Melligen cells using the Cell-in-a-Box® encapsulation technology.

In December 2014, the Company entered the Cannabis Licensing Agreement pursuant to which it acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® encapsulation technology in combination with genetically modified non-stem cell lines which are designed to activate cannabinoid prodrug molecules for development of treatments for diseases and their related symptoms and the use of the Cell-in-a-Box® trademark for this technology. The Company paid Austrianova $2.0 million to secure this license.

In July 2016, the Company entered the Austrianova MOU pursuant to which Austrianova will actively work to seek an investment partner or partners who will finance clinical trials and further develop products for the therapies for cancer, in exchange for which the Company, Austrianova and any future investment partner or partners will each receive a share of the net revenue of applicable products in designated territories.

Effective October 1, 2016, the parties amended the Bavarian Nordic/GSF License Agreement to include the right to import, reflect ownership and notification of improvements, clarify which provisions survive expiration or termination of the Bavarian Nordic/GSF License Agreement, to provide rights to Bio Blue Bird to the clinical data after expiration of the licensed patent rights and to change the notice address and recipients of Bio Blue Bird.

In August 2017, the Company entered into the Binding Term Sheet with SG Austria and Austrianova pursuant to which the parties reached an agreement to amend certain provisions in the SG Austria APA, the Diabetes Licensing Agreement the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement.

In May 2018, the Company entered into agreements with SG Austria and Austrianova to amend certain provisions of the SG Austria APA, the Diabetes Licensing Agreement, the Cannabis Licensing Agreement and the Vin-de-Bona Consulting Agreement pursuant to the Binding Term Sheet. The Binding Term Sheet Amendments provide that the Company's obligation to make milestone payments to Austrianova are eliminated in their entirety under the Cannabis License Agreement and the Diabetes License Agreement, as amended. The Binding Term Sheet Amendments also provide that the Company's obligation to make milestone payments to SG Austria pursuant to the SG Austria APA, as amended and clarified, is eliminated in their entirety. One of the Binding Term Sheet Amendments also provides that the scope of the Diabetes License Agreement is expanded to include all cell types and cell lines of any kind or description now or later identified, including, but not limited to, primary cells, mortal cells, immortal cells and stem cells at all stages of differentiation and from any source specifically designed to produce insulin for the treatment of diabetes.

In addition, one of the Binding Term Sheet Amendments provides that the Company has a 5-year right of first refusal from August 30, 2017 in the event that Austrianova chooses to sell, transfer or assign at any time during this period the Cell-in-a-Box® tradename and its Associated Technologies; provided, however, that the Associated Technologies subject to the right of first refusal do not include Bac-in-a-Box®. Additionally, for a period of one year from August 30, 2017 one of the Binding Term Sheet Amendments provides that Austrianova will not solicit, negotiate or entertain any inquiry regarding the potential acquisition of the Cell-in-a-Box® encapsulation technology and its Associated Technologies.

The Binding Term Sheet Amendments further provide that the royalty payments on gross sales as specified in the SG Austria APA, the Cannabis License Agreement and the Diabetes License Agreement will be changed to 4%. They also provide that the royalty payments on amounts received by the Company from sublicensees' gross sales under the same agreements will be changed to 20% of the amount received by the Company's sublicensees, provided, however, that in the event the amounts received by the Company from sublicensees is 4% or less of sublicensees' gross sales, Austrianova or SG Austria (as the case may be) will receive 50% of what the Company receives up to 2%. In addition, Austrianova or SG Austria (as the case may be) will receive 20% of any amount the Company receives over a 4% royalty payment from sublicensees.

The Binding Term Sheet Amendments also provide that Austrianova will receive 50% of any other financial and non-financial consideration received from the Company's sublicensees of the Cell-in-a-Box® technology.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiaries. The Company operates independently and through four wholly-owned subsidiaries: (i) Bio Blue Bird; (ii) PharmaCyte Biotech Europe Limited; (iii) PharmaCyte Biotech Australia Pty. Ltd.; and (iv) Viridis Biotech, Inc. and are prepared in accordance with U.S. GAAP and the rules and regulations of the Commission. Intercompany balances and transactions are eliminated. The Company's 14.5% investment in SG Austria is presented on the cost method of accounting.

Use of Estimates

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. On an ongoing basis, the Company evaluates these estimates including those related to fair values of financial instruments, intangible assets, fair value of stock-based awards, income taxes and contingent liabilities, among others. 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.

Intangible Assets

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

The Company's intangible assets are licensing agreements related to the Cell-in-a-Box® technology for $1,549,427 and diabetes license for $2,000,000 for an aggregate total of $3,549,427.

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

The Company concluded that there was no impairment of the carrying value of the intangibles for the years ended April 30, 2019 and 2018.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be fully recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. No impairment was identified or recorded during the years ended April 30, 2019 and 2018.

Fair Value of Financial Instruments

For certain of the Company's non-derivative financial instruments, including cash, accounts payable and accrued expenses, the carrying amount approximates fair value due to the short-term maturities of these 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 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. 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, that 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.

The Company adopted ASC subtopic 820-10, Fair Value Measurements and Disclosures and ASC subtopic 825-10, Financial Instruments, which permit entities to choose to measure many financial instruments and certain other items at fair value. The carrying value of cash, accounts payable and accrued expenses, as reflected in the consolidated balance sheets, approximate fair value because of the short-term maturity of these instruments.

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 authority 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 December 22, 2017, the U.S. enacted the Tax Act which made significant changes to U.S. federal income tax law affecting the Company. Set forth below is a discussion of certain provisions of the Tax Act and the Company's assessment of the impact of such provisions on its financial statements.

Effective January 1, 2018, the Company's U.S. income has been taxed at a 21% (subject to IRC Section 15 blended rate provisions) down from the 35 % federal corporate rate. ASC 740-10-25-47 requires the Company to recognize the effect of this rate change on its deferred tax assets and liabilities in the period the tax rate change was enacted. As a result, the Company concluded this caused the Company's net deferred taxes to be remeasured at the new lower tax rate. The Company maintains a full valuation allowance on its U.S. net deferred tax assets. Deferred tax asset remeasurement (tax expense) was offset by a net decrease in valuation allowance, that resulted in no impact on the Company's income tax expense.

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, that are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in the Company's product candidates is expensed as incurred until technological feasibility has been established.

R&D costs for the years ended April 30, 2019 and 2018 were $460,052 and $1,997,811, respectively.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for only those awards ultimately expected to vest on a straight-line basis over the requisite service period of the award. The Company estimates the fair value of stock options using a Black-Scholes-Merton valuation model. This model requires the input of highly subjective assumptions, including the option's expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. Thus, if factors change and the Company uses different assumptions, the stock-based compensation expense could be materially different in the future.

Concentration of Credit Risk

The Company has no significant off-balance-sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains most of its cash balance at a financial institution located in California. Accounts at this institution are insured by the Federal Deposit Insurance Corporation up to $250,000. Uninsured balances aggregated approximately $127,000 and $772,000 at April 30, 2019 and 2018, respectively. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash.

Foreign Currency Translation

The Company translates the financial statements of its foreign subsidiary 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. Gains and losses on short-term intercompany foreign currency transactions are recognized as incurred.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern; however, the following conditions raise substantial doubt about the Company's ability to do so. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern. As of April 30, 2019, the Company has an accumulated deficit of $100,031,371 and incurred a net loss for year ended April 30, 2019 of $4,067,228. The Company requires substantial additional capital to finance its planned business operations and expects to incur operating losses in future periods due to the expenses related to the Company's core businesses. The Company has not realized any revenue since it commenced doing business in the biotechnology sector, and there can be no assurance that it will be successful in generating revenues in the future in this sector.

Over the past year, funding was provided by investors to maintain and expand the Company. Sales of the Company's common stock were made under the Second S-3 allowing for offerings of up to $50 million dollars in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act or transactions structured as a public offering of a distinct block or blocks of the shares of the Company's common stock. Over the past year, the Company continued to acquire funds through the Company's Second S-3 pursuant to which the placement agent sells shares of common stock "at-the-market" in a program which is structured to provide up to $25 million to the Company less certain commissions pursuant to the Second S-3. From May 1, 2018 through April 30, 2019 the Company raised capital of approximately $2.5 million in Block Trade transactions. Subsequent to year end, the Company raised additional capital in the amount of $600,000 from Block Trades. The Company plans to continue selling securities under the Second S-3 and has commitments for $3 million, which the Company expects to receive in the next twelve months. Additionally, the Company has the ability to reduce consulting expenses and the research and development expenses significantly should the funding be delayed.

Management determined that these plans alleviate substantial doubt about the Company's ability to continue as a going concern. The Company believes the cash on hand at April 30, 2019, the ability to use the Second S-3 to raise capital through at-the-market sales and Block Trades, assuming it remains eligible to do so, sales of registered and unregistered shares of its common stock and any public offerings of common stock in which the Company may engage in will provide sufficient capital to meet the Company's capital requirements and to fund the Company's operations through July 31, 2020.

Recent Accounting Pronouncements

ASU No. 2016-02, *Leases (Topic 842): Amendments to the Financial Accounting Standards Board Accounting Standards Codification*("ASU 2016-02") was issued in February 2016. Under ASU 2016-02, lessees will need to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). For income statement purposes, a dual model was retained, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). ASU 2016-02 becomes effective for the Company in the first quarter of fiscal year-end April 30, 2020. The Company plans to adopt this standard using the optional transition method provided for under ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), which will allow us to apply the standard as of May 1, 2019, rather than as of the earliest period presented. The Company plans to elect the package of practical expedients within ASC Topic 842, which, among other things, will allow the Company to carry forward historical lease classification. The Company also plans to elect the practical expedient that will allow it to exclude leases with a term of twelve months or less from the Company's balance sheet. The Company estimates that the adoption of ASU 2016-02 will not materially impact the Company's consolidated balance sheet as of May 1, 2019.

The amendments in the Accounting Standards Update ("ASU") 2018-02 ASC Topic 220: *Income Statement – Reporting Comprehensive Income* provide financial statement preparers with an option to reclassify stranded tax effects within Accumulated Other Comprehensive Income to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or portion thereof) is recorded. The amendments in ASC Topic 220 are effective for public business entities for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. While early application is permitted, including adoption in an interim period, the Company has not elected to early adopt. The adoption of this update is not expected to have a significant effect on the Company's consolidated financial position or results of operations.

The Company does not anticipate any material impact on its consolidated financial statements upon the adoption of the following accounting pronouncements issued during 2018 and 2019: (i) ASU 2018-19, *ASC Topic 326: Codification Improvements to Financial Instruments,*(ii) ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.*

NOTE 3 – ACCRUED EXPENSES

Accrued expenses at April 30, 2019 and 2018 are summarized below:

	2019	2018
Payroll related costs	$ 358,616	$ 283,904
Share issuance compensation	240,015	–
Other	22,335	7,643
Total	$ 620,966	$ 291,547

NOTE 4 – COMMON STOCK TRANSACTIONS

A summary of the Company's non-vested restricted stock activity and related weighted average grant date fair value information for the years ended April 30, 2019 and 2018 are as follows:

During the year ended April 30, 2018, the Company issued 1,750,000 shares of common stock to four directors of the Company's Board pursuant to Board compensation agreements. The terms of the agreements are for twelve months. The shares vested upon issuance and the Company recorded a non-cash expense of $24,165 and $75,985 for the years ended April 30, 2019 and 2018, respectively.

During the year ended April 30, 2018, the Company issued 4,200,000 shares of common stock to three consultants. The terms of two of the agreements are for twelve months and one agreement is for eighteen months. The shares vest monthly over a twelve-month to eighteen-month period and are subject to the consultants providing services under the agreements. The Company recorded a non-cash consulting expense in the amount of $73,800 and $209,730 for the years ended April 30, 2019 and 2018, respectively. There were zero and 1,200,000 unvested shares as of April 30, 2019 and 2018, respectively.

The Company awarded 6,600,000 shares of common stock to officers as part of their compensation agreements for 2018. These shares vest monthly over a twelve-month period and are subject to them continuing service under the agreements. During the years ended April 30, 2019 and 2018, the Company recorded a non-cash compensation expense in the amount of $245,520 and $122,760. There were zero and 4,400,000 unvested shares as of April 30, 2019 and 2018, respectively.

During the year ended April 30, 2019, the four independent directors of the Company's Board pursuant to Board compensation agreements were entitled to 2,000,000 shares of common stock. The terms of the agreements are for twelve months. The shares vest on the directors' anniversary date of their agreements. The Company recorded a non-cash expense of $101,288 for the year ended April 30, 2019.

During the year ended April 30, 2019, the Company issued 4,450,000 shares of common stock to four consultants. The terms of the agreements are for twelve months. The shares vest monthly over a twelve-month period and are subject to the consultants providing services under the agreements. The Company recorded a non-cash consulting expense in the amount of $230,829 for the year ended April 30, 2019. There were 408,333 unvested shares as of April 30, 2019.

During the year ended April 30, 2019, two consultants pursuant to their compensation agreements earned 2,500,000 shares of common stock. The terms of the agreements are for twelve months which covered prior and current years. The shares vest monthly over a twelve-month period and are subject to the consultants providing services under the agreements. The Company recorded a non-cash consulting expense in the amount of $138,728 for the year ended April 30, 2019. These shares remained unissued as of April 30, 2019.

The Company awarded 6,600,000 shares of common stock to officers as part of their compensation agreements for 2019. These shares vest monthly over a twelve-month period and are subject to them continuing service under the agreements. During the year ended April 30, 2019, the Company recorded a non-cash compensation expense in the amount of $47,809. There were 4,400,000 unvested shares as of April 30, 2019.

All shares were issued without registration under the Securities Act in reliance upon the exemption afforded by Section 4(a)(2) of the Securities Act.

On September 28, 2017, the Second S-3 was declared effective by the Commission for a public offering of up to $50 million on a "shelf offering" basis. During the years ended April 30, 2019 and 2018, the Company sold and issued approximately 161.7 and 95.7 million shares of common stock, respectively, at prices ranging from $0.01 to $0.08 per share. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately $2.3 and $2.7 million from the sale of these shares for the years ended April 30, 2019 and 2018, respectively. The Company has filed a prospectus supplement for an "at-the-market" offering with an investment bank as sales agent.

A summary of the Company's non-vested restricted stock activity and related weighted average grant date fair value information for the last three years ended April 30, 2019 are as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, at April 30, 2017	4,400,000	$ 0.10
Granted	12,550,000	0.08
Vested	(11,350,000)	0.07
Forfeited	–	–
Non-vested, at April 30, 2018	5,600,000	0.06
Granted	11,050,000	0.05
Vested	(12,050,000)	0.06
Forfeited	–	–
Non-vested, at April 30, 2019	4,600,000	$ 0.05

NOTE 5 – STOCK OPTIONS AND WARRANTS

Stock Options

As of April 30, 2019, the Company had 107,450,000 outstanding stock options to its directors and officers (collectively, "Employee Options") and consultants ("Non-Employee Options").

During the years ended April 30, 2019 and 2018, the Company granted 11,000,000 and 10,750,000 Employee Options, respectively.

The fair value of the Employee Options at the date of grant was estimated using the Black-Scholes-Merton option-pricing model, based on the following weighted average assumptions:

	Years Ended April 30,	
	2019	**2018**
Risk-free interest rate	2.0%	2.0%
Expected volatility	97%	108%
Expected lives (years)	2.7	3.0
Expected dividend yield	0.00%	0.00%

The Company's computation of expected volatility is based on the historical daily volatility of its publicly traded stock. For stock option grants issued during years ended April 30, 2019 and 2018, 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 five years with the average vesting term of two and one-half years for an average of three years. The dividend yield assumption of zero is based upon the fact the Company has never paid cash dividends and presently has no intention of paying cash dividends. The risk-free interest rate used for each grant is equal to the U.S. Treasury rates in effect at the time of the grant for instruments with a similar expected life.

During the years ended April 30, 2019 and 2018, the Company granted Non-Employee Options of 1,200,000 and 5,400,000, respectively.

The fair value of the Non-Employee Options was estimated using the Black-Scholes-Merton option-pricing model, based on the following weighted average assumptions:

	Years Ended April 30,	
	2019	**2018**
Risk-free interest rate	2.5%	2.5%
Expected volatility	98%	102%
Expected lives (years)	5.0	5.0
Expected dividend yield	0.00%	0.00%

Non-Employee Option grants that do not vest immediately upon grant are recorded as an expense over the vesting period. Effective August 1, 2018 the Company adopted ASU 2018-07 early using the modified retrospective transition approach. The Company determined there was no transition adjustment upon adoption of ASU 2018-07. The Company issued 1,200,000 stock options to a non-employee during the year ended April 30, 2019. The value of these options was determined as of the grant date using the Black-Scholes-Merton option-pricing model and compensation expense is being recognized over the service period.

A summary of the Company's stock option activity and related information for the two years ended April 30, 2019 are shown below:

	Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value per Share
Outstanding, April 30, 2017	79,100,000	$ 0.13	$ 0.09
Issued	16,150,000	0.06	0.06
Forfeited	–	–	–
Exercised	–	–	–
Outstanding, April 30, 2018	95,250,000	0.11	0.11
Issued	12,200,000	0.05	0.05
Forfeited	–	–	–
Exercised	–	–	–
Outstanding, April 30, 2019	107,450,000	$ 0.11	$ 0.11
Exercisable, April 30, 2019	101,250,000	$ 0.11	$ –
Vested and expected to vest	107,450,000	$ 0.11	$ –

A summary of the activity for unvested stock options during the years ended April 30, 2019 and 2018 is as follows:

	Options	Weighted Average Grant Date Fair Value per Share
Non-vested, April 30, 2017	6,800,000	$ –
Granted	16,150,000	0.06
Vested	(15,750,000)	–
Forfeited	–	–
Non-vested, April 30, 2018	7,200,000	–
Granted	12,200,000	0.05
Vested	(13,200,000)	–
Forfeited	–	–
Non-vested, April 30, 2019	6,200,000	$ 0.05

The Company recorded $320,178 and $741,476 of stock-based compensation related to the issuance of Employee Options to certain officers and directors in exchange for services during the years ended April 30, 2019 and 2018, respectively. At April 30, 2019, there remained approximately $226,195 of unrecognized compensation expense related to unvested Employee Options granted to officers and directors, to be recognized as expense over a weighted-average period of the remaining eight months in the calendar year. The non-vested options vest at 750,000 shares per month and are expected to be fully vested on December 31, 2019.

The Company recorded $92,171 and $203,602 of stock-based compensation related to the issuance of Non-Employee Options in exchange for services during the years ended April 30, 2019 and 2018, respectively. The non-vested Non-Employee Options vest at 100,000 shares per month and are expected to be fully vested on June 30, 2019.

The following table summarizes ranges of outstanding stock options by exercise price at April 30, 2019:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (years) of Outstanding Options	Weighted Average Exercisable Price	Number of Options Exercisable	Weighted Average Exercise Price of Exercisable Options
$ 0.190	25,000,000	0.21	$ 0.190	25,000,000	$ 0.190
$ 0.110	27,200,000	0.35	$ 0.110	27,200,000	$ 0.110
$ 0.184	250,000	0.49	$ 0.184	250,000	$ 0.184
$ 0.063	15,600,000	1.00	$ 0.063	15,600,000	$ 0.063
$ 0.104	10,450,000	1.84	$ 0.104	10,450,000	$ 0.104
$ 0.0685	600,000	2.00	$ 0.0685	600,000	$ 0.0685
$ 0.058	2,450,000	2.37	$ 0.058	2,450,000	$ 0.058
$ 0.0734	1,200,000	3.01	$ 0.0734	1,200,000	$ 0.0734
$ 0.0729	1,800,000	3.20	$ 0.0729	1,800,000	$ 0.0729
$ 0.089	1,200,000	3.22	$ 0.089	1,200,000	$ 0.089
$ 0.0553	500,000	1.72	$ 0.0553	500,000	$ 0.0553
$ 0.0558	9,000,000	2.21	$ 0.0558	9,000,000	$ 0.0558
$ 0.0534	1,200,000	4.35	$ 0.0534	1,000,000	$ 0.0534
$ 0.0539	1,000,000	2.00	$ 0.0539	1,000,000	$ 0.0539
$ 0.0683	500,000	2.09	$ 0.0683	500,000	$ 0.0683
$ 0.0649	500,000	2.22	$ 0.0649	500,000	$ 0.0649
$ 0.0495	9,000,000	2.94	$ 0.0495	3,000,000	$ 0.0495
Total	107,450,000	1.17	$ 0.11	101,250,000	$ 0.11

The aggregate intrinsic value of outstanding options as of April 30, 2019 was zero. This represents options whose exercise price was less than the closing fair market value of the Company's common stock on April 30, 2019 of approximately $0.041 per share.

Warrants

The warrants issued by the Company are equity-classified. The fair value of the warrants was recorded as additional paid-in-capital, and no further adjustments are made.

For stock warrants paid in consideration of services rendered by non-employees, the Company recognizes consulting expense in accordance with the requirements of ASC 505.

During the year ended April 30, 2013, the Company entered into numerous "Private Placement" agreements whereby investors, in exchange for their investment, received restricted common stock of the Company and three classes of warrants, all with five-year terms: (i) Class A with an exercise price of $0.075; (ii) Class B with an exercise price of $0.12; and (iii) Class C with an exercise price of $0.18. For each Class of warrant, there were 19,811,200 warrant shares issued.

In January 2014, the Company implemented a "Warrant Conversion Program" ("Program") pertaining to all Class A warrants. The Program consisted of offering each holder of Class A warrants the ability to exercise all their Class A warrants into shares of common stock and to also receive an equal number of new Class D warrants, with an exercise price of $0.25 per warrant share. The Program resulted in 18,755,200 Class A warrants being converted into restricted common stock and the issuance of the same number of Class D warrants to those who participated in the Program.

Also, during the year ended April 30, 2014 four of the Private Placement investors exercised 2,318,000 warrant shares of their Class B warrants into an equal number of shares of restricted common stock.

During the year ended April 30, 2018 all remaining original Private Placement warrants expired: (i) Class A, 1,056,000 warrant shares: (ii) Class B, 17,493,200 warrant shares; (iii) Class C, 18,755,200 warrant shares. All 18,755,200 Class D Warrants expired on December 31, 2016.

Effective May 24, 2017, the Company issued a Common Stock purchase warrant to Chardan for a Block Trade. The Company issued a warrant to purchase 833,333 shares based upon a Block Trade pursuant to the amended engagement agreement dated March 21, 2017 with Chardan. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of $0.03 per share. Using the Black-Scholes-Merton warrant pricing model, the Company determined the aggregate value of these warrants to be approximately $20,000. The warrants have a cashless exercise feature.

Effective July 26, 2017, the Company issued a Common Stock purchase warrant to Chardan for a Block Trade. The Company issued a warrant to purchase 2,000,000 shares based upon a Block Trade pursuant to the amended engagement agreement dated March 21, 2017 with Chardan. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.03 per share. Using the Black-Scholes-Merton warrant pricing model, the Company determined the aggregate value of these warrants to be approximately $39,000. The warrants have a cashless exercise feature.

Effective February 27, 2018, the Company issued a Common Stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,666,667 shares based upon a Block Trade pursuant to the engagement agreement dated February 22, 2018 with Aeon. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of $0.03 per share. Using the Black-Scholes-Merton warrant pricing model, the Company determined the aggregate value of these warrants to be approximately $37,000. The warrants have a cashless exercise feature.

Effective May 30, 2018, the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,388,889 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.02 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $19,000. The warrants have a cashless exercise feature.

Effective June 28, 2018, the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,923,077 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.03 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $38,000. The warrants have a cashless exercise feature.

Effective November 1, 2018, the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 2,272,727 shares of common stock based upon a Block Trade pursuant to the engagement agreement with the Company's placement agent dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $19,000. The warrants have a cashless exercise feature.

Effective March 26, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,250,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $9,000. The warrants have a cashless exercise feature.

Effective March 26, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,250,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $9,000. The warrants have a cashless exercise feature.

A summary of the Company's warrant activity and related information for the two years ended April 30, 2019 are shown below:

	Warrants	Weighted Average Exercise Price
Outstanding, April 30, 2017	67,853,504	$ 0.13
Issued	4,500,000	–
Expired	(38,360,400)	–
Outstanding, April 30, 2018	33,993,104	0.10
Issued	5,084,693	–
Expired	–	–
Outstanding, April 30, 2019	42,077,797	–
Exercisable, April 30, 2019	42,077,797	$ 0.09

The following table summarizes additional information concerning warrants outstanding and exercisable at April 30, 2019:

Exercise Prices	Number of Warrant Shares Exercisable at April 30, 2019	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.12	17,854,308	1.63	
$0.11	10,000,000	0.90	
$0.065	769,231	2.64	
$0.0575	869,565	2.93	
$0.03	2,500,000	3.58	
$0.026	1,923,077	4.16	
$0.025	2,000,000	3.24	
$0.018	1,388,889	4.08	
$0.011	2,272,727	4.51	
$0.01	2,500,000	4.91	
	42,077,797	2.16	$ 0.09

NOTE 6 – LEGAL PROCEEDINGS

The Company is not currently a party to any pending legal proceedings, material or otherwise. There are no legal proceedings to which any property of the Company is subject.

NOTE 7 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the years ended April 30, 2019 and 2018, respectively.

The Company owns 14.5% of the equity in SG Austria and is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand. The Company purchased products and services from these subsidiaries in the approximate amounts of $168,000 and $1,389,000 in the years ended April 30, 2019 and 2018, 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 and diabetes (Prof. Gunzburg 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 incurred for the years ended April 30, 2019 and 2018 were approximately $18,000 and $35,000, respectively. In addition, during the year ended April 30, 2019 the Company issued 2 million common shares to Prof. Günzburg and 500,000 common shares to Dr. Salmons. The Company recorded a noncash consulting expense of approximately $140,000 relating to these share issuances for the year ended April 30, 2019.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company acquires assets still in development and enters research and development 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 life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the license agreements, the Company may have to make royalty payments based upon a percentage of the sales of the pharmaceutical products if regulatory approval for marketing is obtained.

Office Lease

Effective September 1, 2016, the Company entered into a lease for its Leased Premises in California. The term of the lease is for 12 months. In May 2017, the Company entered into an additional two-year lease for the Leased Premises, commencing upon the expiration of the term of the first lease. The term of the new lease expires on August 31, 2019.

On May 29, 2019, the Company entered into an additional twelve-month lease of the Leased Premises, commencing on September 1, 2019. The term of the new lease expires on August 31, 2020.

Rent expenses for these offices for the years ended April 30, 2019 and 2018 were $34,153 and $33,879, respectively.

The following table summarizes the Company's aggregate future minimum lease payments required under the operating lease as of.

Years Ending April 30,	Amount
2020	$ 29,988
2021	9,480
	$ 39,468

Material Agreements

The Company's material agreements are identified and summarized in Note 1 – Nature of Business – Company Background and Material Agreements.

Compensation Agreements

The Company entered into executive compensation agreements with its three executive officers in March 2015, each of which was amended in December 2015. Each amendment has a term of two years with annual extensions thereafter unless the Company or the officer provides written notification of termination at least ninety days prior to the end of the term or subsequent extensions. The Company also entered a compensation agreement with a Board member in April 2015 which continues in effect until the member is no longer on the Board.

In March 2017, the Company amended the executive compensation agreements. The term for each agreement is two years from an effective date of January 1, 2017. At the same time, the Company amended the compensation agreement with the Board member referenced above. It continues in effect until the member is no longer on the Board.

In March 2019, the Company amended the executive compensation agreements to extend the term for one year with an effective date of January 1, 2019. Except for the term being extended for one more year, all other terms of the executive compensation agreements remain the same.

The Company has four independent directors. Each director receives the same compensation: (i) $12,500 in cash for each calendar quarter of service on the Board; (ii) 500,000 fully-paid, non-assessable shares of the Company's restricted common stock ("Shares") annually; and (iii) a five-year option to purchase 500,000 Shares annually at an exercise price equal to the fair market value of the Shares on the date of grant. The Shares and the option Shares fully vest on the date of the grants.

The Company's Chief Medical Officer ("CMO") receives: (i) $10,000 in cash for each calendar month of service as the Company's CMO; (ii) 1,200,000 Shares annually; and (iii) a five-year option to purchase 1,200,000 Shares at an exercise price equal to the fair market value of the Shares on the date of the grant. The Shares and the Option Shares each vest in the amount of 100,000 Shares per month. The Company will indemnify the CMO for her work as the Company's CMO.

NOTE 9 - INCOME TAXES

At April 30, 2019, the Company had federal and state net operating loss carryforwards of approximately $42,396,000 and $43,989,000, respectively, available to offset against future taxable income; these operating loss carryforwards expire in 2019 through 2038.

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,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 11,849,290	11,038,315
Stock compensation	2,233,230	2,117,840
Other	105,251	79,446
Total deferred tax assets	14,187,771	13,235,601
Net deferred tax assets		
Valuation allowance	(14,187,771)	(13,235,601)
	$ –	$ –

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, 2019 and 2018 were increases of $952,170 and $1,714,306, 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,	
	2019	2018
Federal benefit at statutory rate	$ (854,118)	(2,321,806)
State income taxes, net of Federal taxes	(274,538)	(398,121)
Permanent differences	170,032	286,005
Tax rate change	–	887,749
Provision related to change in valuation allowance	952,170	1,714,305
Stock compensation	–	(20,393)
Other, net	6,454	(147,739)
	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended April 30, 2019.

The Company files its income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2019, the tax returns for 2013 through 2018 remain open to examination by the Internal Revenue Service and various state tax authorities.

The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of the years ended April 30, 2019 and 2018, the Company had accrued no interest or penalties related to uncertain tax positions.

NOTE 10 – EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing earnings available to common stockholders by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares and potentially dilutive common shares outstanding during the period increased to include the number of additional shares of common stock that would be outstanding if the potentially dilutive securities had been issued. Potential common shares outstanding principally include stock options and warrants. During the years ended April 30, 2019 and 2018, the Company incurred losses. Accordingly, the effect of any common stock equivalent would be anti-dilutive during those periods and are not included in the calculation of diluted weighted average number of shares outstanding.

The table below sets forth the basic loss per share calculations:

	Years Ended April 30,	
	2019	**2018**
Net loss	$ (4,067,228)	$ (6,828,841)
Basic weighted average number of shares outstanding	1,100,104,338	968,641,686
Diluted weighted average number of shares outstanding	1,100,104,338	968,641,686
Basic and diluted loss per share	$ (0.00)	$ (0.01)

The table below sets forth these potentially dilutive securities:

	Years Ended April 30,	
	2019	**2018**
Excluded options	107,450,000	95,250,000
Excluded warrants	42,077,797	33,993,104
Total excluded options and warrants	149,527,797	129,243,104

NOTE 11 – PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, with a par value of $0.0001, of which 13,500 shares have been designated as "Series E Convertible Preferred Stock." There are no outstanding shares of preferred stock or Series E Convertible Preferred Stock. The Series E Convertible Preferred Stock have the following features:

- The holders of Series E Convertible Preferred Stock are entitled to receive cash out of the assets of the Company before any amount is paid to the holders of any capital stock of the Company of any class junior in rank to the shares of Series E Convertible Preferred Stock;
- Each share of Series E Convertible Preferred Stock is convertible, at the holder's option, into shares of common stock at the average closing bid price of the common stock for five trading days prior to the conversion date; and
- At every meeting of stockholders every holder of shares of Series E Convertible Preferred Stock is entitled to 50,000 votes for each share of Series E Convertible Preferred Stock with the same and identical voting rights as a holder of a share of common stock.

NOTE 12 – SUBSEQUENT EVENTS

On May 29, 2019, the Company entered into a twelve-month office lease extension commencing on September 1, 2019. The lease extension is for the office where the Company is currently located in Laguna Hills, California. The term of the new lease expires on August 31, 2020 and requires monthly lease payments of approximately $2,400.

From May 1, 2019 through August 12, 2019, the Company sold 136,666,667 shares of common stock using the Second S-3 structured as a Block Trade. The issuance of these shares resulted in gross proceeds to the Company of approximately $950,000. Pursuant to the Aeon Agreement, the Company is required to pay Aeon a fee of 7%, $66,500 and provide warrant coverage of 5% of the number of shares of commons stock sold in the Block Trade with a five-year term for approximately 6,833,333 warrant shares.

PHARMACYTE BIOTECH, INC.
SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS
Years Ended April 30, 2019 and 2018

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Charged to Other Accounts	Deductions	Balance at End of Year
Reserve Deducted in the Balance Sheets from the Asset to which it applies:					
Allowance for Deferred Tax Assets					
Year ended April 30, 2019	$ 13,235,601	–	952,170	–	14,187,771
Year ended April 30, 2018	$ 11,521,295	–	1,714,306	–	13,235,601

EXHIBIT 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Organization
Bio Blue Bird AG	Lichtenstein
Viridis Biotech, Inc.	Nevada
PharmaCyte Biotech Australia Pty. Ltd.	Australia
PharmaCyte Biotech Europe Limited	Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Annual Report on Form 10-K of PharmaCyte Biotech, Inc. and subsidiaries for the year ended April 30, 2019 of our report dated August 12, 2019 included in its Registration Statements on Form S-3 (No. 333-220441) relating to the consolidated financial statements and consolidated financial statement schedules for the two years ended April 30, 2019 listed in the accompanying index.

/s/Armanino LLP

Armanino LLP
San Jose, California

August 12, 2019

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, 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, 2019;

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 12, 2019

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
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, 2019;

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 12, 2019

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, 2019 as filed with the Securities and Exchange Commission on the date hereof ("Report"), the undersigned, Kenneth L. Waggoner, 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 12, 2019

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
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 SEC 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 SEC.

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, 2019 as filed with the Securities and Exchange 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 12, 2019

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 SEC 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 SEC.