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, 2016

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.)

12510 Prosperity Drive, Suite 310, Silver Spring, MD 20904
(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
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer (Do not check if a smaller reporting company)	☐	Smaller reporting company	☐

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, 2015: $76,511,294.

As of July 29, 2016, the registrant had 848,054,665 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K ("Report") includes "forward-looking statements" within the meaning of the federal securities laws. 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 the 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" below and for the reasons described elsewhere in this Report, among others, our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; 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; and the difficulties and expenses associated with obtaining and maintaining regulatory approval of 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 treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." Our unique Cell-in-a-Box® technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer, and diabetes will be developed.

We are developing therapies for pancreatic and other solid cancerous tumors involving the encapsulation of live cells placed in the body to enable the delivery of cancer-killing drugs at the source of the cancer. We are also developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes based upon the encapsulation of a human 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® technology. In addition, we are examining ways to exploit the benefits of the Cell-in-a-Box® technology to develop therapies for cancer based upon the constituents of the Cannabis plant, known as "cannabinoids."

Cancer Therapy

Targeted Chemotherapy

We are using the Cell-in-a-Box® technology to develop a therapy for solid cancerous tumors through targeted chemotherapy. For example, for pancreatic cancer we encapsulate 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 tumor. The cancer prodrug ifosfamide will then be given intravenously at one-third the normal dose. In this way, the ifosfamide will be converted at the site of the tumor instead of in the liver where it is normally converted. We believe 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 we believe will result in little to no collateral damage to other organs in the body. In an earlier Phase 1/2 clinical trial which used ifosfamide at one-third the normal dose with the Cell-in-a-Box® technology, this targeted chemotherapy not only reduced the tumor size but also generally resulted in no obvious adverse side effects attributed to this therapy.

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 a generalized graphic depiction of the principal mechanisms of our proposed treatment for pancreatic cancer using our product candidates, Cell-in-a-Box® encapsulated cells plus low-dose ifosfamide, under expected conditions. These product candidates 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 Cell-in-a-Box®, the related encapsulated cells, or the Cell-in-a-Box® and encapsulated cells plus low-dose ifosfamide combination.

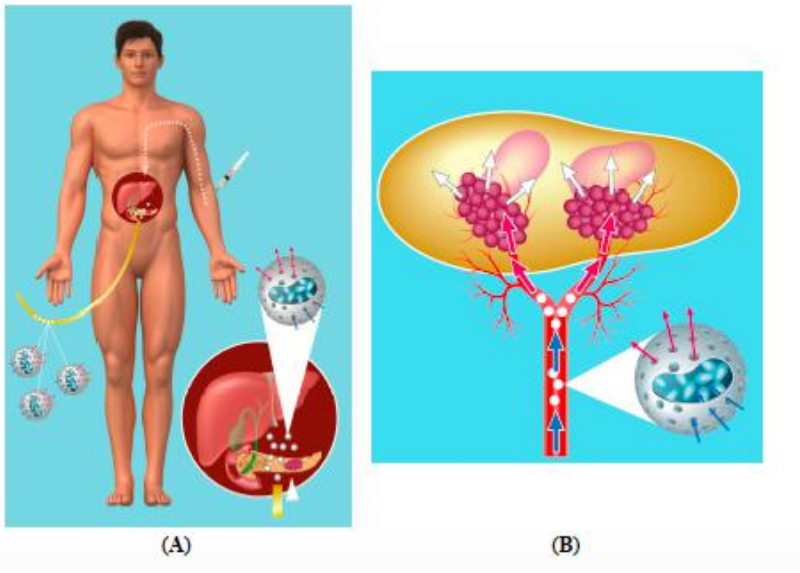

Chart (A)

Capsules containing live ifosfamide-activating cells (shown in white) are implanted in the blood vessels leading to the pancreatic tumors. 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

Pancreatic Cancer

Pancreatic cancer is an aggressive cancer with a poor prognosis. It is the third leading cause of cancer-related deaths in the United States ("U.S.") and the seventh leading cause of cancer-related deaths globally. It has been predicted that this cancer will become the second leading cause of cancer deaths by 2020. The five-year survival rate is 8%, reportedly the lowest survival rate of any cancer. It is expected that in 2016 there will be approximately 53,000 new cases diagnosed in the U.S. and approximately 90,000 new cases diagnosed in Europe. Unfortunately, about 71% of patients will die within the first year of diagnosis. More than 90% will die within two years of diagnosis. Patients have a three and one-half month median life expectance after diagnosis without treatment.

The problem is that patients with pancreatic cancer are not normally diagnosed until the cancer is advanced and inoperable. There is no cure unless the cancer is surgically removed in its earliest stages. Since the first drug (gemcitabine) was approved in the U.S. for pancreatic cancer in 1996, approximately 40 Phase 3 clinical trials have been conducted in an attempt to improve upon the anticancer activity of gemcitabine. Despite these efforts, little improvement in median survival time and percentage of one-year survivors has occurred since 1996. Most of the limited success achieved has been seen when gemcitabine is given in combination with another cancer chemotherapy drug.

The current standard of care for advanced pancreatic cancer is the combination of Abraxane® (nab-paclitaxel) plus gemcitabine. This combination was approved by the U.S. Food and Drug Administration ("FDA") in September 2013. This combination increased the median survival time by 1.8 months, as compared to gemcitabine alone. It increased the one-year survival time from 22% with gemcitabine alone to 38% with Abraxane® plus gemcitabine. There are severe side effects from this combination chemotherapy.

Our Pancreatic Cancer Therapy

We are developing a therapy for pancreatic cancer to address a critical unmet medical need. This need exists for patients with advanced pancreatic cancer whose tumors are locally advanced, non-metastatic and inoperable but no longer respond to Abraxane® plus gemcitabine.

Although several therapies have been tried in this situation, the most commonly used is believed to be the combination of the cancer chemotherapy drug capecitabine plus radiation ("CRT"). However, the results of a Phase 3 clinical trial were recently reported in the Journal of the American Medical Association. This clinical trial addressed whether CRT is more effective than chemotherapy alone. In patients with locally advanced, inoperable pancreatic cancer whose tumors no longer responded to gemcitabine or gemcitabine plus erlotinib (standard initial therapies at the time the clinical trial was conducted) patients were treated with the same chemotherapy or with CRT. In both cases CRT was not meaningfully more effective than chemotherapy alone. Consequently, these patients have no known effective treatment alternative once their tumors no longer respond to this combination therapy.

Subject to FDA approval, we plan to commence a Phase 2b clinical trial later this year. The trial is designed to show that our Cell-in-a-Box® plus low-dose ifosfamide therapy can serve as an effective and safe consolidation chemotherapy for patients whose tumors no longer respond after four to six months of therapy with Abraxane® plus gemcitabine. The trial will take place in the U.S. with study sites in Europe. Translational Drug Development ("TD2") will conduct the trial in the U.S. Clinical Network Services ("CNS") will conduct the trial in Europe in alliance with TD2. TD2 will be responsible for clinical development plans, program analysis, medical writing, clinical management and database development.

The trial will be two-armed and randomized. Patients will be randomized equally into two treatment arms to receive our therapy or gemcitabine alone. Only patients whose tumors are locally advanced, inoperable and non-metastatic will be eligible to be enrolled. Patients must have been treated with Abraxane® plus gemcitabine for four to six months and their tumors must no longer respond to this therapy. Each patient who will receive our therapy will receive a single implantation of 300 Cell-in-a-Box® capsules plus multiple courses of low-dose ifosfamide until they receive no further benefit from this therapy. In two earlier clinical trials using our same therapy discussed below, only two courses of ifosfamide were given.

The primary endpoints, or outcomes being measured, of the trial are progression-free survival assessed after 26 and 52 weeks, as well as safety and tolerability of the comparative therapies. The secondary endpoints include: (i) overall survival at 14, 26 and 52 weeks; (ii) objective response rate at 14, 26 and 52 weeks as measured by CT and PET scans; (iii) assessment of a patient's tumor going from inoperable to operable after 14, 26 and 52 weeks; (iv) time to onset of pain and pain management after 14, 26 and 52 weeks; and (v) assessment of the patients' overall quality-of-life while undergoing our therapy.

Malignant Ascites Fluid Therapy

We are also developing a therapy to delay the production and accumulation of malignant ascites fluid that results from all abdominal tumors. Malignant ascites fluid is secreted by abdominal tumors 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. This fluid accumulates in the abdominal cavity, causing swelling of the abdomen, severe breathing difficulties and extreme pain.

Malignant ascites fluid must be surgically removed on a periodic basis. This is painful and costly. There is no available therapy that prevents or delays the production and accumulation of malignant ascites fluid. We have been involved in a series of preclinical studies at 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 from abdominal cancers. If successful, we plan to conduct a clinical trial in the U.S. with additional study sites in Europe. TD2 will conduct the trial in the U.S., and CNS will conduct the trial in Europe in alliance with TD2. We plan to start a clinical trial in 2017 if the results of our preclinical studies support the trial and we receive FDA approval to do so.

Diabetes Therapy

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") has estimated that 422 million people worldwide have the disease – 314 million more than in 1980. Approximately 8.5% of adults worldwide have diabetes. Approximately $920 billion is spent annually in the treatment of diabetes and related healthcare. Over 20% of healthcare dollars in the U.S. are estimated to be spent on care for people with diagnosed diabetes. Up to 29.1 million people in the U.S. have diabetes. Approximately $615 million was spent annually in treatment of diabetes alone. The worldwide market for diabetes treatments alone has been projected to reach $650 billion by 2020.

Diabetes

Diabetes is caused by insufficient availability of, or resistance to, insulin. Insulin is produced by the 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 (the body's insulin-producing cells) have been destroyed - usually by an autoimmune reaction. Type 1 diabetics require daily insulin administration through injection or through the use of an insulin pump. In Type 2 diabetes the body does not use insulin properly. This means the body has become resistant to insulin. Type 2 diabetes can generally be controlled by diet and exercise in its early stages. 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.

Efforts to Cure for Diabetes

In an effort 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 enrolled remained insulin-independent for one year. But because of the high doses of immune-suppressive drugs that must accompany such transplantations (to avoid rejection of the transplanted islet cells), patients were placed at high risk of infection and even cancer. 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 are associated with serious side effects that have required patients to cease treatment with them. In addition, patients who by necessity are given high doses of immunosuppressive drugs are open to opportunistic infections for as long as they are immunosuppressed. Worldwide, less than 1,000 people with Type 1 diabetes are known to have been transplanted with pancreatic islets from another human.

In an effort 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 resistant to approving the use of such interspecies transplantations. In addition, there are problems besides regulatory approval, the foremost of which is an attack by the body's immune system on the transplanted cells. To protect the non-human cells from attack by the immune system of the human being, they have been encapsulated using other forms of encapsulation technology than 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. In addition, the integrity of capsules composed of alginate has been shown to degrade over time. This then allows for immune system attack on the transplanted pig islets and necessitates additional transplantations. Moreover, 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. Such devices are placed in the body where they can be retrieved and replaced when 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 islets cells. Planar chambers are more stable, but they can cause extensive foreign body reactions in the host resulting in fibrotic overgrowth and thus transplant failure.

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 made their appearance in 1994 when a diabetic patient, already receiving immunosuppressive drugs, was transplanted with these cells encapsulated in alginate and remained insulin-independent for 9 months. However, 22 years and numerous clinical trials later, there are still no reports of long-term insulin-independence in non-immune-suppressed diabetic patients receiving encapsulated pancreatic islet transplants.

Our Bio-Artificial Pancreas for Diabetes

We plan to develop a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes that is unique among available therapies for this disease. We are 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.

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

Austrianova Singapore Pte Ltd ("Austrianova") has already successfully encapsulated live pig pancreatic islet insulin-producing cells using the Cell-in-a-Box® technology and then implanted these encapsulated cells in grossly diabetic rats. Soon after the capsules were implanted, the rats' blood glucose levels normalized and remained normal throughout the study period of approximately six months. No immune system suppressing drugs were needed. Thus, the preclinical proof of principle for a bio-artificial pancreas has already been established using Cell-in-a-Box® capsules containing pig pancreatic insulin-producing cells in a rat model of Type 1 diabetes.

Melligen cells can be readily grown in culture and hence are available in unlimited supply. Compared to native pancreatic beta islet cells, Melligen cells are much more resistant to the pro-inflammatory cytokines that have been shown to be involved in beta islet cell death. We believe that this property makes them the ideal candidate cell line for beta islet cell replacement therapy with the prospect to achieve long-term transplant graft function.

In June 2013, we acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® technology for the development of a treatment for diabetes and the use of Austrianova's Cell-in-a-Box® trademark and its associated technology ("Diabetes Licensing Agreement").

We believe that encapsulating the Melligen cells using the Cell-in-a-Box® technology has numerous advantages over encapsulation of cells with other materials, such as alginate. Since they are composed largely of cellulose (a bio-inert material in the human body), the Cell-in-a-Box® capsules are exceedingly robust. This allows them to remain intact for long periods of time in the body, all the while protecting the cells inside them from immune system attack. Moreover, in prior studies, these capsules and the cells inside them have not caused any immune or inflammatory responses like those seen with alginate-encapsulated cells.

We believe that the combination of the Melligen cells and the Cell-in-a-Box® encapsulation technology could lead to a break-through therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. Encapsulating the Melligen cells could enable us to overcome all of the past "problems" in developing a true bio-artificial pancreas.

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 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. Eva Maria Brandtner, Head of the Bioencapsulation Unit at VIVIT, leads the Consortium and is our Director of Diabetes Program Development. Dr. Brandtner, who provides consulting services to us through our agreement with her employer, previously served as the Chief Scientist with Austrianova. In that role she conducted preclinical studies with the Melligen cells.

Cannabis Therapy

With 25 states and the District of Columbia approving the use of marijuana for medical purposes as of June 2016, a plethora of medical marijuana companies have emerged. Most of these involve the production and distribution of *Cannabis* in its various forms, such as liquid extracts and pills, as well as *Cannabis* delivery systems - such as vapor pens. We are one of the few who are focused on using constituents of *Cannabis* for the treatment of specific diseases.

Our major competitors for the development of *Cannabis*-based treatments for cancer are Cannabis Science, Inc. ("CSI") and GW Pharmaceuticals, Plc. ("GWP"). CSI plans to use complex extracts of *Cannabis* to develop treatments for basal and squamous cell carcinomas and Kaposi's sarcoma. GWP is developing a product portfolio of cannabinoid-based prescription medicines.

In contrast to the work being done by these companies, we plan to use *Cannabis* to develop therapies for two of the deadliest forms of cancer – brain and pancreatic. We also plan to focus initially on developing specific therapies based on carefully chosen molecules rather than using complex *Cannabis* extracts. Targeted cannabinoid-based chemotherapy utilizing our Cell-in-a-Box® technology offers a "green" approach to treating solid-tumor malignancies.

Cannabis has provided a sustainable source of fiber, food, energy and medicine for thousands of years. The plant's constituents (cannabinoids), such as Δ^9-tetrahydrocannabinol and cannabidiol, have been well-documented to have broad anti-inflammatory, antioxidant, analgesic and nerve protecting abilities. However, they also inhibit or prevent the growth and spread of tumors or malignant cells. An understanding of the chemical and biochemical processes involved in the interaction of substances derived from *Cannabis* with live cell encapsulation provides the opportunity to develop "green" approaches to treating cancers, such as pancreatic, brain, breast and prostate, among others. We believe we are in a unique position among medical *Cannabis* and pharmaceutical companies to develop cannabinoid-based therapies utilizing our proprietary Cell-in-a-Box® live cell encapsulation technology as the platform.

In May 2014, we entered into a Research Agreement with the State of Colorado, acting on behalf of the Board of Trustees of the University of Northern Colorado. The goal of the ongoing research is to develop methods for the identification, separation and quantification of constitutes of *Cannabis* (some of which are prodrugs) that may be used in combination with our Cell-in-a-Box® technology to treat diseases. Initial studies have been undertaken using cannabinoid-like model compounds to identify the appropriate cell type that can convert the selected cannabinoid prodrugs into metabolites with antineoplastic activity. Once identified, the genetically modified cells that will produce the appropriate enzyme to convert that prodrug will be encapsulated using our 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 antineoplastic effectiveness.

In December 2014, we acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® 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 ("Cannabis Licensing Agreement").

The agreements identified above and their respective payment obligations are described in more detail below under the caption "—Patents, Intellectual Property and Trade Secrets—Patents and Intellectual Property Agreements" in this Item 1. "Business."

Background of Our Encapsulation Technology

The principal developers of the Cell-in-a-Box® cellulose-based live cell encapsulation technology are Prof. Dr. Walter H. Günzburg ("Dr. Günzburg") and Dr. Brian Salmons ("Dr. Salmons"). Both are officers of SG Austria Pte Ltd ("SG Austria") and its wholly-owned subsidiary, Austrianova. We own a 14.5% equity interest in SG Austria and have contractual relationships, including license agreements, with SG Austria and Austrianova. The success of SG Austria and Austrianova are co-dependent in almost every respect with our success. SG Austria and Austrianova benefit from our success. As we reach certain "milestones" in the progression of our encapsulation technology towards the development of treatments for cancer and diabetes, payments are owed by us to SG Austria or Austrianova.

Key Consultants

Dr. Günzburg and Dr. Salmons are involved in numerous aspects of our scientific endeavors relating to our cancer and diabetes therapies, having initially commenced work for us as consultants at the beginning of 2014 under an oral agreement. They currently 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 into a Consulting Agreement with Vin-de-Bona. The Consulting Agreement has 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 Dr. Günzburg and Dr. Salmons are charged at a negotiated and confidential hourly rate.

The Consulting Agreement requires that Dr. 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. In addition, during the term of the Consulting Agreement and for a period of twelve months after termination or expiration of the Consulting 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 with us.

In September 2014, Dr. Günzburg was appointed as our Chief Scientific Officer. Dr. Günzburg was compensated by paying Vin-de-Bona 500,000 shares of our common stock. The shares were valued at the date of issuance, resulting in a non-cash expense of $98,500. 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. Matthias Löhr, a noted European oncologist and gastroenterologist, will also participate in the development of our pancreatic cancer treatment. 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 (see below) of the combination of CapCell® (now known as and hereinafter referred to as "Cell-in-a-Box®") with low-dose ifosfamide in patients with advanced, inoperable pancreatic cancer. Like Dr. Günzburg and Dr. Salmons, Dr. Löhr is involved in planning and overseeing much of the Phase 2b clinical trial. Dr. Löhr is the Chairman of our Medical and Scientific Advisory Board ("Advisory Board") and a consultant to us. Dr. Löhr received 500,000 shares of our common stock to serve on the Advisory Board and will receive a like amount under a new Professional Services Agreement with us that became effective in May 2016. He also receives fees to provide professional consulting services to us through his consulting company based upon a confidential hourly rate.

The professional services Dr. Günzburg, Dr. Salmons and Dr. Löhr provide to us include work associated with our ongoing preclinical studies and the clinical trial we plan to conduct in the U.S. in 2017 involving malignant ascites, as well as our work in the cancer and diabetes arenas.

Our Business

PharmaCyte Biotech, Inc. is a Nevada corporation incorporated in 1996. In 2013, we restructured our operations in an effort to focus on biotechnology, having been a nutraceutical products company before then. The restructuring resulted in us focusing all of our efforts upon the development of 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 better reflect the nature of our business.

As discussed above, we are now a clinical stage biotechnology company focused on developing and preparing to commercialize therapies for cancer and diabetes using our proprietary cellulose-based live cell encapsulation technology known as Cell-in-a-Box®. This resulted from entering into several important agreements.

On May 26, 2011, we entered into an Asset Purchase Agreement ("SG Austria APA") with SG Austria to purchase 100% of the assets and liabilities of SG Austria. As a result, 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 into 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. In addition, we received nine bearer shares of Bio Blue Bird to reflect our 100% ownership of Bio Blue Bird. 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 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 into the Third Addendum, we and SG Austria entered into 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 for the development of treatments for cancer and use of Austrianova's Cell-in-a-Box® trademark and its associated technology.

Bio Blue Bird licensed certain types of genetically modified human cells ("Cells") from Bavarian Nordic A/S ("Bavarian Nordic") and GSF-Forschungszentrum für Umwelt u. Gesundheit GmbH (collectively, "Bavarian Nordic/GSF") pursuant to a License Agreement ("Bavarian Nordic/GSF License Agreement") to develop a therapy for cancer using encapsulated Cells. The licensed rights to the Cells pertain to the countries in which Bavarian Nordic/GSF obtained patent protection. Hence, facilitated by the acquisition of Bio Blue Bird, the Third Addendum provides us with an exclusive, worldwide license to use the Cell-in-a-Box® technology and trademark for the development of a therapy for cancer using the Cells.

In June 2013, we entered into the Diabetes License Agreement. We paid Austrianova $2.0 million to secure this license.

In October 2014, we entered into the Melligen Cell License Agreement. We are in the process of developing a therapy for diabetes by encapsulating the Melligen cells using the Cell-in-a-Box® technology.

In December 2014, we entered into the Cannabis Licensing Agreement. We paid Austrianova $2.0 million to secure this license. We are in the process of developing therapies for cancer and its symptoms through genetically engineered cells designed to activate cannabinoid molecules that have been encapsulated using the Cell-in-a-Box® technology.

In July 2016, we entered into a Binding Memorandum of Understanding with Austrianova ("Austrianova MOU"). Pursuant to the Austrianova MOU, 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 we, Austrianova and any future investment partner or partners will each receive a share of the net revenue of applicable products.

Our 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, Australia and Canada.

Our strategies to achieve this goal consist of the following:

- The completion of clinical trials in locally advanced, inoperable non-metastatic pancreatic cancer and its associated pain;
- The completion of preclinical studies and clinical trials that will demonstrate the effectiveness of our cancer therapy in reducing the production and accumulation of malignant ascites fluid in the abdomen that is characteristic of pancreatic and other abdominal cancers;
- The completion of preclinical studies and clinical trials that involve the encapsulation of the Melligen cells using the Cell-in-a-Box® technology to develop a treatment for Type 1 diabetes and insulin-dependent Type 2 diabetes;
- The enhancement of our ability to expand into the biotechnology arena through further research and partnering agreements in cancer and diabetes;
- The acquisition of contracts that generate revenue or provide research and development capital utilizing our sublicensing rights;
- The further development of uses of the Cell-in-a-Box® technology platform through contracts, licensing agreements and joint ventures with other companies; and
- The completion of testing, expansion and marketing of existing and newly derived product candidates.

Cell Therapy Product Development

In our effort to bring potential treatments to bear on pancreatic and other solid tumor cancers, we acquired Bio Blue Bird. This subsidiary holds exclusive worldwide licenses to our unique cellulose-based Cell-in-a-Box® live cell encapsulation technology for use in oncology with certain types of live cells. 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 constituents of the *Cannabis* plant.

Initially, focus will be placed on the preparations for our Phase 2b clinical trial in locally advanced, inoperable, non-metastatic pancreatic cancer. These preparations will include the live cell encapsulation of cancer prodrug-activating cells. For the Phase 2b clinical trial, as in the earlier Phase 1/2 and Phase 2 clinical trials, cells expressing a cytochrome P450 isozyme for use in cancer therapy will be utilized. These cells were used in the earlier clinical trials in patients with advanced, inoperable pancreatic cancer. These cells were genetically engineered to convert the cancer prodrug ifosfamide into its active cancer-killing form. When the encapsulated cells were placed in close proximity to the cancerous tumor in the pancreas and then one-third of normal dose of the anticancer prodrug ifosfamide was given intravenously, the passage of the ifosfamide through the capsules created an elevated local concentration of an active chemotherapy drug capable of stopping the growth of or killing the cancer cells. The results of this "targeted chemotherapy" are discussed in more detail below.

The Cell-in-a-Box® encapsulation technology enables living cells to be used as miniature factories. The technology results in the formation of pin-head sized cellulose-based capsules in which genetically modified 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 creates a micro-environment in which these cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors, enabling greater growth and production of the end product.

The Cell-in-a-Box® encapsulation technology enables cells to survive in the human host and function like any other living cell in the body. Since the capsules produced using this technology contain small pores, small molecules (such as nutrients, oxygen and waste products) can pass through the pores of the capsules whereas the encapsulated cells and cells of the immune system cannot, thus enabling the encapsulated therapeutic cells to live in the body, thereby behaving like new miniature organs of the body without any inflammatory response or rejection.

Market Opportunity and the Competitive Landscape

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

The Cell-in-a-Box® capsules are comprised of cotton's natural component - bio-inert cellulose. Other materials used by competitors include alginate, collagen, chitosan, gelatin and agarose. Cellulose appears to be the most robust of these. We believe this inherent strength provides the Cell-in-a-Box® capsules with advantages over the competition. For example, the Cell-in-a-Box® capsules have remained intact for more than two years in humans and for several months in animals during preclinical studies and clinical trials with no evidence of rupture, damage, degradation, fibrous overgrowth or an immune system response. In addition, the cells within the capsules remained alive and well during the course of the studies and trials. Other encapsulating materials degrade over time in the human body, 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 degrade in the body.

We believe our live cell encapsulation technology brings significant new advantages and opportunities to market for us in numerous and developing ways. For example:

- The treatment of diseases by placing encapsulated drug-converting cells that convert the chemotherapeutic agent near the diseased tissue or organ;
- The confinement and maintenance of therapeutic cells at the site of implantation at or near cancerous tumors ensuring "targeted chemotherapy;"
- The increased efficacy of chemotherapeutic drugs allowing for lower dosages and thus reduced side effects;
- The potential for the treatment of systemic diseases of numerous types, including diabetes;
- The provision of a safety mechanism for regulating cells that are introduced that would be desired to be maintained at specific sites in the body as a part of therapy;
- The multi-layered patent and trade secret protection and marketing exclusivity for the technology that is being expanded;
- The capsules that prevent immune system attack of functional cells without immunosuppressive drug therapy; and
- The safety of the technology and the cells used that has already been shown in both human and animal clinical trials.

The field of diabetes cell therapy development is competitive. There are a number of companies developing cell based therapies for diabetes. We estimate that we have numerous competitors developing therapies for diabetes, including companies like Living Cell Technologies, Viacyte, Cellmed, Microislet Sciences, Cerco Medical and BetaCell who are developing some form of encapsulation-based therapy. Although such competition exists, we believe these other companies are developing encapsulation-based therapies using encapsulation materials and methodologies to produce capsules or devices that are far less robust than ours or that are associated with other problems that are not characteristic of the Cell-in-a-Box® capsules.

Estimates indicate that, in approximately 25% of pancreatic cancer patients, the cancer is too advanced for any treatment due to late diagnosis and resulting short survival times. The disease is operable in approximately only 10% of patients after being diagnosed, largely because the disease shows no symptoms until it is at an advanced stage (stage III or IV) 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.

Pancreatic cancer appears to be increasing in most industrialized countries. A 2012 report by the Pancreatic Cancer Action Network predicted that pancreatic cancer will be the second cause of cancer-related deaths in the U.S. by 2020. More than 53,000 new cases of pancreatic cancer will be diagnosed in the U.S. in 2016 and about 41,800 deaths will occur. In Europe, newly diagnosed cases are expected to be about 90,000 this year.

Our goal is to satisfy a clear unmet medical need for patients with locally advanced, inoperable pancreatic cancer whose tumors no longer respond to the after 4-6 months of treatment with the chemotherapy combination of Abraxane® (nanoparticle albumin-bound paclitaxel) plus gemcitabine. For these patients, there is currently no effective therapy. We believe there will be no treatment comparable to our Cell-in-a-Box® plus low dose of ifosfamide combination treatment when it is used in these patients.

There is, however, intense competition for the use of the product candidates being developed by us for treating pancreatic cancer patients. We estimate there are numerous potential competitors trying to improve the outcome for pancreatic cancer patients. There are a number of 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. Some of our competitive strengths include the patents and licensing agreements described in this Report which protect the ability to utilize encapsulated cells as a critical component of the driving force behind our treatments for cancer and diabetes. 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.

Our Cell-in-a-Box® based pancreatic cancer therapy has already shown promise through the completion of a Phase 1/2 and a Phase 2 clinical trial in advanced, inoperable pancreatic cancer. Our diabetes cell therapy has also shown promise; the already completed research studies demonstrated positive responses in animal models using the Melligen cells. We believe we are in a strong competitive position in light of our unique encapsulation technology and the genetically modified cells that we have the exclusive world-wide license to use in the encapsulation process.

As explained above, we estimate that we have two principal competitors for the development of *Cannabis*-based treatments for cancer – CSI and GWP. In contrast to the work being done by these companies, as our preliminary areas of research, we plan to use *Cannabis* to develop treatments for brain and pancreatic cancer.

Earlier Clinical Trials Using Live Cell Encapsulation

The two earlier clinical trials were carried out in Europe in the late 1990s and early 2000s. 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: The 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 clinical 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, an 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 III-IV (IUCC) as determined by histology and measured by CAT scan and with no prior chemotherapy.

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 (~0.8 mm in diameter) contained about 10,000 cells. The cells overexpressed CYP2B1 (a cytochrome P450 isozyme), which catalyzed the conversion of the anticancer drug 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 was 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 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 National Cancer Institute ("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 particular 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" (CTCAE v. 4.0) 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 results according to this system which 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 pancreatic diseases. 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 pancreas disease 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 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 PR; 12 patients exhibited SD; and two patients showed a 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 with no toxicity beyond Grade 2 (moderate adverse effect) being 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 clinical 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 placement.

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.

If a "clinical benefit" is considered to be either no increase or a decrease in pain intensity, then 10 of 14 patients experienced such a benefit. 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.

Comparisons to 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 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 the 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%. By comparison, corresponding values from the Phase 1/2 reported clinical trial of the Cell-in-a-Box® plus ifosfamide combination were 39 weeks (approximately 9.8 months) and 36%, respectively.

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 against 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.

In contrast to the SAE's seen with gemcitabine, as noted above under *Observational Metrics Utilized and Actual Results Observed*, the use of the Cell-in-a-Box® plus ifosfamide combination in this Phase 1/2 clinical trial was not associated with any serious (Grade 3 or 4) treatment-related side effects.

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® plus low-dose ifosfamide is both safe and efficacious. 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 trial only a small number of patients were evaluable. As a result, 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, so 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, but rather the clinical trial allowed us to determine whether the Cell-in-a- Box® plus low-dose ifosfamide combination holds promise as a treatment for advanced pancreatic cancer. In the cancer arena, Phase 1/2 clinical trials are used to first establish the safety of the drug or treatment being investigated and second to 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 fully realize that a large, multicenter, randomized, comparative study with statistically powerful findings would need to be conducted and the results from such a clinical trial would have to confirm those from the previous Phase 1/2 trial before an application for marketing approval could be made for the Cell-in-a-Box® plus low-dose ifosfamide combination as a treatment for advanced pancreatic cancer.

If our cancer therapy is approved by the regulatory agencies, 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. In addition, we believe that success of the live cell encapsulation technology in the pancreatic cancer setting may lead to its successful use in developing treatments 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 IV disease. The remaining patient had Stage III disease. Ten of the 13 patients exhibited metastases.

Duration of Treatment and Dosage Information: The number of capsules implanted varied 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 as for the Phase 1/2 trial except that in this Phase 2 trial, the dose of ifosfamide was doubled to 2 g/m^2 from the $1g/m^2$ used in the Phase 1/2 trial. On days 2-4, patients received 2 g/m^2 in normal saline as a one-hour infusion. In addition, the urinary tract protector Mesna was given as 3 intravenous injections. This regimen was repeated on days 23-25.

Specific Clinical Endpoints: The primary objective 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 of the study 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 aim 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 the majority of 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 could be 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 of the 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 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 prior to starting ifosfamide treatment 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. The majority of 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 Phase 2 clinical trial.

Quality of Life: An assessment of the quality of life of the patients was performed in this Phase 2 clinical trial. Quality of life data were available for all of 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 are 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 $1g/m^2$.

Manufacturing

We are outsourcing all cell growth, processing and encapsulation services needed in connection with our future clinical trials of the encapsulated cell-based cancer and diabetes treatments. The encapsulation will be done by Austrianova in its GMP-compliant manufacturing facility in Bangkok, Thailand.

We have engaged ViruSure GmbH ("ViruSure"), a professional cell growing and adventitious agent testing company that has had extensive experience with the CYP2B1-expressing cells that will be needed for our pancreatic cancer treatment. We did so in order to recover them from frozen stocks of similar cells and regenerate new stocks for use by us in our preclinical studies and clinical trials. ViruSure is in the process of cloning new cells from a selected clone. Those clones will be grown to populate a master cell bank ("MCB") and a working cell bank ("WCB") for our future clinical trials.

In April 2014, we entered into a Master Services Agreement with ViruSure pursuant to which ViruSure will 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). ViruSure is developing the MCB and, from that, the WCB. The MCB is to be used as a "safe" repository of the cloned cells we will use in our cancer therapy. The WCB will 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 treatment for advanced pancreatic and other forms of solid tumor cancers. Compensation to ViruSure is set forth in separate agreements corresponding to specific orders. The price, fees and payment schedule depend upon the particular work being undertaken by ViruSure on our behalf.

In March 2014, we entered into 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 also have contracted with Austrianova to provide encapsulated insulin-producing cells for our preclinical studies in diabetes. At the appropriate time, we will enter into a similar Manufacturing Framework Agreement with Austrianova for the encapsulated cells we will need for our diabetes therapy.

Pursuant to the terms of the Austrianova MOU, Austrianova and we have agreed to commence negotiating during the third quarter of this calendar year 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 cannabinoid molecules that have been encapsulated using the Cell-in-a-Box® technology to conduct a Phase 3 clinical trial in the United States with 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 ("FDC Act") 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 be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way through the European Medicines Agency ("EMA"), but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful.

Regulatory approval, if and 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, which 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 FDC Act 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 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, animal 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 current good manufacturing practices ("GMP"), and to assure that the facilities, methods and controls are adequate;
- submission to the FDA of an IND (defined below) to support human clinical testing in the U.S.;
- approval by an IRB at each clinical site before each trial may be initiated;
- 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 of a New Drug Application ("NDA") for a drug, or Biologics License Application ("BLA") for a biologic, to the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval of the NDA or BLA.

Clinical Development

Before a product may be given to humans, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate's chemistry 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 Investigational New Drug application ("IND") which must be reviewed by the FDA for safety and other considerations before a 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 of any new drug or biologic product to humans in the U.S. that is not the subject of an approved NDA or BLA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, 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.

Typically, a clinical trial in humans involves a three-phase process. We devote significant resources to research and development programs in an effort 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, resulting 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 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 also determines 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 with the targeted disease. An initial evaluation of the product candidate's effectiveness on subjects is performed and additional information on the product candidate's safety and dosage range is obtained. For many diseases, a Phase 2 clinical trial normally includes 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 to ensure that study results are statistically significant. During a Phase 3 clinical trial, physicians monitor subjects to determine efficacy and to gather further information on safety. A Phase 3 clinical trial is designed to generate all of the clinical data necessary to submit an application 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 or 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 clinical trial's patients. 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 or not a trial may move forward at designated check points. 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 participants or patients are being exposed to an unacceptable health risk. In addition, there are 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 an SPA and provide information regarding the design and size of the proposed clinical trial. An 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. An 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 an SPA. Having an 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

In order 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 non-clinical 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 ("CMC"), 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 a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and 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. Most such applications for standard review product candidates are reviewed within ten to twelve months. 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 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 GMP standards. The FDA may refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP standards. Manufacturers of human cellular or tissue-based biologics also must comply with the FDA's Good Tissue Practices, as applicable, and the general biological product standards. After the FDA evaluates the NDA or BLA and the 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 in order 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 NDA/BLA supplement before the change can be implemented. An NDA/BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA/BLA supplements as it does in reviewing NDAs/BLA.

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 maintained by the National Institutes of Health. Information related to the product, patient population, phase of investigation, study sites and investigator, 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 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 a number of post-approval requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved NDA or BLA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to GMP 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 GMP standards, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from GMP standards and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with GMP standards and other aspects of regulatory compliance.

U.S. Patent Restoration and Marketing Exclusivity

In seeking approval for a drug through a NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA") or 505(b)(2) application. An ANDA provides for marketing of a drug product that has the same active ingredients, same strengths and dosage form, as the listed drug and has been shown through testing to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are generally not required to conduct, or submit results of, preclinical studies or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contain full safety and effectiveness data as an NDA, but at least some of this information comes from studies not conducted by or for the applicant. The ANDA or 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed upon by the new product. The ANDA or 505(b)(2) applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain (or removes) any language regarding a patented method of use rather than certify to such listed method of use patent. If the applicant does not challenge the listed patents by filing a certification that the listed patent is invalid or will not be infringed by the new product, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe upon the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until 30 months, at the earliest, of expiration of the patent, settlement of the lawsuit and a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

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 similar to an approved innovator biologic, among other requirements. The BPCIA, however, 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 (restoration) under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration 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 restoration is related to the length of time the drug, biologic or medical device is under regulatory review and is calculated as half of the testing phase, which is the time between the IND submission becoming effective and the NDA, BLA or premarket approval ("PMA") submission, and all of the review phase, which is 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 or restoration. 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 and when any of our product candidates receive FDA approval, we expect to apply for patent term restoration 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 the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the 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 that requires 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 IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug or biologic under European Union regulatory systems, we must submit a marketing authorization application ("MAA") with the EMA. It is generally similar to the NDA or BLA, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP 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 six months to several years, depending on a number of 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 an NDA, an MAA or a BLA. Each country-specific regulatory agency requires monitoring of all aspects of clinical trials and reports of all adverse events must be made. 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, 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, 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 trials, 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 have an effect on 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 therapy on 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 take action 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. 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 is particular to the approved indication and does not prevent another company from seeking approval of an off-patent 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 an NDA or 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, 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, and a cap on the total rebate amount for innovator drugs at 100% of the AMP;

- 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 new 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;

- new 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 new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- a new 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, which 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 U.S. federal government's 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 years 2015 or 2016.

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, 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, CMS issued a final rule regarding the Medicaid drug rebate program. The final rule, effective April 1, 2016, among other things, revises the manner in which 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. Additionally, there has been recent 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 and 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.

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 of the FDA-approved drugs for a particular 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 order 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 (including the TRICARE retail pharmacy program), 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 Public Health Service Act, 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 particular product as calculated under the Medicaid drug rebate program, discussed above.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. The European Union 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 products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, 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 programs. 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 and 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 a number of 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 of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. Failure to meet all of the requirements of a particular 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 of 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 in order 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 civil monetary penalties statute, imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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. As a result of a modification made by 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 in connection 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, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, 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.

Additionally, the federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biologicals 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 and to report 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, and 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. 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.

In order 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, as well as to 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 of 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, including criminal and significant 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 into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that 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, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order 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 by definition 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, and Schedule V substances presenting 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 new 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 new 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 particular 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 the amount of 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 or not 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 and some of our subsidiaries license patents and trademarks and have exclusive worldwide licensing rights to numerous patents in multiple countries over three technical 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 (iii) encapsulation of cells for producing retroviral particles for gene therapy. In addition, we 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 the constituents of *Cannabis*. 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.

Patents and Intellectual Property Agreements

The following patents and agreements constitute our material IP:

- We have the Bavarian Nordic/GSF License Agreement. The licensors are Bavarian Nordic/GSF. The licensee is Bio Blue Bird, our wholly owned subsidiary. The Bavarian Nordic/GSF License Agreement was signed in July 2005. The licensors have rights to terminate the license in the event that 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 Bavarian Nordic/GSF License Agreement relates to the patent US 6893634 B1 that claims "A capsule comprising a porous membrane formed by a polyelectrolyte complex which encapsulates cells which express cytochrome P450 as a cell membrane bound protein, wherein the porous membrane of the capsule is permeable to prodrug molecules and the cells are retained within the capsule" and further claims based on this;

- We have an exclusive license to the US Patent US 6,776,985 B1 that claims "Encapsulated retroviral packaging cells producing retroviral vectors, comprising capsules having a porous capsule wall which is permeable to said retroviral particles" and further claims based on this. This patent would be broadly applicable to the delivery of retroviral vectors by encapsulated packaging of cells for a variety of indications;

- We acquired 100% ownership of Bio Blue Bird, the licensee of the patents identified above, pursuant to the Third Addendum;

- The Third Addendum and the Clarification Agreement provide us with and exclusive world-wide license, with a right to sublicense, to use the Cell-in-a-Box® technology 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 world-wide license, with a right to sublicense, to use the Cell-in-a-Box® 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 world-wide 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 activate members of the cannabinoid family of molecules derived from *Cannabis* to develop therapies involving *Cannabis*, including the activation of cannabinoids; and

- The Melligen Cell License Agreement provides us with an exclusive world-wide license, with a right to sublicense, to use genetically modified human cells that have been modified to comprise pancreatic islet cell glucokinase for use in developing a therapy for diabetes.

We have assumed Bio Blue Bird's responsibilities under the Bavarian Nordic/GSF License Agreement, which include making royalty payments and bearing all of the licensor's external costs and fees for filing, prosecuting and maintaining any patent claims covering inventions in the licensed patent product. The only other payment obligations we have are the quarterly encapsulation patent upkeep fees to Bavarian Nordic, yearly license maintenance fees and auditing fees. We are to devote all reasonable efforts to develop product as promptly as possible, provide licensors with updates on the progress of the development and sale of the products and a summary of results of clinical study protocols regarding human clinical trials at the end of a pivotal (for marketing application purposes) trial, such as a Phase 3 clinical trial, and devote all reasonable efforts to commence manufacturing and commercialization as promptly as possible. We are also responsible, at our expense, for conducting any recalls of defective licensed products marketed by us.

Our royalty payments commence on the date of the first commercial sale of the licensed product in a particular country and continue on a country by country basis until expiration of the last valid claim within the licensed patent rights in such country. The territories where such commercial sales are anticipated are in the U.S., Europe and Japan. The future royalty and milestone payments are as follows: (i) approximately seven percent royalty on all gross sales; (ii) approximately eight percent royalty on gross revenues from sublicensing; (iii) milestone payments of $130,000 after the enrollment of the first human patient in the first Phase 3 clinical trial; (iv) an additional $130,000 after the conclusion of the Phase 3 clinical trial; and (v) $650,000 after obtaining a marketing authorization. Our patents covering encapsulated cells producing retroviral particles in the U.S. and multiple other countries expired June 24, 2016.

Summary of Patents

Set forth in the tables below is information regarding the relevant patents described above:

Encapsulated Cells Producing Cytochrome P450

- Claims cover capsules encapsulating cells expressing cytochrome P450 and treatment methods using same.
- There are no contested proceedings or third party claims known to us.
- We have an exclusive license from joint patent owners Bavarian Nordic/GSF.

Patent No.	Expiration Date	Country
US 6,540,995	03/27/2017	US
US 6,893,634	03/27/2017	US
AU 713382	03/27/2017	Australia
EP 892852	03/27/2017	Switzerland
EP 892852	03/27/2017	Germany
EP 892852	03/27/2017	Spain
EP 892852	03/27/2017	France
EP 892852	03/27/2017	Great Britain
EP 892852	03/27/2017	Italy
IL 125795	03/27/2017	Israel
JP 4229982	03/27/2017	Japan

Encapsulated Cells Producing Retroviral Particles

- Claims cover capsules which have walls that are permeable to retroviral particles, methods for producing same and methods of using same for gene therapy in countries where this protection is available.
- There are no contested proceedings or third party claims known to us.
- We have an exclusive license from joint patent owners Bavarian Nordic/GSF.

Patent No.	Expiration Date	Country
US 6,776,985	06/24/2016	US
AU 708273	06/24/2016	Australia
EP 835137	06/24/2016	Switzerland
EP 835137	06/24/2016	Germany
EP 835137	06/24/2016	Spain
EP 835137	06/24/2016	France
EP 835137	06/24/2016	Great Britain
EP 835137	06/24/2016	Italy
IL 122119	06/24/2016	Israel
JP 4119852	06/24/2016	Japan
JP 4848348	06/24/2016	Japan
KR 484883	06/24/2016	South Korea

Third Addendum to the SG Austria APA

In June 2013, we and SG Austria entered into the Third Addendum and the Clarification Agreement. The Third Addendum requires us to make the following payments for the purchased assets, which 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 $10-17,000 to the Singapore Government;
- $500,000 to be used to pay off the existing debt of Bio Blue Bird; and
- $1,000,000.

The Third Addendum provides that if the payments listed above are insufficient or fail to meet specified payment deadlines, the Third Addendum and the SG Austria APA automatically terminate and will be deemed null and void.

Pursuant to the Third Addendum, we agreed to enter into a manufacturing agreement with SG Austria on specified payment terms for initiating, carrying out and completing the clinical preparation of the pancreatic cancer treatment trial material, the licenses for which were included in the assets purchased under the SG Austria APA. The payment terms for the manufacturing agreement to be entered into with SG Austria agreed to in the Third Addendum were superseded by the Manufacturing Framework Agreement. Austrianova is a wholly-owned subsidiary of SG Austria. 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 one-time manufacturing setup fee. In addition, the Manufacturing Framework Agreement requires us to pay a fee for producing the final encapsulated cell product of $647 per vial of 300 capsules after production with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product. The fees under the Manufacturing Framework Agreement are subject to annual increases according to the annual inflation rate in the country in which the encapsulated cell products are manufactured.

The Third Addendum is an outright purchase. The Third Addendum requires us to make future royalty and milestone payments as follows:

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

We were granted a right of first refusal pursuant to the Third Addendum with respect to any offers made by SG Austria related to the granting of a license with respect to any patents or technologies related to live cell encapsulation that can be applied to use the Cell-in-a-Box® technology to create products in the following areas: (i) dermal fillers; (ii) medical marijuana; (iii) diabetes; and (iv) virally caused infectious diseases.

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 into between the parties, a one-time manufacturing setup fee in the amount of $633,144, 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 $633.14 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 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 the gross sale of all products we sell;
- Twenty percent royalty of the amount actually received by us from sub-licensees on sub-licensees' 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 due 60 days after having a NDA or a BLA approved by the FDA or a MAA approved in Europe or its equivalent based on the country in which it is accepted for each product.

The license under the Diabetes Licensing Agreement 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 any and all of the necessary and required research having been successful and the relevant product being sufficiently prepared for being able to enter into such clinical trials):

- If we do not enter into a research program with technology in the scope of the license providing a total funding equal to or greater than $400,000 with European academic university partners within three years of June 25, 2013, the effective date of the Diabetes Licensing Agreement; or
- If we do not enter into a clinical trial or its equivalent for a product within seven years of the effective date of the Diabetes Licensing Agreement.

In June 2016, the parties amended the Diabetes Licensing Agreement with respect to the requirement that we enter into a research program with the technology within three years of the effective date of the Diabetes Licensing Agreement to provide that such research program need not be with European academic university partners.

Melligen Cell License Agreement

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. It does not require any "up-front" payment to UTS. 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 Melligen cells.
The Melligen Cell License Agreement requires that we pay royalty and milestone payments to UTS as follows:

- Six percent gross exploitation revenue on product sales;
- Twenty-five percent of gross revenues if the product is sub-licensed by us; and
- Milestone payments of AU$ 50,000 at the successful conclusion of clinical studies, AU$ 100,000 at the successful conclusion of Phase 1 clinical trials, AU$ 450,000 at the successful conclusion of Phase 2 clinical trials, and AU$ 3,000,000 at the conclusion of Phase 3 clinical trials.

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.

Cannabis Licensing Agreement

Pursuant to the Cannabis Licensing Agreement, we acquired from Austrianova an exclusive world-wide license world 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

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Under the Cannabis Licensing Agreement, we are required to pay Austrianova an Upfront Payment of $2,000,000. 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 Payments 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 into 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 according to 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 actually received by us from sub-licensees on sub-licensees' gross sales value; 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 in Europe or its equivalent based on the country in which it is accepted for each product.

The license under the Cannabis Licensing Agreement 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 into a research program involving the scope of the license within three years of December 1, 2014, the effective date of the Cannabis Licensing Agreement; or
- If we do not enter into a clinical trial or its equivalent for a product within 7 years of the effective date of the Cannabis Licensing Agreement

Sources and Availability of Raw Materials

The entire encapsulation process relating to the encapsulation of the cells for the oncology and diabetes based treatment is to be carried out by Austrianova. It is responsible for acquiring the necessary raw materials including the cellulose sulfate necessary for encapsulating the live cells. As mentioned above, we have engaged ViruSure to clone new cells from a selected clone. Those clones will be grown to populate a MCB and WCB for our future clinical trials. See also "—Manufacturing" in this Item 1. "Business."

Employees

As of April 30, 2016, we had four full-time employees and three consultants who function as our Chief Scientific Officer, our Director of Diabetes Program Development and the Chairman of our Advisory Board. We use consulting scientists, physicians, academics and other professionals for the majority of our research, clinical development and operations.

Medical and Scientific Advisors

We have established our Advisory Board. We regularly seek advice and input from these experienced clinical leaders on matters related to our research and development programs. The members of our Advisory Board consist of experts across a range of key disciplines relevant to our 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. Our Advisory Board members 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 technologies that may compete with ours. All of the members of our Advisory Board are affiliated with other entities and devote only a small portion of their time to us. The members of our Advisory Board are not officers or directors of the Company. Our current advisors are set forth below:

- Dr. Matthias Löhr – Professor of Gastroenterology & Hepatology, Karolinska Institute, Stockholm, Sweden
- Dr. Manuel Hidalgo – Clinical Director of the Leon V. & Marilyn L. Rosenberg Clinical Cancer Center and Chief of the Division of Hematology-Oncology at Beth Israel Deaconess Medical Center Boston, Massachusetts
- 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®
- Dr. Mark L. Rabe – Chief Executive Officer of Rabe Medical Solutions, San Diego, California

Financial Information Concerning Geographic Areas

We had no revenues in the fiscal years ended April 30, 2016, 2015 and 2014, including no revenues from foreign countries. We have long-lived assets, other than financial instruments, located in the following geographical areas:

	FY 2016	FY 2015	FY 2014
United States:	$5,129,474	$5,129,474	$5,129,474
All foreign countries, in total:	$0	$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.”

Available Information

We file periodic and other reports with the Commission, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports. Those reports as well as other documents we file with the Commission, are available free of charge through the Investor Relations section of our web site (http://ir.pharmacytebiotech.com/all-sec-filings) as soon as reasonably practicable after such material is electronically filed with or furnished to the Commission. The public can read and copy any documents that we file with the Commission at the Commission's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. The Commission maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission at www.sec.gov. The address of the home page of our web site is http://pharmacyte.com/. The information on, or that may be accessed through, our web site is not incorporated by reference into and should not be considered a part of this Report.

This Report includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Report are the property of their respective owners.

ITEM 1A. RISK FACTORS

You should carefully consider these factors that may affect future results, together with all of 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 it currently deems immaterial also may become important factors that affect its business and result 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 future 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 such revenues from the sale of product candidates. You must consider our business and prospects in light of the risks and difficulties we will encounter as an early-stage biotech company in a new and rapidly evolving business 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 a history of losses from operations which may continue and which may harm our ability to obtain financing and continue our operations.

Our operations are subject to the risks and competition inherent in an early-stage biotech company. We may not generate sufficient revenues from operations to achieve or sustain profitability in the future. Our revenues and profits, if any, will depend upon various factors, including whether our existing products and services or any new products and services we develop will achieve any level of market acceptance. If we continue to incur losses, our accumulated deficit will continue to increase which might significantly impair our ability to obtain additional financing. As a result, our business, results of operations and financial condition would be significantly harmed, and we may be required to reduce or terminate our operations.

We are a pre-revenue company and may not achieve profitability.

We are a pre-revenue company. An investor cannot readily determine if we will become profitable. We are likely to continue to experience financial difficulties during this early revenue stage and beyond. We may be unable to operate profitably, even if we generate revenues. We may not obtain the necessary working capital to continue developing and marketing our product candidates. Furthermore, the present products may not receive sufficient interest to generate revenues or achieve profitability.

We will need additional capital to continue our business plans.

We will need additional capital to continue our operations. 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 a number of factors, including how quickly enrollment of patients in our planned clinical trials can be commenced and the duration of such clinical trials. 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 and such additional equity securities may 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.

As a result 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 and on our ability to fulfill such orders, both of which may not occur. 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) ability to obtain and retain customers; (ii) attract new customers at a steady rate and maintain customer satisfaction with products; (iii) the 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, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell 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 similar to 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 a large number of companies developing or marketing treatments 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 are able to enter the market and or slow our regulatory approval.

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 industries 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 Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

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 be approved by 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 takes many years, if approval is obtained at all. This process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing that product candidate. 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. 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 product candidate is in mid-stage clinical development, and the risk of its 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 testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. 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 and 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 as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result 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 final results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face additional 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 the 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.

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.

We intend to seek FDA acceptance of an IND in order to commence a Phase 2b clinical trial of genetically engineered live human cells encapsulated using our Cell-in-a-Box® technology in combination with ifosfamide. A prior Phase 1/2 clinical trial and Phase 2 clinical trial were previously conducted using Cell-in-a-Box® 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, which may result in additional total costs to us and/or 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 time that has elapsed since such trials were conducted or because the clinical trial material for our proposed Phase 2b clinical trial is slightly different from that used in the earlier clinical trials as a result of cloning the cells used in the earlier trials and certain 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 trials 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, 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 our development of the 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 schema;
- 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, impose similar restrictions. We may never receive such approvals. We must complete extensive 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 an 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 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 boxed 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.

Positive results in previous clinical trials of our encapsulated live cell and ifosfamide 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 may not be predictive of similar results in future clinical trials. Such previous Phase 1/2 and Phase 2 clinical trials featured a relatively limited number of patients. Such 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 final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage 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 of a number of possible unforeseen events in connection with 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, or as a result of, 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 into 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 a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, 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; 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 a sufficient number of 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 or not to grant priority review status to a product candidate, so even if we believe a particular 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 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 has an effect on 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 submit an application for accelerated approval or under another expedited regulatory designation (such as the breakthrough therapy 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 period 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. Even if we obtain Orphan Drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. 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 designation by a 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 for any of our product candidates but intend to seek such designation. 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. Regulatory agencies have broad discretion whether or not to grant this designation. Even if we believe a particular 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 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 approval.

A Breakthrough Therapy designation by a 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 for any of our product candidates but may seek such designation.

Designation as a Breakthrough Therapy is within the discretion of a regulatory agency. 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, a regulatory agency may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy 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 qualify as Breakthrough Therapies, a regulatory agency may later decide that such product candidates no longer meet the conditions for qualification.

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

In order 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. The regulatory approval process outside the U.S. generally includes all of 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. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, GMP 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, criminal sanctions, 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 in September 2014. 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 number of 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, 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, 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 new 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.

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 a number of 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 payers;
- 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 into clinical trials. 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 particular 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 into acceptable sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidate that we develop if and 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, we expect to license our encapsulated live cell plus ifosfamide product candidate 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. As a result of entering into 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 into 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 our clinical trials. We expect to continue to rely heavily on third parties, such as contract research organizations, clinical data management organizations, medical institutions, clinical investigators and others to 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 into 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 of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, regulatory agencies require us to comply with current GCP 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 stated 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 a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay our potential development schedule or increase our expenditures and undertake preclinical and clinical development activities at our own expense. If we fail to enter into 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 into 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 for a product candidate or have to repeat or conduct new preclinical and clinical development for 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 for 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 of 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 into 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 for the production of clinical quantities of our encapsulated live cell and ifosfamide product and other 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 synthesis 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, or an alternative manufacturer, would be capable of continuing to produce our product candidates or products, 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, 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 are able to 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 GMP 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 GMP certification of the manufacturing facility of Austrianova 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 GMP 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 capital 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. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. 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 manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers 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 patent applications in the U.S. and abroad related to our novel technologies and product candidates. Our patent portfolio includes patents and patent applications we exclusively licensed from Bavarian Nordic/GSF, SG Austria, Austrianova and UTS. Two of our U.S. patents and nine of our foreign patents, each of which covers capsules encapsulating a cell expressing cytochrome P450 and treatment methods using the same, will expire on March 27, 2017. We cannot at this time estimate the financial or other impact of the expiration of these patents.

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 behind 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 owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, 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 a number of 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, in particular, 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.

Moreover, 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. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 order 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.

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 a number of 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 on the grounds that 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 into license agreements in order 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 connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

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 were able to 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.

Presently we have rights to intellectual property to develop our product candidates. 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 a number of more 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 into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants; however, we cannot be certain that such agreements have been entered into with all relevant parties.

Moreover, to the extent we enter into 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.

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, including those that resulted in the restatement of our consolidated financial statements disclosed in Amendment No. 2 to our Annual Report on Form 10-K for the year ended April 30, 2015, filed with the Commission on January 19, 2016, and in Item 9A of this Report, 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 and negatively impact our business.

The alternative medicine industry 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 and when 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 in order 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.

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 in order 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.

The insurance coverage and reimbursement status of newly-approved products is 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 payers 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 the Europe may be more conservative than CMS. For example, a number of 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 are able to 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, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection 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. As a result, 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 a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, 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, 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. If we ever obtain regulatory approval and successfully commercialize any of our product candidates, these new 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 and consultants 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 employee fraud and other misconduct. Misconduct by employees or consultants 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. Employee and consultant misconduct could also involve the improper use of information obtained in the course of 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 employee and consultant misconduct. The precautions we take to detect and prevent this activity, such as employee training on enforcement of the Code of Business Conduct and Ethics, 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 be in compliance 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 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 of 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 our clinical trials 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 will incur increased costs as a result of operating as a public company, and our management will be 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, and 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 SEC. 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 costly. 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 the Company's Board of Directors ("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 listed 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 of time.

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 a number of 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 our projects operate and the project companies generally; and
- General economic and other national and international conditions.

Our ability to access the capital markets is limited by our 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. As a result, our ability to raise, and the cost of raising, future capital could be adversely affected by our 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 would have to exceed $75 million; or (ii) our common stock would have to be listed and registered on a national securities exchange. As of the filing of this Report, we do not meet either of those 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.

Due to our present inability to use Form S-3, if we determine it to be necessary or advisable to raise funds, we would be limited in our options. If market and other conditions allow, we could seek to conduct a registered offering of securities to investors, but we would be required to use "long form" registration and would most likely experience delays and costs greater than those that would be associated with a "shelf" offering under a Form S-3 registration statement. Alternatively, we may instead determine it necessary or advisable to issue securities in private placements or raise funds by other means, if available, which would most likely entail a greater cost of capital to us and may be dilutive to stockholders' present ownership levels and have rights, preferences, or privileges that are senior to those of our outstanding common stock. Furthermore, the terms of any financing transaction we may deem necessary to conduct may not be advantageous to us or we may be unable to obtain financing on commercially reasonable terms in a timely fashion, which could result in our inability to commence or complete our planned clinical trials or continue to operate as a going concern.

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 in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 jointly. 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 has suffered in recent years 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;
- "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 are 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 programs;
- 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 as a result of future decisions of our Board to issue shares without shareholder approval for cash transactions, services rendered, acquisitions, payment of debt, sale of shares under our Form S-3 Registration Statement (if and when we are eligible to use Form S-3 for primary issuances), 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 and Chief Operating 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, 2016, we had four employees and several 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. 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 executive officers or other key employees or consultants could 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 of time 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 as a result 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. As a result, 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 in connection 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.

We are dependent on business relationships with parties in multiple countries, as disclosed under the caption "—Risks Related to Our Dependence on Third Parties."

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. This office, which consists of approximately 1,900 square feet, is leased pursuant to a lease ending July 31, 2016. Our landlord has agreed to extend the lease until August 31, 2016. We are in discussions with our landlord to lease other space in the same building. The leased property is adequate at the present time. If we are unable to lease other space in the same building, we believe that we will be able to lease office space on commercially acceptable terms on other premises within a reasonable period of time.

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 or, to our knowledge, against any of our officers or directors in their capacity as such. To our knowledge, 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, 2016 and 2015. 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 2016	HIGH	LOW
First Quarter	$ 0.17	0.10
Second Quarter	$ 0.13	0.07
Third Quarter	$ 0.11	0.04
Fourth Quarter	$ 0.08	0.05
FY 2015		
First Quarter	$ 0.34	$ 0.21
Second Quarter	$ 0.30	$ 0.17
Third Quarter	$ 0.26	$ 0.10
Fourth Quarter	$ 0.26	$ 0.10

At April 30, 2016, the market price of our common stock was $0.07 per share.

As of April 30, 2016, there were 781,233,338 issued and outstanding shares of common stock. We were 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 at this time. 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 the year ended April 30, 2016.

For information on securities authorized for issuance under equity compensation plans, see Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Recent Issuance of Unregistered Securities

In addition to issuances of unregistered securities by us previously disclosed in our Quarterly Reports on Form 10-Q, as amended, and our Current Reports on Form 8-K, during the year ended April 30, 2016, we issued 750,000 shares of common stock to consultants for services to us. The non-cash expense for these share issuances totals $48,000.

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 shares certificates issued to prevent a public distribution of the relevant securities. No underwriters were involved in any of the foregoing issuances.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected historical consolidated financial data for each of our five fiscal years during the period ended April 30, 2016. This information should be read in conjunction with the consolidated financial statements of the Company and Notes thereto included in Part II, Item 8 of this Report.

Statement of Operations Data

	Years Ended				
	April 30, 2016	April 30, 2015 (As Restated)	April 30, 2014	April 30, 2013	April 30, 2012
Total revenue	$ –	$ –	$ –	$ 12,160	$ 66,558
Loss from operations	$ (6,073,133)	$ (13,260,735)	$ (18,979,142)	$ (1,684,361)	$ (1,949,182)
Consolidated net loss	$ (6,063,784)	$ (9,927,706)	$ (27,254,020)	$ (1,598,102)	$ (1,899,312)
Loss per shares:					
Basic and diluted	$ (0.01)	$ (0.01)	$ (0.05)	$ (0.00)	$ (0.01)
Shares used in calculating loss per share					
Basic and diluted	752,403,049	704,327,656	583,219,665	440,954,850	374,763,486

Balance Sheet Data

	April 30, 2016	April 30, 2015 (As Restated)	April 30, 2014	April 30, 2013	April 30, 2012
Cash	$ 1,920,825	$ 2,699,737	$ 3,616,470	$ 199,303	$ 15,723
Total assets	$ 7,160,325	$ 9,297,492	$ 9,316,050	$ 2,876,931	$ 2,087,508
Total liabilities	$ 637,639	$ 1,520,366	$ 373,666	$ 3,798,387	$ 3,787,358
Total stockholders' equity (deficit)	$ 6,522,686	$ 7,777,126	$ 8,942,384	$ (1,501,456)	$ (2,279,850)

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 treatments for cancer and diabetes based upon our proprietary cellulose-based live cell encapsulation technology, which 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 clinical trial of our pancreatic cancer therapy using encapsulated live cells similar to those used in the previous Phase 1/2 and Phase 2 clinical trials discussed above. We are involved in preclinical studies to determine if our pancreatic cancer therapy can slow the production or accumulation of malignant ascites. We are also involved in preclinical studies for the development of a therapy for Type 1 and insulin dependent Type 2 diabetes. Finally, we are conducting preliminary research relating to the use of constituents of the *Cannabis* plant in treating cancer and its symptoms.

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 cells and having them encapsulated for the planned preclinical studies and clinical trials; (iv) have regulatory work completed to enable studies and trials to be submitted to regulatory agencies; (v) initiate all purity and toxicology cellular assessments; and (vi) ensure completion of the production of GMP encapsulated cells according to GMP standards to use in our clinical trials.

There are numerous factors required to be completed successfully in order to ensure our final product candidates are ready for use in our clinical trial and preclinical studies. Therefore, 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. From our assessments to date, we do not believe there are factors which will cause materially different amounts to be reported than those presented in this Report and aim to assess this regularly to provide the most accurate information to our shareholders.

Quarterly Financial Data

The following table sets forth unaudited statements of operations data for each quarter during our most recent two fiscal years. This quarterly information has been derived from our unaudited condensed financial statements and, in the opinion of management, includes all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the information for the periods covered. The quarterly financial data should be read in conjunction with our consolidated financial statements and related notes. The operating results for any quarter are not necessarily indicative of the operating results for any future period.

	Quarter Ended July 31	Quarter Ended Oct 31	Quarter Ended Jan 31	Quarter Ended April 30
2016				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,514,311	1,635,818	1,792,151	1,130,853
Other income (expenses), net	(727)	236	1,054	8,786
Net loss	$ (1,515,038)	$ (1,635,582)	$ (1,791,097)	$ (1,122,067)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.00)	$ (0.00)	$ (0.00)

	Quarter Ended July 31	Quarter Ended Oct 31	Quarter Ended Jan 31	Quarter Ended April 30
2015				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,583,160	6,200,845	1,456,554	4,020,176
Other income (expenses), net	(1,664)	3,336,402	(1,496)	(213)
Net loss	$ (1,584,824)	$ (2,864,443)	$ (1,458,050)	$ (4,020,389)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.01)	$ (0.00)	$ (0.01)

Liquidity and Capital Resources

Our consolidated financial statements and related disclosures 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. Accordingly, 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. In addition, development activities, preclinical studies, clinical trials and commercialization of our product candidates will require significant additional financing. Our deficit accumulated through April 30, 2016 was $84,691,617. We expect to incur substantial and increasing losses in future periods. Our total cash was $1,920,825 and $2,699,737 as of April 30, 2016 and 2015. Our net loss was $6,063,784, $9,927,706 and $27,254,020 for the years ended April 30, 2016, 2015 and 2014. Cash flows from investing activities were $0 and $0 for the years ended April 30, 2016 and 2015 and $3,559,069 net cash used in investing for during the year ended April 30, 2014. Net cash provided by financing activities was $3,568,150, $3,641,974 and $8,530,944 for the years ended April 30, 2016, 2015 and 2014. 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, competition from third parties, uncertainty of capital availability, uncertainty in our ability to enter into 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, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our planned products. We believe that our cash as of April 30, 2016, combined with the sales of our common stock described below, will provide us with the ability to fund our operations through our fiscal year end 2017. However, there can be no assurance in this regard. Such actions primarily include raising additional capital from existing investors or securing additional financing as required.

From our present assessments, 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 our projected preclinical and clinical projects based on our available cash. We have no contractual obligations to perform clinical trials. We anticipate that, during the latter part of this year or next, we will perform certain clinical trials based on the availability of our cash. 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 trials and other research and development costs. Our ability to raise additional capital is limited by our inability to use a short form registration statement on Form S-3. As of the date of filing this Report, we do not meet the eligibility requirements in order for us to be able to conduct a primary offering of our common stock under Form S-3 or file a new Registration Statement on Form S-3. We may be able to regain the use of Form S-3 if we meet one of the eligibility criteria, including: (i) the aggregate market value of our common stock held by non-affiliates exceeds $75 million; or (ii) our common stock is listed and registered on a national securities exchange.

Due to our present inability to use Form S-3, if we determine it to be necessary or advisable to raise funds, we would be limited in our options. If market and other conditions allow, we could seek to conduct a registered offering of securities to investors, but we would be required to use "long form" registration and would most likely experience delays and costs greater than those that would be associated with a "shelf" offering under a Form S-3 registration statement. Alternatively, we may instead determine it necessary or advisable to issue securities in private placements or raise funds by other means, if available, which would most likely entail a greater cost of capital to us and may be dilutive to stockholders' present ownership levels and have rights, preferences, or privileges that are senior to those of our outstanding common stock. Furthermore, the terms of any financing transaction we may deem necessary to conduct may not be advantageous to us or we may be unable to obtain financing on commercially reasonable terms in a timely fashion, which could result in our inability to commence or complete our planned clinical trials or continue to operate as a going concern.

Overall, 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 relationships between changes in operating results may induce changes in liquidity, in particular material changes in working capital components as seen by both acquisition of new capital through the "at-the-market" facility described below and 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 if and when needed.

We do not utilize any advanced methodology of cash management beyond paying our normal expenses, yet we have begun to make important risk management policies to maintain success and ease the assessment of our financial condition.

On May 28, 2014, we entered into 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 in connection with 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 connection with such transactions, we agreed to pay 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. In addition, we agreed to reimburse certain expenses of Chardan in an amount not to exceed $15,000. Thus far, we have raised approximately $6.25 million through Chardan in connection with the Chardan Agreement.

In January 2016, we sold to two existing stockholders of the Company, in equal amounts, an aggregate of 17,000,000 unregistered shares of our common stock and warrants to purchase an aggregate of 17,000,000 unregistered shares for gross proceeds of $1,020,000 in a private placement.

With the proceeds received upon the sale of shares of common stock to Lincoln Park, through bridge financing being provided by new investors and existing shareholders and with the sale of our stock under the Chardan Agreement, we have been able to maintain sufficient capital resources to meet projected cash flow needs. If we are unable to raise sufficient funds through the sale of our common stock and we are unable to raise additional capital on acceptable terms through other means, our business, results of operations, liquidity and financial condition will be materially adversely affected. We believe that the sale of our shares in any private placements and/or public offerings we may undertake will provide sufficient capital to fund our operations through July 31, 2017. Our current cash expenditures are approximately $150,000 per month. As of July 28, 2016, we had approximately $2.2 million in cash.

Year ended April 30, 2016 compared to years ended April 30, 2015 and 2014

Revenue

We had no revenues in the fiscal years ended April 30, 2016, 2015 and 2014.

Operating Expenses

The total operating expenses during the year ended April 30, 2016 decreased by $7,187,602 to $6,073,133 from $13,260,735 in the year ended April 30, 2015. The decrease is mainly attributable to a reduction in research and development costs and in compensation expense as we awarded less stock based compensation in 2016 than in 2015. For the year ended April 30, 2015, there was a decrease in operating expenses of $5,718,407 to $13,260,735 from $18,979,142 in the year ended April 30, 2014. The decrease was mainly attributable to a decrease in stock based compensation in 2015 net of an increase in research and development costs in 2015. The table below provides additional details relating to our operating expenses.

Operating expenses:	Year ended April 30, 2016	Change - Increase (Decrease) and Percent	Year ended April 30, 2015	Change - Increase (Decrease) and Percent	Year ended April 30, 2014
Research and development	$ 1,406,939	$ (2,069,973) -60%	$ 3,476,912	$ 3,153,412 975%	$ 323,500
Compensation expense	$ 1,871,795	$ (4,617,539) -71%	$ 6,489,334	$ (7,120,661) -52%	$ 13,609,995
Director fees	$ 45,000	$ 27,000 150%	$ 18,000	$ (750,000) -98%	$ 768,000
General and administrative, legal and sales and marketing	$ 2,749,399	$ (527,090) -16%	$ 3,276,489	$ (1,001,158) -23%	$ 4,277,647

Loss from operations

Loss from operations during the year ended April 30, 2016 decreased by $7,187,602 from $13,260,735 in the year ended April 30, 2015 to $6,073,133. The decrease is mainly attributable to a reduction in research and development costs and in compensation expense as we awarded less stock based compensation in 2016 than in 2015. For the year ended April 30, 2015, there was a decrease in loss from operations of $5,718,407 to $13,260,735 from $18,979,142 in the year ended April 30, 2014. The decrease was mainly attributable to a decrease in stock based compensation in 2015.

Other income (expenses), net

Other income, net for the year ended April 30, 2016 was $9,349 as compared to other income, net of $3,333,029 in the year ended April 30, 2015. Other income, net for the year ended April 30, 2016 is mainly attributable to gain on foreign exchange income on currency translations. Other income, net for the year ended April 30, 2015 was $3,333,029 as compared to other expenses, net of $8,274,878 in the year ended April 30, 2014. Other income, net for the year ended April 30, 2015 is attributable the gain on the recovery of 15.6 million shares from officers and directors as part of three settlements. Other expenses, net for the year ended April 30, 2014 are attributable to a non-cash expense of $5,895,000 on the conversion of preferred stock, a non-cash expense of $3,993,295 for settlement of debt and a recovery of $1,633,380 on the forgiveness of debt.

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, 2016, 2015 and 2014.

	Year Ended April 30, 2016	Year Ended April 30, 2015	Year Ended April 30, 2014
Net cash used in operating activities:	$ (4,346,406)	$ (4,560,169)	$ (1,554,708)
Net cash used in investing activities:	$ –	$ –	$ (3,559,069)
Net cash provided by financing activities:	$ 3,568,150	$ 3,641,974	$ 8,530,944
Effect of currency rate exchange	$ (656)	$ 1,462	$ –
Increase (decrease) in cash	$ (778.912)	$ (916,733)	$ 3,417,167

Operating Activities:

The cash used in operating activities for the years ended April 30, 2016, 2015 and 2014 are a result of our net losses offset by securities issued for services and compensation, changes to prepaid expenses, accounts payable, accrued expenses and license agreement obligation for 2016, for the year ended April 30, 2015, gains on settlements and license agreement obligation and for the year ended April 30, 2014 increased by the loss on recovery of shares for compensation and services, the loss on settlement of preferred stock, forgiveness of debt, changes to prepaid expenses, accounts payable and accrued expenses.

Investing Activities:

The cash used in investing activities for the year ended April 30, 2014, is mainly attributable to the purchase of licenses.

Financing Activities:

The cash provided from financing activities for the years ended April 30, 2016, 2015 and 2014 are 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 future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

As we reach certain "milestones" in the progression of the live cell encapsulation technology towards the development of treatments for cancer and diabetes, payments are owed by us to SG Austria or Austrianova. The future royalty and milestone payments are as follows: (i) two percent royalty on all gross sales; (ii) ten percent royalty on gross revenues from sublicensing; (iii) milestone payments of $100,000 after enrollment of the first human patient in the first clinical trial for each product; (iv) $300,000 after the enrollment of the first human patient in the first Phase 3 clinical trial; and (v) $800,000 after obtaining a marketing authorization the regulatory agencies. Additional milestone payments of $50,000 after the enrollment of the first veterinary patient for each product and $300,000 after obtaining marketing authorization for each veterinary product are required.

Contractual Obligations

The following table presents certain payments due by the Company as of April 30, 2016 with respect to our known contractual obligations:

Payments due by period

Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital Leases	$ –	$ –	$ –	$ –	$ –
Operating Leases	12,873	12,873	–	–	–
Purchase Obligations	–	–	–	–	–
Other Long-Term Liabilities Reflected on the Company's Balance Sheet under GAAP	–	–	–	–	–
Total	$ 12,873	$ 12,873	$ –	$ –	$ –

As of April 30, 2016, we leased office space in Silver Spring, Maryland under a lease ending July 31, 2016. As of April 30, 2016, we have a deferred tax asset of approximately $16.7 million. The deferred tax asset is offset in its entirety by the valuation allowance. As a result of the valuation allowance the value of the deferred tax asset is zero.

Critical Accounting Estimates and Policies

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). In connection with the preparation of our consolidated financial statements, 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 3 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

Research and development 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 employee compensation plans are described in Note 8 of the Notes to Financial Statements. 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.

For stock warrants paid in consideration of services rendered by non-employees, we recognize compensation expense in accordance with the requirements of ASC 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50").

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 approximately 153,019,908, 125,419,908 and 57,665,600 shares at April 30, 2016, 2015 and 2014, 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 "New Accounting Pronouncements" in Note 3 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 exposed to market risks, which may result in potential losses arising from adverse changes in, among other things, foreign exchange rates. We have not taken steps to try and manage foreign exchange rate fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes to manage this risk. As indicated below, we do not believe we are exposed to material market risk with respect to our cash.

We currently have no operations outside the U.S., but we have contracted with third parties to manufacture our encapsulated live cell product and other product candidates in Thailand and Australia for preclinical and clinical trials. Manufacturing and research costs related to these operations are paid for in a combination of U.S. dollars and local currencies. Accordingly, we are subject to limited foreign currency exchange rate risk. It is not possible to estimate with any degree of accuracy the degree of this risk on a percentage basis. As of April 30, 2016, we do not believe foreign currency exchange rate risk is a substantial risk at this time due to the limited extent of our operations; however, if we conduct additional clinical trials and seek to manufacture a more significant portion of our product candidates outside of the U.S. in the future, we could incur significant foreign currency exchange rate risk.

As of April 30, 2016, we had cash of approximately $1.9 million. We do not engage in any hedging activities against changes in interest rates or foreign currency exchange rates. Because of the short-term nature of our cash, we do not believe that an immediate 10% increase in interest rates would have any significant impact on the fair value of our cash.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated balance sheets as of April 30, 2016 and 2015, consolidated statements of income, cash flows and stockholders' equity for each of the three years in the period ended April 30, 2016, consolidated notes thereto and schedules, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report and are incorporated by reference herein.

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

In early 2015, our principal certifying accountant, Robison, Hill & Company ("RHC"), elected to cease representing public companies, causing us to search for a replacement. On May 26, 2015, we engaged Farber Hass Hurley LLP ("FHH") as our principal certifying accountant. The change in accountants was approved by our Board. The engagement did not result from any dissatisfaction with the quality of professional services rendered by RHC.

RHC's report on our consolidated financial statements for the fiscal year ended April 30, 2014 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles. During our fiscal year ended April 30, 2015 and the subsequent interim period through May 26, 2015, FHH was our principal accountant, there were no disagreements with FHH on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to FHH's satisfaction, would have caused them to make reference to the subject matter in connection with their report on our consolidated financial statements for such period.

During our fiscal years ended April 30, 2015 and 2014, and the subsequent interim period through May 26, 2015, 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.

On October 29, 2015, we dismissed FHH as our principal accountant, and on October 30, 2015, we engaged Armanino LLP ("Armanino") as our principal accountant. The change in accountants was approved by our Board and did not result from any dissatisfaction with the quality of professional services rendered by FHH.

FHH's report on our consolidated financial statements for the fiscal year ended April 30, 2015 did not contain an adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles. During our fiscal year ended April 30, 2015 and the subsequent interim period through October 29, 2015, there were no disagreements with FHH on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure which, if not resolved to FHH's satisfaction, would have caused them to make reference to the subject matter in connection with their report on our consolidated financial statements for such periods.

During our fiscal year ended April 30, 2016, 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

Our management, including our Chief Executive Officer, President and General Counsel, as our principal executive officer and acting principal financial officer ("Principal Executive Officer" or "Principal Executive Officer and Acting Principal Financial Officer"), and our Vice President of Finance ("Vice President of Finance"), 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 is recorded, processed, summarized and reported within the time period specified by the Commission's rules and forms and is accumulated and communicated to our management, including our Principal Executive Officer, as appropriate to allow timely decisions regarding required disclosures. Based upon this evaluation, the Principal Executive Officer and Vice President of Finance have concluded that, as of April 30, 2016, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting described under *Management's Report on Internal Control over Financial Reporting* below.

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. Additionally, 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, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as that term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting is 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.

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

Under the supervision and with the participation of the Principal Executive Officer and the Vice President of Finance, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of April 30, 2016 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 control over financial reporting:

- Ineffective corporate governance;
- Ineffective communication of internal information;

- Insufficient procedures and control documentation;
- Insufficient segregation of duties; and
- Insufficient information technology controls and documentation.

In their evaluation, the Principal Executive Officer and the Vice President of Finance also identified material weaknesses relating to accounting for a consultant agreement, warrants, certain issuances of shares of common stock and certain disclosures relating to issuances of options and common stock to directors and officers, which necessitated the restatement of our financial statements for the fiscal year ended April 30, 2015 and the periods ended July 31, 2015 and October 31, 2015 (collectively, "Restatements"). These material weaknesses resulted in a material misstatement of our liabilities, total stockholders' equity, consolidated other income, consolidated general and administrative expenses and certain non-cash compensation expenses set forth in our consolidated financial statements as of and for the year ended April 30, 2015 and the periods ended July 31, 2015 and October 31, 2015. For more information on the Restatements, see Amendment No. 2 to our Annual Report on Form 10-K for the year ended April 30, 2015, filed with the Commission on January 19, 2016, Amendment No. 2 to Quarterly Report on Form 10-Q for the quarter ended October 31, 2015 and Amendment No. 1 to Quarterly Report on Form 10-Q for the quarter ended July 31, 2015.

Because of these material weaknesses, the Principal Executive Officer and the Vice President of Finance concluded that, as of April 30, 2016, our internal control over financial reporting was not effective based on the COSO criteria.

We have begun the process of investigating new procedures and controls in fiscal year 2016 and to review further our procedures and controls in 2016. Although, we expect to make changes to our infrastructure and related processes that we believe are also reasonably likely to strengthen and materially affect our internal control over financial reporting, we have not yet made any such changes.

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. Moreover, 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 some persons, 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, and 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.

The Certifications of our Principal Executive and Acting 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.

The effectiveness of our internal control over financial reporting as of April 30, 2016 has been audited by Armanino, our independent registered public accounting firm, as stated in their report which is part of this Report. They have audited our consolidated financial statements and the effectiveness of our internal control over financial reporting as of April 30, 2016. Their reports appear on page F-2 through F-4 of this Report.

Changes in Internal Control over Financial Reporting

There were no changes, other than those detailed above under *Management's Report on Internal Control over Financial Reporting* (including the material weaknesses relating to the Restatements), in our internal control over financial reporting during the most recent fiscal quarter that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited PharmaCyte Biotech, Inc.'s (the "Company"), formerly known as Nuvilex, Inc., internal control over financial reporting as of April 30, 2016, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1**)** pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. The Company has an insufficient number of personnel to adequately segregate internal controls over financial reporting. The Company does not have adequate documentation of its internal controls and policies and procedures over financial reporting, including information technology controls and procedures. The Company's policies and procedures do not provide sufficient assurance that the Company's personnel will internally communicate financial and operational information on an accurate and timely basis. The Company's corporate governance structure does not provide sufficient oversight over the Company's financial and operational key controls. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2016 consolidated financial statements, and this report does not affect our report dated July 29, 2016, on those consolidated financial statements.

In our opinion, because of the effect of these material weaknesses described above on the achievement of the objectives of the control criteria, PharmaCyte Biotech, Inc., has not maintained effective internal control over financial reporting as of April 30, 2016, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet and the related statements of operations, comprehensive loss, stockholders' equity (deficiency), and cash flows of PharmaCyte Biotech, Inc., and our report dated July 29, 2016, expressed an unqualified opinion.

/s/ ARMANINO LLP

San Ramon, California

July 29, 2016

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and executive officers as of July 29, 2016, are as follows:

	Age	Position
Kenneth L. Waggoner, JD	67	Chairman of the Board, Chief Executive Officer, President and General Counsel
Gerald W. Crabtree, PhD	75	Director and Chief Operating Officer
Thomas Liquard	43	Director

Kenneth L. Waggoner, JD

Kenneth L. Waggoner began working for us as an independent contractor in September 2013. 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. Mr. Waggoner has been a member of the Board since September 2014. Mr. Waggoner has over four decades 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, Europe 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. Gerald W. 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.

A highlight of Dr. Crabtree's professional career was his tenure as 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 a department that monitored and coordinated the development of all oncologic and immunologic drugs from initial discovery through regulatory approval within BMS and served as Project Manager for the development of the major anticancer agent, Taxol®, the "number one" drug under development at BMS at that time. Taxol® ultimately became a multi-billion-dollar drug for BMS and is still widely used to treat a variety of cancers.

From 1989 to 1990, Dr. Crabtree was Director of Pharmacology at Viratek, Inc., a subsidiary of ICN Pharmaceuticals, Inc. in Costa Mesa, California, where he worked on the development of anticancer drugs first developed at the Nucleic Acid Research Institute ("NARI"), a joint venture between Eastman Kodak and ICN Pharmaceuticals and with ribavirin (Virazole®), Viratek's landmark antiviral drug. Prior to that, from 1985 to 1989, Dr. Crabtree served as Head of the Department of Molecular Pharmacology at NARI where his department was tasked with elucidating the mechanisms of action of anticancer and antiviral drugs developed by NARI chemists. From 1970 to 1985, Dr. Crabtree held several faculty positions at Brown University in Providence, Rhode Island as well as at the Roger Williams Cancer Center ("RWCC") at that institution. These positions culminated in his attaining the rank of Associate Professor of Medicine. During his time at Brown and the RWCC, Dr. Crabtree studied the mechanisms of action of putative anticancer and antiparasitic drugs and participated in clinical trials of anticancer agents.

After leaving BMS in 1997, Dr. Crabtree consulted with several biotech companies, all of which were developing cancer drugs or treatments. Then, from 2000 to 2003, Dr. Crabtree served as Vice President of R&D at ETEX Corporation, a "device" company, where he was tasked with developing that company's proprietary calcium phosphate formulations as depot/delivery platforms for cancer drugs. Upon leaving ETEX, he resumed his consulting business, which soon became focused on PhytoCeutica, Inc. located in the Yale Science Park in New Haven, Connecticut, where he assisted in the preparation and review of FDA documents, clinical study protocols, investment acquisitions, and contracts and business plans. PhytoCeutica was developing a traditional Chinese medicine four-herb combination as a treatment for liver and pancreatic cancer. During his time with PhytoCeutica, Dr. Crabtree assumed ever-increasing responsibilities and from 2009 to 2010, ultimately serving as its Interim chief executive officer. Dr. Crabtree resumed his consulting business after leaving PhytoCeutica until he joined us.

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 both the American Society of Clinical Oncology and the American Association for Cancer Research and has served on research grant review committees for the National Institutes of Health and the American Cancer Society.

Dr. Crabtree has spent almost 50 years working in academic, biotech and pharmaceutical companies with the majority of that vast experience being in the development of drugs and treatments for cancer. He has held positions of ever-increasing importance over that time. In addition, over the past few years, Dr. Crabtree has developed a significant knowledge base concerning diabetes and its treatments, because of his personal health issues with that disease.

Thomas Liquard

Thomas Liquard was appointed to the Board in 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 big pharma and biotech companies. From 2013 to 2014, Mr. Liquard was chief operating officer, and then chief executive officer, of Alchemia Limited ("Alchemia"), an Australian biotech company (ASX: ACL) with an FDA-approved sterile injectable and a late stage oncology platform. During that time, Mr. Liquard administered an AU$ 25 million budget and Alchemia had revenues of AU$ 15 million. While at Alchemia, Mr. Liquard rebuilt that company's valuation which had lost 23% after the departure of the prior chief executive officer, brought two major investors into the register, improved its stock price to a 52-week high and led all business development and corporate development activities.

Prior to joining Alchemia, Mr. Liquard spent seven years with Pfizer, Inc. ("Pfizer") in New York, where he held various commercial roles of increasing scope and responsibility, including most recently 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 and managed more than 70 opportunities at various stages of execution. During his tenure at Pfizer, Mr. Liquard also spent three years as a key member of the company's Established Products US Brands P&L Leadership Team where he engineered the group's 505(b)(2) investment strategy, culminating in the $700M acquisition of NextWave Pharmaceuticals, Inc. ("NextWave"). He also led the NextWave pre- and post- acquisition integration efforts. In addition, Mr. Liquard worked as a Director within the New Product Planning and Portfolio & Decision Analysis groups at Pfizer from 2007 to 2010. There he was responsible for formulating investment decisions on business development opportunities and internal development programs across multiple therapeutic areas including oncology and metabolic diseases, including diabetes and central nervous system.

From 2004 to 2007, Mr. Liquard served as Senior Consultant to the Frankel Group, where he specialized in the life sciences. While at the Frankel Group, Mr. Liquard was lead consultant for global "war-gaming" in support of a $3.0 billion supportive care biologic drug, facilitated multiple competitive planning sessions in the U.S., Europe and Canada and performed due diligence analyses on multiple potential in-licensing targets. Mr. Liquard holds an MBA from Columbia Business School and a Bachelor of Science degree from the University of Southern California.

Mr. Liquard was appointed to the Board because of his experience and expertise in leading positions with life science-oriented biotech and pharmaceutical companies. In particular, his 7-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 believed to be a much needed asset to us.

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, 2016, our personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the Rules and Regulations of the Commission.

Corporate Governance

The corporate governance as of April 30, 2016 includes Board meetings which are run by the Board, with Mr. Waggoner as Chairman of the Board and Secretary leading the meetings. Directors include Mr. Waggoner, Dr. Crabtree and Mr. Liquard.

Board Leadership Structure

Our Board has a chairman, currently Mr. Waggoner, who has authority, among other things, to call and preside over Board meetings, to set meeting agendas and to determine materials to be distributed to the Board. Accordingly, the chairman has substantial ability to shape the work of the Board.

The positions of Chief Executive Officer and Chairman of our Board are held by the same person. The Chairman of our Board chairs director and stockholder meetings and participates in preparing their agendas. Mr. Waggoner, as our Chief Executive Officer, also serves as a focal point for communication between management and the Board between Board meetings, although there is no restriction on communication between directors and management.

We believe that our current leadership structure is appropriate, as the Board considers all of its members equally responsible and accountable for oversight and guidance of its activities.

Board Committees

Our Board has formed an Audit Committee pursuant to the NASDAQ Listing Rules and is in the process of forming a Nominating Committee and a Compensation Committee in accordance with those same Rules. Charters for each Committee have been adopted by 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 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. Our directors are expected to attend annual meetings of stockholders, but we do not have a formal policy requiring them to do so.

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 it at our address given above. These communications will be reviewed by one or more of our employees designated by our Board, who will determine whether they 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.

Code of Business Conduct and Ethics

In September 2014, our Board adopted a Code of Business Conduct and Ethics. This can be found on our website at www.pharmacyte.com and in Exhibit 14.1 to this Report. The information on, or that may be accessed through, our web site is not incorporated by reference into and should not be considered a part of this Report.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

The following discussion and analysis describes our executive compensation philosophy, components and policies, including analysis of the compensation earned by our named executive officers ("Named Executive Officers") during the period covered by this Report.

The following executives were our Named Executive Officers for the period ended April 30, 2016:

Name	Position
Kenneth L. Waggoner, JD	Chief Executive Officer, President and General Counsel
Gerald W. Crabtree, PhD	Chief Operating Officer

This discussion and analysis is comprised of the following sections explaining the decisions that we made in determining the compensation for each Named Executive Officer:

- Executive Summary: Highlights our compensation philosophy and elements;
- Compensation Philosophy and Objectives: Discusses the philosophy behind our compensation practices;
- Compensation Process: Discusses how each element of compensation is determined; and
- Elements of Executive Compensation and Analysis: Provides greater detail on each element of compensation and the individual compensation of each Named Executive Officer.

Executive Summary

The Compensation Committee is responsible for assisting the Board in determining executive officer compensation and overseeing and reporting to the Board as appropriate on our compensation and benefit policies, programs and plans, including our stock-based compensation programs. The Compensation Committee is also responsible for engaging and evaluating any compensation consultants, independent counsel and other advisers used to assist in the evaluation of director or executive compensation. We have not engaged a compensation consultant, but we plan to do so before the end of our fiscal year for the period ended April 30, 2017.

In making our determination with respect to the compensation of each Named Executive Officer, the Compensation Committee considers, among other things, the performance of each Named Executive Officer in advancing the goal we have set for the Company and the implementation of the strategies to achieve that goal. In making its determination with respect to the compensation of the Named Executive Officers, the Compensation Committee also takes into account the recommendations of the Chief Executive Officer (with respect to Named Executive Officers other than himself). The Compensation Committee makes all final decisions with respect to compensation of our Named Executive Officers.

We compensate our Named Executive Officers through: (i) base salary; and (ii) long-term equity compensation in the form restricted common stock and options to purchase common stock. Our executive compensation program is designed to attract, retain and motivate talented executive officers who are capable of providing leadership, innovation and implementation necessary to achieve our corporate objectives. The Compensation Committee believes that Named Executive Officer compensation should align the interests of the Named Executive Officers with those of our stockholders and provide individual Named Executive Officers with the opportunity to earn compensation at levels that are competitive with executives in comparable jobs at comparable companies within our industry. We plan to undertake a compensation peer review process before the end of our fiscal year for the period ended April 30, 2017 to determine our place within the compensatory practices and levels in our industry.

Actions that the Compensation Committee took during the period covered by this Report with respect to the Named Executive Officers are summarized below.

- Base Salaries. The Compensation Committee considered increasing the base salary of each Named Executive Officer, but deferred doing so until a compensation peer review process could be completed; and
- Long-term Equity Compensation. The Compensation Committee determined that Mr. Waggoner's stock options should be changed from an annual grant of 2,400,000 options to a grant of 6,000,000 options for this year only. The Compensation Committee also determined that Dr. Crabtree's stock options should be changed from an annual grant of 2,400,000 options to a grant of to a grant of 4,800,000 options for this year only. Corresponding amendments were made to the employment agreement of each such Named Executive Officer.

Compensation Philosophy and Objectives

The Compensation Committee believes that the compensation packages provided to our Named Executive Officers should typically include both cash and, when appropriate, stock-based compensation and should, in part, be correlated with our results to reward performance as measured against certain goals. Since we are a clinical stage biotechnology company, it is difficult to measure performance on a predetermined set of operational goals. Thus, we measure the performance of our Named Executive Officers based upon the progress being made to enter the clinic with our leading product candidate and the progress being made in the preclinical studies underway for our other product candidates.

In setting the compensation for our Named Executive Officers during the period of this Report, the Compensation Committee:

- Assessed the performance of the Named Executive Officers and considered the scope of responsibility and strategic impact of their respective roles within our company;
- Emphasized performance-based compensation to motivate our Named Executive Officers to achieve our business objectives and align their compensation with their performance; and
- Assessed whether our Named Executive Officers had sufficient equity interests in our company to ensure their alignment with stockholder interests.

Compensation Process

The Compensation Committee met to review the compensation of the Named Executive Officers in December 2015 and decided to defer increasing the base salary of the Named Executive Officers under their existing compensation agreements until after a compensation peer review could be performed. However, the Compensation Committee decided to increase the stock option compensation component of the equity based compensation as an interim measure to more align compensation with other biotechnology companies like ours.

No Named Executive Officer provides input to the Compensation Committee in setting his own compensation. However, in making its determination with respect to the compensation of our Named Executive Officers, the Compensation Committee takes into account the recommendations of the Chief Executive Officer, who is responsible for annually evaluating the performance of the executive officers (except himself) and making recommendations to the Compensation Committee based on a review for the compensation of each Named Executive Officer. The Chief Executive Officer's recommendations are one factor the Compensation Committee considers in making final compensation decisions. However, the Compensation Committee makes all final decisions with respect to compensation of our Named Executive Officers.

Elements of Executive Compensation and Analysis of Compensation Decisions

The primary elements of compensation of our Named Executive Officers are described below.

Compensation Element	Purpose	Approach
Base Salary	Annual cash compensation for services rendered during the year.	Executive salary is based on a holistic assessment by the Compensation Committee of the scope of position, experience, overall contributions to our company's success and individual performance and may be outside of this range.
Long-term Equity Compensation	Stock options or restricted common stock that are designed to drive Named Executive Officers' focus on long-term growth and increased stockholder value.	Equity award grants are established based on a review and evaluation of the market data and corporate performance. Equity levels vary among participants based on position and current equity interests.

Currently, we have not adopted a cash bonus program for our Named Executive Officers. We are waiting until after a compensation peer review has been accomplished and plan to adopt this element of executive compensation, assuming such review would recommend the implementation of such a program. The Compensation Committee believes that such cash bonus, if any, will be linked to the achievement of pre-specified predetermined goals and objectives.

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities of our employees, including our Named Executive Officers. The Compensation Committee annually reviews and evaluates the base salaries of the Named Executive Officers for adjustments based on the scope of each executive officer's responsibilities, individual contribution, prior experience and sustained performance. Base salaries are also reviewed and adjusted, as deemed appropriate, in other circumstances, such as significant changes in responsibility. The Named Executive Officers are not contractually entitled to any specific base salary increase in any given year.

The following table sets forth the annual base salaries of the Named Executive Officers as of April 30, 2016 and April 30, 2015, as well as the percentage increase from Fiscal 2015 to Fiscal 2016:

Name	Fiscal 2015 Base Salary	Fiscal 2016 Base Salary	Percent Increase
Kenneth L. Waggoner, JD	$ 150,000.00	$ 195,000.00	30%
Gerald W. Crabtree, PhD	$ 140,000.00	$ 169,000.00	21%

The annual base salaries of the Named Executive Officers were increased because the Compensation Committee believed that such increase would bring their respective salaries more in line with base salary compensation in our industry.

Cash Bonus

Our Named Executive Officers do not participate in a cash bonus plan. However, in December 2015, the Compensation Committee awarded Mr. Waggoner a cash bonus of $15,000 and Dr. Crabtree a cash bonus of $13,000. The Compensation Committee deferred implementing a cash bonus plan until after a compensation peer review could be performed. Our plan is to use annual cash bonuses to compensate our Named Executive Officers and other key employees for the achievement of specified goals and objectives. However, we have not yet adopted this element of compensation for our Named Executive Officers.

Long-term Equity Compensation

We typically make equity awards to our officers as an incentive to align management's interests with that of our stockholders and to enhance long-term stockholder value. Equity awards are typically granted when the person is first hired, receives a promotion or other significant change in responsibility occurs. Thereafter, we make such awards once annually as a part of our equity compensation program determined by our Compensation Committee at or near the beginning of the fiscal year or any other reporting period.

Pursuant to an amendment to each Named Executive Officer's employment agreement, as described more fully below, on January 1, 2016, we granted 6,000,000 and 4,800,000 options to Mr. Waggoner and Dr. Crabtree, respectively. Each grant of options has a term of five years, an exercise price of $0.063, (which represented the fair market value on the date of grant) and, subject to the Named Executive Officer's continued employment, $1/12^{th}$ of the grant vests monthly after the grant date. The rationale for the equity compensation was to bring the compensation of our Named Executive Officer more in line with industry standards. The vesting of the stock options was to incentivize our Named Executive Officers to remain employed during the term of their respective compensation agreements.

Pursuant to the compensation agreements with our Named Executive Officers, each of Mr. Waggoner and Dr. Crabtree received a restricted stock grant of 2,400,000 and 1,200,000 shares of our common stock, respectively, on January 1, 2016. Also pursuant to their respective employment arrangements, $1/12^{th}$ of each grant vests monthly after the grant date, subject to the Named Executive Officer's continued employment.

Compensation Agreements

We have entered into compensation agreements with each Named Executive Officer. These agreements were designed to be a part of a competitive compensation package for a publicly-traded company and to keep our Named Executive Officers focused on our business goals and objectives. These compensation agreements specify the Named Executive Officer's base salary and provide that the Named Executive Officer is eligible to receive certain payments and benefits if the Named Executive Officer's employment is involuntarily terminated under specified circumstances. We believe these protections are appropriate for the senior executives of a biotechnology company such as ours. We believe that providing severance protection in the event of a change of control of the Company allows our Named Executive Officers to focus their attention on building our business rather than on the personal implications of a transaction. These arrangements also serve as consideration for the post-termination non-competition and non-solicitation covenants we require from each of our Named Executive Officers.

In December 2015, we entered into an amendment agreement with each Named Executive Officer to eliminate the annual grant of 2,400,000 options to each Named Executive Officer and to provide for a one-time grant of 6,000,000 and 4,800,000 options to Mr. Waggoner and Dr. Crabtree, respectively. These option grants were made on January 1, 2016.

The compensation agreements for each of our currently employed Named Executive Officers are described in detail in the narrative disclosure following the Summary Compensation Table below under the heading "*Employment Arrangements."*

Benefits and Other Compensation

We have not yet established any benefit plans for our Named Executive Officers. When we do so, we believe that each Named Executive Officer will be eligible to participate in each of our employee benefit plans, in each case, on the same general basis as other employees.

As described more fully under the heading "*Employment Arrangements,"* our Named Executive Officers are entitled to receive tax gross-ups to offset the effect of any excise tax imposed under Section 280G of the Code in the event that a Named Executive Officer's compensation in connection with a change in control is subject to an excise tax.

Federal Tax Considerations under Section 162(m)

Section 162(m) of the Internal Revenue Code ("Code") disallows a federal income tax deduction to any publicly traded corporation for any remuneration in excess of $1.0 million of compensation paid to specified executive officers in a calendar year. Compensation in excess of $1.0 million may be deducted if, among other things, it qualifies as performance-based compensation within the meaning of Section 162(m). We expect that our Compensation Committee will periodically consider the potential consequences of Section 162(m) on the various elements of our executive compensation program. In its judgment, where the Compensation Committee determines it is reasonably practicable and consistent with our overall compensation program objectives, it will seek to structure the equity incentives component of our executive compensation program to comply with the exemptions in Section 162(m). However, we do not consider Section 162(m) to be a priority for us given the levels of compensation we pay to our Named Executive Officers. Additionally, now and in the future, the Compensation Committee will retain the discretion and flexibility to pay compensation in excess of the limit impose under Section 162(m).

The following tables provide information about all compensation earned during our fiscal years ended April 30, 2016, 2015 and 2014 by our named executive officers and directors, respectively. There were no forms of compensation provided to our directors or officers in the form of health or life insurance benefits, options plans, car or other allowances or key-man life insurance that are not shown below.

Named Executive Officers

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	2016	$ 195,000	$ 190,320	$ 276,058	$ 661,378
		2015	$ 150,000	$ 450,150	$ 778,172	$ 1,378,322
		2014	$ 50,000	$ 3,180,000		$ 3,230,000
Gerald W. Crabtree, PhD(2)	Chief Operating Officer	2016	$ 169,000	$ 95,160	$ 256,356	$ 525,516
		2015	$ 140,000	$ 242,860	$ 778,172	$ 1,161,032
		2014	$ 59,830	$ 3,338,380		$ 3,398,210

(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 7 and Note 9 of the Consolidated Financial Statements to this Report.

(2) We did not pay or accrue any other compensation, in the form of bonus, incentive plan compensation or nonqualified deferred compensation earnings to any executive officer for services as an executive officer during the fiscal years ended April 30, 2016 and 2015; neither were there any prerequisites or other personal benefits. We do not have any 401(k) plan or other retirement plan at the present time.

Grants of Plan-Based Awards

Name	Grant Date	Estimated future payouts under non-equity incentive plan awards: Threshold ($)	Target ($)	Maximum ($)	Estimated future payouts under equity incentive plan awards: Threshold ($)	Target ($)	Maximum ($)	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/SH)	Grant Date Fair Value of Stock and Option Awards
Kenneth L.	1/1/2016	$ –	$ –	$ –	$ –	$ –	$ –	2,400,000			$190,680
Waggoner		$ –	$ –	$ –	$ –	$ –	$ –		6,000,000	$ 0.063	$378,000
Gerald W.		$ –	$ –	$ –	$ –	$ –	$ –	1,200,000			$ 95,340
Crabtree	1/1/2016	$ –	$ –	$ –	$ –	$ –	$ –		4,800,000	$ 0.063	$302,400

(1) The amounts in the column under "All Other Stock Awards" represent shares of restricted stock that vest over time. Subject to the Named Executive Officer's continued employment, 1/12th of the grant vests monthly after the grant date.

(2) The amounts in the column under "All Other Option Awards" represent shares underlying options awarded, each of which has a term of five years and vests over time. Subject to the Named Executive Officer's continued employment, 1/12th of the grant vests monthly after the grant date.

(3) The amounts in the column under "Grant Date Fair Value of Stock and Option Awards" with respect to stock awards and option awards reflect the grant date fair values of such awards made during the identified fiscal year, as computed in accordance with FASB ASC Topic 718 and the assumptions stated in footnote #9 of the Consolidated Financial Statements to this Report.

Outstanding Equity Awards at Fiscal Year End

	Option awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	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	03/20/2020	1,800,000	$ 122,400	–	$ –
	2,400,000	–	–	$ 0.110	03/20/2020	–	$ –	–	$ –
	6,000,000	4,000,000	–	$ 0.063	12/31/2020	–	$ –	–	$ –
Gerald W. Crabtree	10,000,000	–	–	$ 0.110	03/20/2020	900,000	$ 61,200	–	$ –
	2,400,000	–	–	$ 0.110	03/20/2020	–	$ –	–	$ –
	4,800,000	3,200,000	–	$ 0.063	12/31/2020	–	$ –	–	$ –

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

(2) The market value is based on the closing stock price of $0.068 on April 29, 2016, the last day of trading in this fiscal year.

Option Exercises and Stock Vested

	Option awards		Stock Awards	
Name	Number of Shares Acquired on Exercise	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)(1)
Kenneth L. Waggoner	–	$ –	2,400,000	$ 190,680
Gerald W. Crabtree	–	$ –	1,200,000	$ 95,340

(1) The value realized on vesting on stock awards is based on the closing price of our common stock on each applicable date of vesting.

Employment Arrangements

Kenneth L. Waggoner, JD

Effective as of January 1, 2015 ("Commencement Date"), we entered into an Executive Compensation Agreement with Mr. Waggoner ("Waggoner Compensation Agreement"). The Waggoner Compensation Agreement is for a term of two years 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 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 Viridis Biotech. Mr. Waggoner will be paid a base salary of $180,000 subject to annual increases in the discretion of our Compensation Committee. The Waggoner Compensation Agreement also provides that, during his continued employment, Mr. Waggoner would receive annual stock grants of 2,400,000 shares on each anniversary of the Commencement Date. Each such grant would, subject to his continued employment, vest as to 600,000 each quarter. The Waggoner Compensation Agreement also provided that Mr. Waggoner would receive annual option grants with respect to 2,400,000 shares; however, on December 30, 2015, we entered into Amendment No. 1 to the Waggoner Compensation Agreement, which eliminated this annual grant and provided Mr. Waggoner with a one-time grant of 6,000,000 stock options. This option was granted on January 1, 2016, has a term of five years, an exercise price of $0.063, (which represented the fair market value on the date of grant) and vests at the rate of 500,000 shares per month, subject to Mr. Waggoner's continued employment. 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 the any unvested stock or option awards and (iv) continued health coverage and life insurance coverage, if any, for 12 months at the Company's expense. Additionally, if Mr. Waggoner terminated his employment prior to the 2 nd anniversary of the Commencement Date, he will be obligated to remain as a consultant to the Company until the 2nd anniversary of the Commencement Date.

Notwithstanding the foregoing, if Mr. Waggoner's employment is terminated by us without cause or by him for good reason in connection with a "Change in Control" (as such term is defined in the Waggoner Compensation Agreement) then the base salary component of severance would be paid in lump sum. Additionally, 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 continuation and life insurance premium continuation, however, he 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 the Company's 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 (24) months after termination of employment.

Assuming one of the following events occurred on April 30, 2016, 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	–	–(3)	13,900 (4)	– (5)	20,000	122,400	156,300
Disability	–	–(3)	– (6)	–	–		–
Without Cause or for Good Reason	390,000(7)	–(3)	– (6)	–	20,000	122,400	532,400
Without Cause or for Good Reason in connection with a Change in Control	390,000(8)	–(3)	– (6)	– (9)	20,000	122,400	532,400
Change in Control (without termination)	–	–	–	–	–	–	–

(1) This amount represents the value of an option to purchase 4,000,000 otherwise unvested shares of our common stock, based on $0.068, the closing price of our Common Stock on April 30, 2016 and the exercise price of such option at $0.063 per share.

(2) This amount represents the value of 1,800,000 shares of otherwise unvested shares of our common stock, based on $0.068, the closing price of our Common Stock on April 30, 2016.

(3) There was no bonus payable to Mr. Waggoner in the 2016 fiscal year; nor did he have a target bonus for the 2016 fiscal year, accordingly, no severance would be payable under the Waggoner Compensation Agreement with respect to his bonus.

(4) This amount represent 12 months of Company paid health insurance continuation premiums for Mr. Waggoner's dependents.

(5) There was no life insurance policy for Mr. Waggoner in the 2016 fiscal year; accordingly, no life insurance benefits would be payable under the Waggoner Compensation Agreement.

(6) There were no life or health insurance policies for Mr. Waggoner in the 2016 fiscal year; accordingly, no life or health insurance continuation benefits would be payable under the Waggoner Compensation Agreement.

(7) 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.

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

(9) 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 his compensation arrangement. However, based on current estimates, the Company does 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, 2016. Accordingly, no gross-up would need to have been made.

Gerald W. Crabtree, PhD

Effective as of January 1, 2015 ("Commencement Date"), we entered into an Executive Compensation Agreement with Dr. Crabtree ("Crabtree Compensation Agreement"). The Crabtree Compensation Agreement is for a term of two years 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 Viridis Biotech. Dr. Crabtree will be paid a base salary of $156,000 subject to annual increases in the discretion of our Compensation Committee. The Crabtree Compensation Agreement also provides that, during his continued employment, Dr. Crabtree would receive annual stock grants of 1,200,000 shares on each anniversary of the Commencement Date. Each such grant would, subject to his continued employment, vest as to 300,000 each quarter. The Crabtree Compensation Agreement also provided that Dr. Crabtree would receive annual option grants with respect to 2,400,000 shares; however, on December 30, 2015, we entered into Amendment No. 1 to the Crabtree Compensation Agreement, which eliminated this annual grant and provided Dr. Crabtree with a one-time grant of 4,800,000 stock options. This option was granted on January 1, 2016, has a term of five years, an exercise price of $0.063, (which represented the fair market value on the date of grant) and vests at the rate of 400,000 shares per month, subject to Dr. Crabtree's continued employment. 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 and life insurance coverage, if any, for 12 months at the Company's expense. Additionally, if Dr. Crabtree terminated his employment prior to the 2nd anniversary of the Commencement Date, he will be obligated to remain as a consultant to the Company until the 2nd anniversary of the Commencement Date.

Notwithstanding the foregoing, if Dr. Crabtree's employment is terminated by us without cause or by him for good reason in connection with a "Change in Control" (as such term is defined in the Crabtree Compensation Agreement) then the base salary component of severance would be paid in lump sum. Additionally, 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 the Company's expense.

Additionally, 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 (24) months after termination of employment.

Assuming one of the following events occurred on April 30, 2016, 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	–	–(3)	– (4)	– (5)	16,000	61,200	77,200
Disability	–	–(3)	– (6)	–	–		–
Without Cause or for Good Reason	338,000(7)	– (3)	– (6)	–	16,000	61,200	415,200
Without Cause or for Good Reason in connection with a Change in Control	338,000(8)	–(3)	– (6)	0 (9)	16,000	61,200	415,200
Change in Control (without termination)	–	–	–	–	–	–	–

(1) This amount represents the value of an option to purchase 4,000,000 otherwise unvested shares of our common stock, based on $0.068, the closing price of our Common Stock on April 30, 2016 and the exercise price of such option at $0.063 per share.

(2) This amount represents the value of 1,800,000 shares of otherwise unvested shares of our common stock, based on $0.068, the closing price of our Common Stock on April 30, 2016.

(3) There was no bonus payable to Dr. Crabtree in the 2016 fiscal year, nor did he have a target bonus for the 2016 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 in the 2016 fiscal year; accordingly, no health insurance continuation premiums benefit would be payable under the Crabtree Compensation Agreement.

(5) There was no life insurance policy for Dr. Crabtree in the 2016 fiscal year; accordingly, no life insurance benefits would be payable under the Dr. Crabtree Compensation Agreement.

(6) There were no life or health insurance policies for Dr. Crabtree in the 2016 fiscal year; accordingly, not life or health insurance continuation benefits would be payable under the Crabtree Compensation Agreement.

(7) 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.

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

(9) If Dr. Crabtree 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 his compensation arrangement. However, based on current estimates, the Company does 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, 2016. Accordingly, no gross-up would need to have been made.

Directors

The following table sets forth information concerning compensation paid or to our non-employee directors during the year ended April 30, 2016.

Director Compensation

Directors:

Name	Salary ($)	Stock Awards Shares	Stock Value ($)	Option Awards ($)	Total ($)
Richard Goldfarb, MD(1)	$ 9,000				$ 9,000
Thomas Liquard	$ 36,000				$ 36,000

(1) Dr. Goldfarb ceased to be a director on September 28, 2015, the effective date of his resignation from the Board.

Non-employee members of our Board were previously compensated for performance of their duties as directed by the Chairman of the Board, in her discretion. Until April 27, 2015, the Board had not set a fixed compensation plan for the non-employee directors, but chose to review Board and individual director performance on an annual basis with non-employee director compensation being earned on a merit-system, as determined by the Chairman of the Board. Effective April 27, 2015, the Board approved a compensation plan for the non-employee directors. The plan commenced April 1, 2015 and continues until such director's resignation or removal or until a successor director is duly elected and qualified. Mr. Liquard is to receive $9,000 per quarter on a pro-rated basis for periods of less than a quarter. In addition, Mr. Liquard received an option to purchase 250,000 shares of our common stock at an exercise price equal to the fair market value of our common stock on the date of the grant of the option. Dr. Goldfarb received $9,000 with respect to his service for the first quarter of the 2016 fiscal year.

Non-employee directors do not receive any additional compensation for participation in either board or committee meetings.

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

The following table sets forth as of April 30, 2016, 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	Number of Shares Beneficially Owned (1)	Percentage of Common Stock (1)
Kenneth L. Waggoner, JD, Chairman of the Board, Chief Executive Officer, President and General Counsel	15,900,000	2.04%
Gerald W. Crabtree, PhD, Chief Operating Officer and Board Member	13,800,000	1.77%
Richard Goldfarb, MD, FACS, Former Board Member	(2)	
Thomas Liquard, Board Member	0	
All directors and executive officers as a group (4 persons)	29,700,000	3.80%

(1) Percentages based on 781,233,338 shares of common stock issued and outstanding as of April 30, 2016.

(2) Effective September 28, 2015, Dr. Goldfarb resigned from the Board. We believe that Dr. Goldfarb has sold some of the shares he was awarded during his tenure with us. We have no information as to the number of shares he has sold.

The address of all beneficial owners is 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. 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 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, 2016:

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	0	0	0
Equity compensation plans not approved by security holders	32,400,000	$0.10	10,400,000
Total	32,400,000	$0.10	10,400,000

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

We had the following related party transactions:

As of April 30, 2016, 2015 and 2014, we owed Berkshire Capital $0, $0 and $0, respectively, for operating expenses. Berkshire Capital was, at certain times when such amounts were outstanding, the holder of more than 5% of our outstanding shares of common stock. The highest amount outstanding during the fiscal year ended April 30, 2015 and 2014 were $0 and $471,011, respectively. All loans bear interest at 6% and were due within one to three years. During the fiscal year ended April 30, 2014, we repaid $471,011 of principal and $30,195 in accrued interest with the issuance of 26 million shares of common stock.

During the year ended April 30, 2016, we issued stock options to directors and officers (see Note 10 of the consolidated financial statements).

With the exception of Mr. Liquard, our Board has determined that none of our directors satisfies the definition of an “Independent Director” as established in the NASDAQ Stock Market Rules (“Independent Director”). Mr. Liquard has been determined by our Board to be an Independent Director.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

A summary of the fees billed by our former independent audit firm, RHC for professional services rendered for fiscal year ended April 30, 2014 and through the period ended January 31, 2015 is set forth below. A summary of the fees billed by our former independent audit firm, FHH, for professional services rendered for fiscal year ended April 30, 2015, and through the period ended October 31, 2015 is set forth below. A summary of the fees billed by our current independent audit firm, Armanino, for professional services rendered through the year ended April 30, 2016 is set forth below.

Service	2016	2015
Audit Fees (total)	$ 118,728	$ 63,750
Audit Fees	$ 62,375	$ 40,000
Quarterly Review Fees	$ 56,353	$ 23,750
Tax Fees	$ 6,500	$ 6,500
All Other Fees	$ –	$ –
Total	$ 125,228	$ 70,250

During the year ended April 30, 2015, the Company paid RHC approximately $40,000 in annual audit fees and $23,750 in quarterly review fees. During the year ended April 30, 2016, the Company paid FHH $54,500 in annual audit fees and $6,000 in quarterly review fees. During the year ended April 30, 2016, the Company paid Armanino $7,875 in annual audit fees and $50,353 in quarterly review fees.

Our Chief Executive Officer, in consultation with our Vice President of Finance, pre-approves all services to be performed by our independent auditor. All of the services listed above have been pre-approved by him.

ITEM 15. EXHIBITS

(a) Documents filed as part of this Report:

(1) Financial Statements.

Our consolidated financial statements and schedule and consolidated notes thereto as of April 30, 2016, 2015 and 2014, and for each of the three years in the period ended April 30, 2016, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report.

(2) Financial Statement Schedules.

Schedule II - Valuation and Qualifying Accounts for the Years Ended 2016, 2015 and 2014 is incorporated by reference to page F-27 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	Asset Purchase Agreement, dated August 24, 2005, between PharmaCyte Biotech, Inc. (formerly Nuvilex, Inc., "Company") and Mark Taggatz.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on August 30, 2005.
2.2	Share Purchase Agreement, dated August 31, 2005, between the Company and Dr. Richard Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 7, 2005.
2.3	Addendum to Share Purchase Agreement, dated August 31, 2005, between the Company and Dr. Richard Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 7, 2005.
2.4	Share Exchange Agreement, dated January 12, 2009, between the Company and Freedom2 Holdings, Inc.	Incorporated by reference from the Company's Current Report on Form 10-K filed with the SEC on August 13, 2009.
2.5	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.
2.7	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 Registration Statement on Form.
3.4	Certificate of Amendment of Articles of Incorporation dated June 30, 2008.	Incorporated by reference from the Company's Registration Statement on Form.
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.

Exhibit No.	Description	Location
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.
4.3	Mutual Termination and Release Agreement dated as of May 28, 2014 between Lincoln Park Capital Fund, LLC and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 29, 2014.
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 June [ ] 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, 2005.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.3	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.

Exhibit No.	Description	Location
10.4	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.
10.5	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.
10.6	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.**
10.7	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.**
10.8	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.
10.9†	Memorandum of Understanding dated as of January 31, 2011 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.10†	Employment Agreement made the 31st day of January 2012 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.11	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.**
10.12	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.**
10.13	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.**
10.14	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.
10.15†	Settlement Agreement dated as of September 19, 2014, by and between PharmaCyte Biotech, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
10.16†	Asset Purchase Agreement dated as of September 19, 2014, by and between PharmaCyte Biotech, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.

Exhibit No.	Description	Location
10.17†	Consulting 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.
10.18†	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.
10.19†	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.
10.20†	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.
10.21†	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.
10.22†	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.
10.23†	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.
10.24†	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.
10.25†	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.
10.26†	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.
10.27†	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.
10.28†	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.
10.29†	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.
10.30	First Amendment to Licensing Agreement dated as of December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company, effective June 30, 2015.	Filed herewith.
10.31	Second Amendment to Licensing Agreement dated as of December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company, effective October 19, 2015.	Filed herewith.
10.32†	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.
10.33†	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.
10.34†	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.
10.35†	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.
10.36	Variation to License Agreement dated as of October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia, effective April 20, 2016.	Filed herewith.

Exhibit No.	Description	Location
10.37	First Amendment to Licensing Agreement dated as of June 25, 2013, between Austrianova and the Company, effective June 24, 2016.	Filed herewith.
10.38	Binding Memorandum of Understanding dated as of July 28, 2016, between the Company and Austrianova Singapore Pte Ltd.	Filed herewith.
14.1	PharmaCyte Biotech, Inc. Code of Business Conduct and Ethics.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
15(a)(2)	Schedule II - Valuation and Qualifying Accounts for the Years Ended April 30, 2016, 2015 and 2014.	Incorporated by reference to page F-27 of the financial statements included herewith.
21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of Armanino LLP	Filed herewith.
23.2	Consent of Farber Hass Hurley LLP	Filed herewith.
23.3	Consent of Robison, Hill & Co.	Filed herewith.
31.1	Certification of Chief Executive Officer (Principal Executive Officer and acting 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 and acting 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, 2015.	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-27 of this Report:

Schedule II — Valuation and Qualifying Accounts for the years ended April 30, 2016, 2015 and 2014.

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

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMACYTE BIOTECH, INC.

July 29, 2016 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer, Chairman of the Board and Director
(Principal Executive Officer and acting Principal Financial and Principal Accounting Officer on behalf of Registrant)

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.

July 29, 2016 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer, Chairman of the Board and Director
(Principal Executive Officer and acting Principal Financial and Principal Accounting Officer on behalf of Registrant)

July 29, 2016 By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, PhD, Director

July 29, 2016 By: /s/ Thomas Liquard
Thomas Liquard, Director

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of PharmaCyte Biotech, Inc., formerly known as Nuvilex, Inc. (the "Company"), as of April 30, 2016, and the related statements of operations, comprehensive loss, stockholders' equity (deficiency), and cash flows for the year ended April 30, 2016. Our audit also included the financial statement schedule listed in the Index as Item 15a(2). The Company's management is responsible for these consolidated financial statements and related financial statement schedule. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of PharmaCyte Biotech, Inc., as of April 30, 2016, and the results of its operations and its cash flows for the year ended April 30, 2016, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), PharmaCyte Biotech, Inc.'s, internal control over financial reporting as of April 30, 2016, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated July 29, 2016, expressed an adverse opinion.

/s/ ARMANINO LLP

San Ramon, California

July 29, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM[1]

To the Board of Directors and
Stockholders of PharmaCyte Biotech, Inc., formerly known as Nuvilex, Inc.

We have audited the accompanying consolidated balance sheet of PharmaCyte Biotech, Inc., formerly known as Nuvilex, Inc. (the Company) as of April 30, 2015, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficiency), and of cash flows for the year ended April 30, 2015. Our audit also included the financial statement schedule listed in the Index at Item 15a(2). PharmaCyte Biotech, Inc.'s management is responsible for these financial statements and schedule. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of PharmaCyte Biotech, Inc., formerly known as Nuvilex, Inc. as of April 30, 2015, and the results of its operations and its cash flows for the year ended April, 30, 2015, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), PharmaCyte Biotech, Inc., formerly known as Nuvilex, Inc.'s internal control over financial reporting as of April, 30, 2015, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated July 28, 2015, expressed an adverse opinion.

As discussed in Notes 1A, 2, 3, 7, 9, 13, 14 and 15 to the consolidated financial statements, the consolidated financial statements as of April 30, 2015 and for the year then ended have been restated to correct a misstatement.

/s/ Farber Hass Hurley LLP

Chatsworth, California
July 28, 2015 (Except for Notes 1A, 2, 3, 7, 9, 13, 14 and 15 as to which the date is January 19, 2016)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of
Nuvilex, Inc. and Subsidiaries, now known as PharmaCyte Biotech, Inc.

We have audited the accompanying consolidated statement of operations, comprehensive loss, stockholders' equity (deficiency) and cash flows of Nuvilex, Inc., now known as PharmaCyte Biotech, Inc., and Subsidiaries ("Company") as of April 30, 2014. Our audit also included the financial statement schedule listed in the Index at Item 15a(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements and schedule. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company and Subsidiaries as of April 30, 2014, and the results of its operations and its cash flows for the year ended April 30, 2014, are in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion, the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects the information set forth herein.

/s/ Robison, Hill & Co.
Certified Public Accountants
Salt Lake City, Utah
August 1, 2014

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
CONSOLIDATED BALANCE SHEETS

	April 30, 2016	April 30, 2015 (As Restated)
ASSETS		
Current assets:		
Cash	$ 1,920,825	$ 2,699,737
Prepaid expenses and other current assets	110,026	1,468,281
Total current assets	2,030,851	4,168,018
Other assets:		
Intangibles	3,549,427	3,549,427
Investment in SG Austria	1,572,193	1,572,193
Other assets	7,854	7,854
Total other assets	5,129,474	5,129,474
Total Assets	$ 7,160,325	$ 9,297,492
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 336,009	$ 496,699
Accrued expenses	151,630	23,667
License agreement obligation	150,000	1,000,000
Total current liabilities	637,639	1,520,366
Total Liabilities	637,639	1,520,366
Commitments and Contingencies (Notes 10 and 12)		
Stockholders' equity:		
Common stock, authorized 1,490,000,000 shares, $0.0001 par value, 781,233,338 and 732,760,536 shares issued and outstanding as of April 30, 2016 and 2015, respectively	78,127	73,273
Additional paid in capital	91,135,370	86,330,224
Accumulated deficit	(84,691,617)	(78,627,833)
Accumulated other comprehensive income	806	1,462
Total stockholders' equity	6,522,686	7,777,126
Total Liabilities and Stockholders' Equity	$ 7,160,325	$ 9,297,492

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

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30,		
	2016	2015 (As Restated)	2014
Revenue	$ –	$ –	$ –
Cost of revenue	–	–	–
Gross margin	–	–	–
Operating Expenses:			
Sales and marketing	–	230,500	872,200
Research and development costs	1,406,939	3,476,912	323,500
Compensation expense	1,871,795	6,489,334	13,609,995
Director fees	45,000	18,000	768,000
Legal and professional	458,397	884,346	1,487,668
General and administrative	2,291,002	2,161,643	1,917,779
Total operating expenses	6,073,133	13,260,735	18,979,142
Loss from operations	(6,073,133)	(13,260,735)	(18,979,142)
Other income (expense):			
Gain on forgiveness of debt	–	–	1,633,380
Loss on conversion of preferred stock	–	–	(5,895,000)
Loss on settlement of debt	–	–	(3,993,295)
Gain on settlements	–	3,337,967	–
Other income	10,540	–	–
Interest expense, net	(1,191)	(4,938)	(19,963)
Total other income (expense), net	9,349	3,333,029	(8,274,878)
Net loss	$ (6,063,784)	$ (9,927,706)	$ (27,254,020)
Basic and diluted loss per share	$ (0.01)	$ (0.01)	$ (0.05)
Weighted average shares outstanding basic and diluted	752,403,049	704,327,656	583,219,665

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

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

	Years Ended April 30,		
	2016	2015 (As Restated)	2014
Net Loss	$ (6,063,784)	$ (9,927,706)	$ (27,254,020)
Other comprehensive income (loss):			
Foreign currency translation adjustment	(656)	1,462	–
Other comprehensive income (loss)	(656)	1,462	–
Comprehensive loss	$ (6,064,440)	$ (9,926,244)	$ (27,254,020)

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

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)
YEARS ENDED APRIL 30, 2016, 2015 AND 2014

	Common stock		Paid in	Common Stock	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Capital	to be issued	Deficit	Income	(Deficiency)
Balance, April 30, 2013	**482,106,348**	**$ 48,211**	**$ 39,896,440**	**$ –**	**$ (41,446,107)**	**$ –**	**$ (1,501,456)**
Shares issued for compensation	44,370,000	4,437	13,329,351	–	–	–	13,333,788
Shares issued for Director fees	8,000,000	800	767,200	–	–	–	768,000
Shares issued for services	18,819,166	1,882	3,813,139	11,500	–	–	3,826,521
Shares issued for settlement of debt	28,670,600	2,868	4,780,803	–	–	–	4,783,671
Shares issued for cash	35,000,000	3,500	5,414,500	1,500,000	–	–	6,918,000
Conversion of warrants	19,649,600	1,965	1,527,555	63,360	–	–	1,592,880
Conversion of preferred stock	54,000,000	5,400	6,469,600	–	–	–	6,475,000
Net loss	–	–	–	–	(27,254,020)	–	(27,254,020)
Balance, April 30, 2014	**690,615,714**	**69,063**	**75,998,588**	**1,574,860**	**(68,700,127)**	**–**	**8,942,384**
Shares issued for compensation	7,200,000	720	734,468	–	–	–	735,188
Shares issued for services	8,446,650	845	1,280,362	(11,500)	–	–	1,269,707
Shares issued for cash	41,362,135	4,137	5,215,695	(1,500,000)	–	–	3,719,832
Conversion of warrants	1,078,000	108	129,253	(63,360)	–	–	66,001
Recovery of shares issued for compensation	(15,606,667)	(1,566)	(3,336,401)	–	–	–	(3,337,967)
Recovery of shares issued for consulting expense	(335,296)	(34)	(74,402)	–	–	–	(74,436)
Stock options granted	–	–	5,236,901	–	–	–	5,236,901
Warrants granted	–	–	1,145,760	–	–	–	1,145,760
Foreign currency translation adjustment	–	–	–	–	–	1,462	1,462
Net loss (As Restated)	–	–	–	–	(9,927,706)	–	(9,927,706)
Balance, April 30, 2015, as restated	**732,760,536**	**73,273**	**86,330,224**	**–**	**(78,627,833)**	**1,462**	**7,777,126**
Shares issued for compensation	4,800,000	480	404,600	–	–	–	405,080
Shares issued for services	750,000	75	47,925	–	–	–	48,000
Shares issued for cash	42,922,802	4,299	3,563,851	–	–	–	3,568,150
Stock options granted	–	–	788,770	–	–	–	788,770
Foreign currency translation adjustment	–	–	–	–	–	(656)	(656)
Net loss	–	–	–	–	(6,063,784)	–	(6,063,784)
Balance, April 30, 2016	**781,233,338**	**$ 78,127**	**$ 91,135,370**	**$ –**	**$ (84,691,617)**	**$ 806**	**$ 6,522,686**

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

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30,		
	2016	2015 (As Restated)	2014
Cash flows from operating activities:			
Net loss	$ (6,063,784)	$ (9,927,706)	$ (27,254,020)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock issued for services	491,684	826,023	17,928,309
Stock issued for compensation	405,080	735,189	–
Stock based compensation - options	788,770	5,236,901	–
Stock based compensation - warrants	905,340	240,420	–
Gain on settlements	–	(3,337,967)	–
Gain on recovery of stock issued for services	–	(74,436)	–
Loss on settlement of debt	–	–	3,993,295
Loss on conversion of preferred stock	–	–	5,895,000
Gain of forgiveness of debt	–	–	(1,633,380)
Change in assets and liabilities:			
(Increase) / decrease in prepaid expenses and current assets	9,231	450,849	(442,236)
Increase / (decrease) in accounts payable	(160,690)	308,654	(59,191)
Increase / (decrease) in accrued expenses	127,963	(18,096)	17,515
Increase / (decrease) in license agreement obligation	(850,000)	1,000,000	–
Net cash used in operating activities	(4,346,406)	(4,560,169)	(1,554,708)
Cash flows from investing activities:			
Purchase of intangibles	–	–	(3,500,000)
Payment towards lease deposit	–	–	(7,854)
Payments towards acquisition	–	–	(51,215)
Net cash used in investing activities	–	–	(3,559,069)
Cash flows from financing activities:			
Proceeds from sale of common stock	3,568,150	3,785,833	8,510,880
Proceeds from borrowings, related party	–	–	81,586
Repayment of debt, related party	–	(143,859)	(61,522)
Net cash provided by financing activities	3,568,150	3,641,974	8,530,944
Effect of currency rate exchange on cash	(656)	1,462	–
	–	–	–
Net increase (decrease) in cash	(778,912)	(916,733)	3,417,167
Cash at beginning of the year	2,699,737	3,616,470	199,303
Cash at end of the year	$ 1,920,825	$ 2,699,737	$ 3,616,470
Supplemental disclosures of cash flows information:			
Cash paid during the years for interest	$ 1,191	$ 45,141	$ 4,117
Non cash investing and financing activities:			
Common stock issued in settlement of debt	$ –	$ –	$ 765,981

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

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – NATURE OF BUSINESS

During 2013, the Company restructured its operations in an effort to focus on biotechnology, having been primarily a nutraceutical products company in the recent past. The restructuring resulted in the Company focusing all of its efforts upon the development of unique, effective and safe ways to treat cancer and diabetes. On January 6, 2015, the Company changed its name from Nuvilex, Inc. to PharmaCyte Biotech, Inc. to better reflect the nature of its business.

The Company is now a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®". This technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer, and diabetes are being developed.

On May 26, 2011, the Company entered into an Asset Purchase Agreement ("SG Austria APA") with SG Austria Private Limited ("SG Austria") to purchase 100% of the assets and liabilities of SG Austria. As a result, Austrianova and Bio Blue Bird AG ("Bio Blue Bird"), 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 Company's common stock and for the Company to receive 100,000 shares of Austrianova's common stock and nine Bio Blue Bird bearer shares.

Through two addenda to the SG Austria APA, the closing dates were extended.

In June 2013, the Company and SG Austria entered into a Third Addendum to the SG Austria APA ("Third Addendum"). Under the terms of the Third Addendum, the transaction contemplated by the SG Austria APA changed substantially. The Third Addendum provided that the Company acquire 100% of the equity interests in Bio Blue Bird and receive a 14.5% equity interest in SG Austria. In addition, the Company received nine bearer shares of Bio Blue Bird to evidence its 100% ownership. Under the Third Addendum, 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 its 14.5% equity interest. The Third Addendum returned the original 100,000,000 shares of common stock held by SG Austria to the Company treasury, and the 100,000 Austrianova shares of common stock held by the Company were returned to SG Austria.

Effective in June 2013, the Company and SG Austria entered into 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 the Company an exclusive, worldwide license to use, with a right to sublicense, the Cell-in-a-Box® technology for the development of treatments for cancer and use of Austrianova's Cell-in-a-Box® trademark and its associated technology.

Bio Blue Bird licenses certain types of genetically modified human cells ("Cells") from Bavarian Nordic A/S ("Bavarian Nordic") and GSF-Forschungszentrum für Umwelt u. Gesundheit GmbH (collectively, "Bavarian Nordic/GSF") pursuant to a License Agreement ("Bavarian Nordic/GSF License Agreement") to develop a therapy for cancer using encapsulated Cells. The licensed rights to the Cells pertain to the countries in which Bavarian Nordic/GSF obtained patent protection. Through the acquisition of Bio Blue Bird, the Third Addendum therefore provides the Company with an exclusive, worldwide license to use the Cell-in-a-Box® technology and trademark, with a right to sublicense, for the development of a therapy for cancer using the Cells.

In June 2013, the Company also acquired from Austrianova the exclusive, worldwide license to use the cellulose-based live cell encapsulation technology for the development of a treatment for diabetes and the use of Austrianova's "Cell-In-A-Box®" trademark for this technology ("Diabetes Licensing Agreement"). The Company made its first $1,000,000 payment to secure its exclusive, worldwide license to use the encapsulation technology for the treatment of diabetes on October 30, 2013. The second and final payment of $1,000,000 was made on February 25, 2014, thereby fulfilling all financial obligations required to be met by the Company under its licensing agreement with Austrianova.

In October 2014, the Company acquired from the University of Technology Sydney ("UTS") the exclusive license world-wide to use genetically modified cells ("Melligen Cells") that have been modified to produce, store and then release insulin "on demand" in developing a treatment for insulin-dependent diabetes ("Melligen Cells License Agreement"). In addition, the Company obtained the non-exclusive worldwide rights to "know-how" associated with the Melligen cells. The Company intends to use the Melligen cells, after they have been encapsulated using its Cell-in-a-Box® technology, as a treatment for insulin-dependent diabetes.

In December 2014, the Company acquired from Austrianova the exclusive, worldwide license to use the Cell-in-a-Box® technology in combination with compounds from constituents of *Cannabis* for development of disease treatments and the use of Austrianova's "Cell-in-a-Box®," trademark for this technology ("Cannabis Licensing Agreement"). As of April 30, 2016, the Company paid Austrianova $1.85 million of a $2.0 million "Upfront Payment" required by the Company to be made for this license. As of the date of this Report, the Company has paid $2.0 million of the Upfront Payment.

NOTE 1A – RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

The Company restated its consolidated financial statements as of and for the year ended April 30, 2015 on Form 10-K/A Amendment No. 3 filed on March 2, 2016 ("10-K/A") to correct certain errors in accounting for warrants and common stock. The nature and impact of the restated consolidated financial statements are detailed and explained in the 10-K/A. The amounts as of and for the year ended April 30, 2015 in the accompanying consolidated financial statements reflect the restated numbers, as previously reported in the 10-K/A.

NOTE 2 – LIQUIDITY AND MANAGEMENT PLANS

Liquidity

The Company's consolidated financial statements are prepared using United States ("U.S.") generally accepted accounting principles in the ("U.S. GAAP") applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. As of April 30, 2016, the Company has an accumulated deficit of $84,691,617 and incurred a net loss for year ended April 30, 2016 of $6,063,784.

Over the past year, funding was provided by investors to maintain and expand the Company. The remaining challenges, beyond the regulatory and clinical aspects, include accessing funding for the Company to cover its future cash flow needs. Over the past year, the Company continued to acquire funds through the Company's S-3 Registration Statement pursuant to which its exclusive placement agent, Chardan Capital Markets, LLC ("Chardan"), sells shares of common stock "at-the-market" in a program which is structured to provide up to $50 million dollars to the Company less certain commissions.

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 material 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. The Company believes that cash as of April 30, 2016 and the proceeds from the additional sale of registered and unregistered shares of its common stock will raise sufficient capital to meet its capital requirements. From May 1, 2016 through July 29, 2016; the Company raised additional capital of approximately $1 million in "at-the-market" transactions. The Company believes that sales of unregistered shares of its common stock any public offerings of common stock the Company may engage in will provide sufficient capital to fund its operations through July 31, 2017. However, the Company's ability to raise additional capital is limited by its inability to use a short form registration statement on Form S-3. As of July 29, 2016, the Company does not meet the eligibility requirements in order for it to be able to conduct a primary offering of its common stock under Form S-3 or to file a new Registration Statement on Form S-3. The Company may be able to regain the use of Form S-3 if it meets one or more of the eligibility criteria, including: (i) the aggregate market value of the Company's common stock held by non-affiliates exceeds $75 million; or (ii) the common stock is listed and registered on a national securities exchange.

If the Company is not able to raise substantial additional capital in a timely manner, the Company may not be able to commence or complete its planned clinical trials.

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

Management Goal and Strategies

The Company's goal is to become an industry-leading biotechnology company using the Cell-in-a-Box® technology as a platform upon which treatments for cancer and diabetes are developed and obtain marketing approval for these treatments from regulatory agencies in the U.S., the European Union, Australia and Canada.

The Company's strategies to achieve this goal consist of the following:

- The completion of clinical trials in locally advanced, inoperable non-metastatic pancreatic cancer and its associated pain;
- The completion of preclinical studies and clinical trials that will demonstrate the effectiveness of our cancer therapy in reducing the production and accumulation of malignant ascites fluid in the abdomen that is characteristic of pancreatic and other abdominal cancers;
- The completion of preclinical studies and clinical trials that involve the encapsulation of the Melligen cells using the Cell-in-a-Box® technology to develop a treatment for Type 1 diabetes and insulin-dependent Type 2 diabetes;
- The enhancement of the Company's ability to expand into the biotechnology arena through further research and partnering agreements in cancer and diabetes;
- The acquisition of contracts that generate revenue or provide research and development capital utilizing the Company's sublicensing rights;

- The further development of uses of the Cell-in-a-Box® technology platform through contracts, licensing agreements and joint ventures with other companies; and

- The completion of testing, expansion and marketing of existing and newly derived product candidates

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The Company operates independently and through 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 Securities and Exchange Commission ("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 evaluate 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 $2,000,0000 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, 2016, 2015 and 2014.

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, 2016, 2015 and 2014.

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 of time 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 Accounting Standards Codification subtopic 825-10, Financial Instruments, which permits entities to choose to measure many financial instruments and certain other items at fair value. Neither of these statements had an impact on the Company's financial position, results of operations or cash flows. 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 of 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, among other things, on 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 of our deferred tax assets, including tax loss carry forwards, that 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. If and 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 Company accounts for its uncertain tax positions in accordance with U.S. GAAP. The purpose of this method is to clarify accounting for uncertain tax positions recognized. 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.

Research and Development

Research and development 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.

Under the Cannabis Licensing Agreement, the Company acquired from Austrianova an exclusive, world-wide 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.*

Under the Cannabis Licensing Agreement, the Company is required to pay Austrianova an Upfront Payment of $2,000,000. The Company has 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 Payments must be paid in full by no later than June 30, 2016. As of April 30, 2016, the Company has paid Austrianova $1.85 million of the Upfront Payment. The $2 million cost of the license has been recorded as research and development costs during the year ended April 30, 2015.

Research and development costs for the years ended April 2016, 2015 and 2014 were $1,406,939, $3,476,912, and $323,500, 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, net of an estimated forfeiture rate. The Company estimates the fair value of stock options using a Black-Scholes-Merton valuation model, which 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. As a result, if factors change and the Company uses different assumptions, its 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 $1,656,000 and $2,331,000 at April 30, 2016 and 2015, respectively. The Company has not experienced any losses in such accounts, and 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 US 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.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09 " *Revenue from Contracts with Customers*" ("Topic 606"). Topic 606 supersedes the revenue recognition requirements in Topic 605, *"Revenue Recognition",* including most industry-specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments create a new Subtopic 340-40, *"Other Assets and Deferred Costs—Contracts with Customers".* In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. For a public entity, the amendments in this Update are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period; early application is not permitted. The Company is currently evaluating the impact this guidance will have on its consolidated financial position and consolidated statement of operations. In August 2015, the FASB issued ASU No. 2015-14, *Revenue with Customers – Deferral of the Effective Date*, as an amendment to ASU No. 2014-09, which defers the effective date of ASU No. 2014-09 by one year.

ASU No. 2014-15, *"Presentation of Financial Statements – Going Concern"*, Subtopic 205-40, *"Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern."* The amendments in this ASU apply to all entities and require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments: (i) provide a definition of the term *substantial doubt*; (ii) require an evaluation every reporting period including interim periods; (iii) provide principles for considering the mitigating effect of management's plans; (iv) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (v) require an express statement and other disclosures when substantial doubt is not alleviated; and (vi) require an assessment for a period of one year after the date that the financial statements are issued or available to be issued. The amendments in this update are effective for the annual period ending after December 15, 2016. For annual periods and interim periods thereafter; early application is permitted. The Company is currently evaluating the impact this guidance will have on its consolidated financial position and results of operations.

ASU No. 2015-07, *Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent)* ("ASU 2015-07"), was issued in May 2015. This ASU removes the requirement to categorize within the fair value hierarchy table investments without readily determinable fair values in entities that elect to measure fair value using net asset value per share or its equivalent. ASU 2015-07 requires that these investments continue to be shown in the fair value disclosure in order to allow the disclosure to reconcile to the investment amount presented in the balance sheet. An entity is required to adopt ASU 2015-07 for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company does not expect the adoption of this ASU to have a material impact on our consolidated financial statements.

ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"), was issued in November 2015. ASU 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. This ASU does not, however, change the existing requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount. The Company does not expect the adoption of ASU 2015-17 to have a material impact on the consolidated financial statements.

ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-2") was issued in February 2016, which provides guidance on lease amendments to the FASB Accounting Standard Codification. This ASU will be effective for us beginning in May 1, 2019. The Company does not expect the adoption of ASU 2016-2 to have a material impact on the consolidated financial statements.

NOTE 4 – BUSINESS ACQUISITION

In June 2013, the Company completed the purchase of Bio Blue Bird. Shares for both Austrianova and the Company originally held in escrow under the SG Austria APA were returned to the original owners. The 100,000,000 shares of the Company were cancelled. The acquisition was accounted for under ASC Topic 805, " *Business Combination*." Accordingly, the assets and liabilities were fair valued and purchase accounting applied.

The assets of Bio Blue Bird are licenses related to the Cell-in-a-Box® technology with a fair value of $1,549,427. The assets acquired were accounted for at the fair value at the acquisition date based on current information that management believes is reasonable. After the acquisition, Bio Blue Bird became a wholly-owned subsidiary of the Company.

Since the Company's acquisition of Bio Blue Bird, no revenues have been generated from the licenses; therefore, no pro-forma information has been prepared. The licenses will be used in the development of the Company's product candidate in advanced pancreatic cancer.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses at April 30, 2016 and 2015 are summarized below:

	2016	2015
Deferred rent	$ 371	$ 1,480
Payroll related costs	74,877	19,539
Other	76,382	2,648
Total	$ 151,630	$ 23,667

NOTE 6 – LICENSE AGREEMENT OBLIGATION

The Company entered into a licensing agreement for a license to use the Cell-in-a-Box® technology to develop therapies involving Cannabis for a total amount of $2,000,000 "Upfront Payment" for the license (see Note 12). At April 30, 2016 and 2015, the Company's license agreement obligations were $150,000 and $1,000,000, respectively.

NOTE 7 – COMMON STOCK TRANSACTIONS

During the year ended April 30, 2014, the Company issued 28,670,600 shares of common stock to settle debts of $985,518. The shares were valued using the closing share prices of the common stock of the day of issuances ranging from $0.08 to $0.18, resulting in a net loss on debt settlements of $3,798,153.

During the year ended April 30, 2014, a shareholder converted 8,500 shares of the Company's Series E Preferred Stock (see Note 9) into 54,000,000 shares of common stock. The shares were valued using the closing share price of the common stock on the day of issuance for a total of $6,475,000 resulting in a loss on conversion of $5,895,000.

During the year ended April 30, 2014, 52,370,000 shares of common stock were issued to officers and directors of the Company for compensation. These shares were valued using the closing share price of the common stock on the day of issuance for a total non-cash expense of $14,101,788.

During the year ended April 30, 2014, 13,756,666 shares of common stock were issued to consultants for services rendered to the Company. The shares were valued using the closing share price of the common stock price on the day of issuance for a total non-cash expense of $1,810,348. As of April 30, 2014, $528,808 of this expense had been deferred to prepaid expenses and will be expensed to future periods as determined by the term of each agreement.

During the year ended April 30, 2014, the Company sold 27,000,000 shares of common stock for $4,918,000. As of April 30, 2014, 17,000,000 of these shares had not yet been issued and were disclosed as common stock to be issued. The 17,000,000 shares were issued during the year ended April 30, 2015.

During the year ended April 30, 2014, the Company converted some of its Class A and Class B warrants into 19,649,600 shares of common stock for $1,592,880.

On February 14, 2014, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Lincoln Park initially purchased 8 million shares of common stock at $0.25 per share for $2 million and had committed to invest up to an additional $25 million of equity capital over the term of the purchase agreement. As consideration for its commitment to purchase shares of common stock pursuant to the purchase agreement, the Company issued to Lincoln Park 5,062,500 shares of common stock upon execution of the purchase agreement. These shares were valued at $0.169, the closing price of the stock on February 14, 2014, for non-cash expense of $855,653. On May 28, 2014 the Company and Lincoln Park executed a mutual termination and release agreement releasing all parties from certain obligation under the purchase agreement. As consideration for terminating the purchase agreement, the Company issued Lincoln Park an additional 1,062,500 shares of common stock. These shares were valued at $0.28 for total non-cash expense of $297,500.

During the year ended April 30, 2015, 300,000 shares of common stock were issued to an officer of the Company for compensation. The shares were valued using the closing share price of the common stock on the day of issuance for a total non-cash expense of $86,100.

During the year ended April 30, 2015, the Company sold 200,000 shares of common stock for $20,000.

During the year ended April 30, 2015, the Company converted some of its Class B warrants into 550,000 shares of common stock for $66,000.

During the year ended April 30, 2015, 17,628,000 shares of common stock were issued to fully satisfy all stock payables due in the amount of $1,574,860.

During the year ended April 30, 2015, the Company issued 1,700,000 shares of common stock to officers as part of their employment agreements. The shares were valued using the closing share price of the common stock on the date the accrual of the compensation for a total of a non-cash expense of $394,250.

During the year ended April 30, 2015, the Company, as a result of settlement agreements, accepted the return of 15,606,667 shares of its common stock from three officers. The Company adopted subtopic ASC 845-10-30 "*Treasury Stock Acquisition in Connection with a Settlement Agreement*" to account for the shares the Company received. The shares were valued at the closing price on date of their return. The Company recognized a non-cash gain equal to the fair value of the shares in the amount of $3,337,967 and is included in other income, net in the consolidated statements of operations.

During the year ended April 30, 2015, the Company entered into a mutual termination agreement with a consultant. The original consulting agreement called for the issuance of 800,000 shares. The mutual termination agreement resulted in a return of 335,296 shares of the 800,000 share issued. The Company adopted subtopic ASC 845-10-30 to account for the shares returned. The shares were valued at the closing price on the date the mutual termination agreement was signed. The Company recognized a non-cash gain of $74,436, which is included in consulting expense in the consolidated statements of operations.

During the year ended April 30, 2015, 400,000 shares of common stock were issued to two officers of the Company for compensation. The shares were valued using the closing share price of the common stock on the day of the issuance for a total non-cash expense of $87,200.

During the year ended April 30, 2015, the Company issued 7,284,150 shares of common stock to consultants. These share issuances resulted in a non-cash expense of $528,522 for the year end April 30, 2015 and $443,684 for the year ended April 30, 2016.

The Company issued 3,600,000 shares of common stock to officers as part of their compensation agreements in the year ended April 30, 2015. These shares vest on a quarterly basis over a twelve-month period. During the year ended April 30, 2015, 900,000 shares vested and the Company recorded a non-cash compensation expense of $125,460. During the year ended April 30, 2016, 2,700,000 shares vested and the Company recorded a non-cash compensation expense of $231,920. There were no unvested shares as of April 30, 2016 related to these compensation agreements.

The Company issued 1,200,000 shares of common stock to an employee as part of an employee agreement in the year ended April 30, 2015. These shares vest on a quarterly basis over a twelve-month period. During the year ended April 30, 2015, 300,000 shares vested and the Company recorded a non-cash expense of $41,820. During the year ended April 30, 2016, 900,000 shares vested and the Company recorded a non-cash expense of $73,310. There were no unvested shares as of April 30, 2016 related to this compensation agreement.

The Company awarded 3,600,000 shares of common stock to officers as part of their compensation agreements for 2016. These shares vest on a quarterly basis over a twelve-month period and are subject to their continuing service under the agreements. During the year ended April 30, 2016, the Company recorded a non-cash compensation expense in the amount of $71,880.

The Company awarded 1,200,000 shares of common stock to an employee as part of his compensation agreement for 2016. These shares vest on a quarterly basis over a twelve-month period and are subject to the employee providing services under the agreement. During the year ended April 30, 2016, the Company recorded a non-cash compensation expense in the amount of $23,960.

During the year ended April 30, 2016, the Company entered into a stock and warrant purchase agreement with two investors ("Stock and Warrant Purchase Agreements") and closed a private placement to them. Pursuant to the Stock and Warrant Purchase Agreements, the Company sold in equal amounts to each investor 8,500,000 unregistered shares of its common stock at a purchase price of $0.06 per share and warrants to purchase 8,500,000 unregistered shares of its common stock for gross proceeds of $1,020,000 (see Note 10).

During the year ended April 30, 2016, the Company issued 750,000 shares of common stock to consultants. The non-cash expense for these share issuances total $48,000. All shares were issued without registration under the Securities Act of 1933, as amended ("Securities Act"), in reliance upon the exemption afforded by Section 4(a)(2) of the Securities Act.

On October 28, 2014, the Company's Registration on Form 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, 2016 and 2015, the Company sold and issued approximately 25.9 and 24.2 million shares of common stock, respectively, at prices ranging from $0.06 to $0.24 per share. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately $6.25 million from the sale of these shares. The Company has filed a prospectus supplement for an "at-the-market" offering with an investment bank as sales agent. As of July 29, 2016, the Company does not meet the eligibility requirements in order for it to be able to conduct a primary offering of its common stock under Form S-3 or to file a new Registration Statement on Form S-3. See Note 2 for additional information.

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, 2016 are as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-vested, at April 30, 2013	–	$ –
Granted	79,419,803	0.23
Vested	(79,419,803)	0.23
Forfeited	–	–
Non-vested, at April 30, 2014	–	–
Granted	33,924,650	0.12
Vested	(30,324,650)	0.12
Forfeited	–	–
Non-vested, at April 30, 2015	3,600,000	0.14
Granted	22,550,000	0.06
Vested	(22,550,000)	0.06
Forfeited	–	–
Non-vested, at April 30, 2016	3,600,000	$ 0.06

NOTE 8 – PREFERRED STOCK

The Company has one authorized series of preferred stock designated as "Series E Preferred Stock." The Series E Preferred Stock has the following features:

- Series E Preferred Stock authorized shares 10,000,000 par value $0.0001;
- Series E Preferred Stock shares issued, zero and shares outstanding, zero;
- Series E Preferred Stock does not bear any dividends;
- Each share of Series E Preferred Stock is entitled to receive its share of assets distributable upon the liquidation, dissolution or winding up of the affairs of the Company. The holders of the Series E 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 Preferred Stock;
- Each share of Series E 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 Preferred Stock is entitled to 50,000 votes for each share of Series E Preferred Stock, with the same and identical voting rights as a holder of a share of common stock.

During the year ended April 30, 2014, a shareholder converted 8,500 shares of the Company's Series E Preferred Stock (consisting of all outstanding shares of Series E Preferred Stock) into 54,000,000 shares of common stock. These shares were valued using the closing share price of the common stock on the day of issuance for a total of $6,475,000 resulting in a loss on conversion of $5,895,000. There are no shares of Series E Preferred Stock currently outstanding.

Holders of Series E Preferred Stock have specific rights to be paid in cash out of the assets of the Company prior to any junior class of common stock. As a result of the obligations for Series E Preferred Stock, the Company has determined these redemption features have the potential to be outside the control of the Company and, therefore, the Company has classified the Series E Preferred Stock outside of shareholders' equity in accordance with ASC 480 regarding instruments with debt and equity features

NOTE 9 – STOCK OPTIONS AND WARRANTS

Stock Options

The Company granted stock options to its directors, officers and an employee during the years ended April 30, 2016, 2015 and 2014, based on compensation and director agreements.

The Company has adopted the provisions of ASC 718, "*Compensation-Stock*," which requires the measurement and recognition of compensation expense for all stock-based awards made to employees.

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

	April 30,		
	2016	2015	2014
Risk-free interest rate	2%	2%	–
Expected volatility	140%	145%	–
Expected lives (years)	3.0	2.7	–
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, 2016, 2015 and 2014, the Company used a calculated volatility for each grant. The Company lacks adequate information about the exercise behavior at this time 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.

Presented below is the Company's stock option activity for officers, directors and employees.

A summary of the Company's stock option activity and related information for the three years ended April 30, 2016 are shown below:

	Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value per Share
Outstanding, April 30, 2013	–	$ –	$ –
Issued	–	–	–
Exercised	–	–	–
Outstanding, April 30, 2014	–	–	–
Issued	52,450,000	0.15	0.11
Exercised	–	–	-
Outstanding, April 30, 2015	52,450,000	0.15	0.11
Issued	15,600,000	0.06	0.05
Exercised	–	–	–
Outstanding, April 30, 2016	68,050,000	0.13	0.10
Exercisable, April 30, 2016	57,650,000	$ 0.14	–
Vested and expected to vest	68,050,000	$ 0.13	$ –

A summary of the activity for unvested employee stock options during the three years ended April 30, 2016 is as follows:

	Options	Weighted Average Grant Date Fair Value per Share
Non-vested, April 30, 2013	–	$ –
Granted	–	–
Vested	–	–
Forfeited	–	–
Non-vested, April 30, 2014	–	–
Granted	52,450,000	0.11
Vested	(45,850,000)	-
Forfeited	–	–
Non-vested, April 30, 2015	6,600,000	-
Granted	15,600,000	0.05
Vested	(11,800,000)	-
Forfeited	–	–
Non-vested, April 30, 2016	10,400,000	$ 0.05

The Company recorded approximately $789,000, $5,237,000 and $0 of non-cash charges related to the issuance of stock options to certain officers, directors and employees in exchange for services during the years ended April 30, 2016, 2015 and 2014, respectively. At April 30, 2016, there remained approximately $512,000 of unrecognized compensation expense related to unvested stock options granted to employees and directors, to be recognized as expense over a weighted-average period of one year. The non-vested options vest at 1,300,000 per month and are expected to be fully vested on December 31, 2016.

The following table summarizes ranges of outstanding stock options by exercise price at April 30, 2016:

	Exercise Price			
Exercise Price	$ 0.19	$ 0.11	$ 0.18	$ 0.063
Number of Options Outstanding	25,000,000	27,200,000	250,000	15,600,000
Weighted Average Remaining Contractual Life (years) of Outstanding Options	3.42	3.67	3.97	4.67
Weighted Average Exercise Price	$ 0.19	$ 0.11	$ 0.18	$ 0.063
Number of Options Exercisable	25,000,000	27,200,000	250,000	5,200,000
Weighted Average Exercise Price of Exercisable Options	$ 0.19	$ 0.11	$ 0.18	$ 0.063

The aggregate intrinsic value of outstanding options as of April 30, 2016 was approximately $85,800. This represents options whose exercise price was less than the closing fair market value of the Company's common stock on April 30, 2016 of approximately $0.069 per share.

Warrants

The warrants issued by the Company are classified as equity. 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 505-50 and ASC 505, as amended.

On January 21, 2014, the Company began the implementation of its "Warrant Conversion Program." The program consists of offering every holder of Class A warrants the ability to exercise their Class A warrants, with an exercise price of $0.075 per share, into shares of common stock and an equal number of new Class D warrants, with an exercise price of $0.25 per warrant share. As of April 30, 2016, 18,755,200 Class A warrants had been converted for total cash proceeds of $1,380,720 and conversion of $25,920 of debt to an officer. The Company has also begun to offer holders of its Class B warrants, with a conversion price of $0.12 per share, with the same terms. As of April 30, 2016, 2,318,000 Class B warrants had been exercised for total cash proceeds of $278,160. An aggregate of 18,755,200 Class D Warrants have been issued in connection with this program.

On September 1, 2014 the Company granted 854,308 Class D Warrants to purchase common stock as part of the Warrant Conversion Program. This resulted in an expense of $100,000 under a consulting agreement to facilitate the Warrant Conversion Program. This expense is included in general and administrative expense in the consolidated statements of operations.

On March 23, 2015, the Company granted 10,000,000 cashless warrants to acquire stock at an exercise price of $0.11 per share, which expire on March 23, 2020. These warrants were accounted for using the equity method and resulted in a non-cash expense of $791,506 and $122,764 for the years ended April 30, 2016 and 2015, respectively.

On March 23, 2015, the Company granted 5,000,000 warrants to acquire stock at an exercise price of $0.11 per share. The warrants expired on December 31, 2015 without the warrants being exercised. These warrants were accounted for using the equity method and resulted in a non-cash expense of $113,834 and $17,656 for the years ended April 30, 2016 and 2015, respectively.

On December 31, 2015, warrants to purchase 5,000,000 shares of unregistered common stock of the Company expired. The warrant agreement was dated March 23, 2015 and the terms stated the exercise price of warrants was $0.11 per share.

On January 7, 2016, the Company entered into Stock and Warrant Purchase Agreements with two investors and closed a private placement to them. Pursuant to the Stock and Warrant Purchase Agreements, the Company sold to the investors, in equal amounts, an aggregate of 17,000,000 shares of its unregistered common stock, and also sold to the investors, in equal amounts, unregistered warrants to purchase an additional total of 17,000,000 shares of its unregistered common stock, for $1,020,000 in aggregate gross proceeds. The terms of the Stock and Warrant Purchase Agreements for these warrants state the exercise price is $0.12 per share and the expiration date of these warrants is January 7, 2021. Using the Black Scholes warrant pricing model, the Company determined the aggregate value of these warrants to be approximately $967,000. These warrants have a cashless exercise feature.

A summary of the Company's warrant activity and related information for the three years ended April 30, 2016 are shown below:

	Warrants	Weighted Average Exercise Price
Outstanding, April 30, 2013	59,433,600	$ 0.125
Issued	–	–
Exercised	(1,768,000)	–
Outstanding, April 30, 2014	57,665,600	0.18
Issued	15,854,308	–
Exercised	(550,000)	–
Outstanding, April 30, 2015	72,969,908	0.17
Issued	17,000,000	–
Expired	(5,000,000)	–
Outstanding, April 30, 2016	84,969,908	–
Exercisable, April 30, 2016	84,969,908	$ 0.16

The following table summarizes additional information concerning warrants outstanding and exercisable at April 30, 2016:

Range of Exercise Prices	Number of Warrant Shares Exercisable at 04/30/2016	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.075, $0.11, $0.12, $0.18 and $0.25	84,969,908	2.55	0.16
Five Year Term - $0.075	1,056,000	1.45	
Five Year Term - $0.12	35,347,508	3.17	
Five Year Term - $0.18	19,811,200	1.67	
Five Year Term - $0.25	18,755,200	1.68	
Five Year Term - $0.11	10,000,000	3.90	
	84,969,908		

NOTE 10 – 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. However, in the past the Company has been the subject of litigation, claims and assessments arising out of matters occurring in its normal business operations. In the opinion of management, none of these had a material adverse effect on the Company's consolidated financial position, operations and cash flows.

A summary of past litigation and claims which have been resolved from January 1, 2012 to present follows:

During the period January 1, 2012 through March 31, 2013, Pauline M. Muggli ("Muggli"), doing business as Internet Pro Designs, and Ron Simper ("Simper") provided information technology consulting services ("IT Services") to the Company. Muggli submitted invoices to the Company for IT Services allegedly performed at the request of the Company in excess of $60,000 ("IT Invoices"). The Company disputed the IT Services and the amount of the IT Invoices. Effective October 23, 2013, the Company, Muggli and Simper entered into a settlement agreement pursuant to which the Company paid Muggli $3,000 in cash and issued 141,667 shares of common stock in exchange for a release of all claims that either Muggli or Simper have against the Company. The Company provided a similar release of all claims against Muggli and Simper. The settlement has been fully implemented. The cash consideration has been paid and the shares of common stock have been issued to Muggli and the mutual general releases are in effect.

Freedom-2, Inc. and The General Hospital Corporation ("General Hospital") are parties to a Master Agreement dated October 1, 1999 and associated License Agreement (collectively, "MGH Agreements"). Since entering into the MGH Agreements, Freedom-2, Inc. ("Freedom-2") became a wholly owned subsidiary of the Company. General Hospital claimed that Freedom-2 owed General Hospital $69,095 under the MGH Agreements ("Debt"). The Company and Freedom-2 denied liability for the Debt, but elected to resolve the dispute without becoming involved in time consuming and costly litigation. Effective November 1, 2013, a settlement agreement was entered into between General Hospital, the Company and Freedom-2 pursuant to which all of the Company's rights to five patents related to permanent, removable tissue markings were transferred to General Hospital. In exchange, General Hospital provided a general release of all claims, including the Debt. The Company provided General Hospital a general release of all claims. The settlement has been consummated and the mutual general releases are in effect.

The Company's wholly owned subsidiary Freedom-2 and Brown University ("Brown") are parties to an intellectual property license agreement dated May 16, 2009 ("License Agreement"). Brown asserted a claim against the Company and Freedom-2 for $400,000 under the License Agreement. Although the Company and Freedom-2 denied liability, they nevertheless wanted to resolve the dispute without becoming embroiled in time consuming and costly litigation. Effective December 9, 2013 a settlement agreement was entered into between Brown the Company and Freedom-2 pursuant to which the parties released each other for all claims relating to the License Agreement. In addition, the Company agreed to issue 2,000,000 shares of common stock to Brown to consummate the settlement. The shares were valued at $0.11 per share. The shares of common stock have been issued and the settlement has been concluded.

NOTE 11 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions.

As of April 30, 2013, the Company owed Berkshire Capital $393,158 for operating expenses. Berkshire Capital was, at certain times when amounts were outstanding, the holder of more than 5% of our outstanding shares of common stock. The highest amount outstanding during the fiscal year ended April 30, 2014 was $471,011. All loans bear interest at 6% and were due within one to three years. During the fiscal year ended April 30, 2014, the Company repaid $471,011 of principal and $30,195 in accrued interest with the issuance of 26 million shares of common stock. The shares were issued at prices ranging from $0.14 to $0.18.

As of April 30, 2013, the Company owed the Company's former Chief Financial Officer and Chairman of the Board, Patricia Gruden, $23,200 in principal and $2,740 in interest for a total of $25,940, respectively, for a loan she made to the Company in 2011. The loan bore interest at 8% and was due on demand. During the year ended April 30, 2014, the Company paid the outstanding principal balance of $23,200 and accrued interest of $4,117.

As of April 30, 2013, the Company owed Robert F. Ryan ("Ryan"), the Company's former Chief Scientific Officer, $201,143 of principal and $20,171 of accrued interest on a loan that is due on demand and accruing interest at 8% per year. During the year ended April 30, 2014, the Company repaid $35,095 of principal in cash and converted $25,920 of principal to common stock. No payments were made towards accrued interest. As of April 30, 2014, the balance on this loan was $140,143 of principal and $33,960 of accrued interest. During the year ended April 30, 2015, the Company repaid an additional $20,000 of principal. Effective as of September 19, 2014, Ryan resigned from the Board and from his position as the Chief Scientific Officer of the Company. In connection with his departure, the Company entered into a settlement agreement pursuant to which the Company paid Ryan $183,000, which included accrued interest of $38,685 in settlement of the full amount of his loan.

The Company owns 14.5% of the equity in SG Austria and is reported on the cost method of accounting. The Company paid SG Austria a one-time manufacturing setup fee, as required by the Third Addendum, in two installments in the amounts of $323,500 and $323,500 in the years ended April 30, 2015 and 2014, respectively. In addition, SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand Ltd. The Company purchased products from these subsidiaries in the approximate amount of $364,000 and $63,000 in the years ended April 30, 2016 and 2015, respectively.

In April 2014, the Company entered into a consulting agreement with Vin-de-Bona Trading Company Pte Ltd ("Vin-de-Bona") pursuant to which Vin-de-Bona agreed to provide professional consulting services to the Company. Vin-de-Bona is owned by Prof. Walter H. Günzburg and Dr. Brian Salmons. 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 amount paid as of April 30, 2016 and 2015 are approximately $60,000 and $81,000. In addition, during the year ended April 30, 2016, the Company issued 250,000 shares to Dr. Salmons for his services on the Company's Scientific Advisory Board. During the year ended April 30, 2015, the Company has issued 500,000 shares of common stock in connection with Dr. Günzburg's services as the Chief Scientific Officer of the Company and 250,000 shares to Dr. Salmons for his services on the Company's Medical and Scientific Advisory Board.

Under the Cannabis Licensing Agreement, the Company acquired from Austrianova an exclusive, world-wide 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.*

Under the Cannabis Licensing Agreement, the Company is required to pay Austrianova an Upfront Payment of $2,000,000. The Company has 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, as amended, the Upfront Payments must be paid in full by no later than June 30, 2016. As of April 30, 2016 and 2015, the Company has paid Austrianova $1.85 million and $1 million of the Upfront Payment, respectively. During the year ended April 30, 2015, the $2 million cost of the license has been recorded as research and development costs (see Note 7).

During the years ended April 30, 2016 and 2015, the Company issued stock options to officers, directors and employees (see Note 10).

With the exception of Thomas Liquard, the Board has determined that none of the Company's directors satisfies the definition of Independent Director as established in the NASDAQ Marketplace Rules. Mr. Liquard has been determined by the Board to be an Independent Director.

NOTE 12 – COMMITMENTS AND CONTINGENCIES

The Company acquires assets still in development and enters into 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 in the event that regulatory approval for marketing is obtained.

Office Lease

The Company currently leases office space at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. The current lease is due to expire on July 31, 2016. Rent expense for the years ended April 30, 2016, 2015 and 2014 were $53,225, $49,250 and $49,085, respectively.

Year ending, April 30,	Amount
2017	$ 12,873
	$ 12,873

License Agreements

The Third Addendum

The Third Addendum 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 any sublicense or right to use the patents or the licenses granted by us or our affiliates;
- Milestone payments of $100,000 due 30 days after enrollment of the first human patient in the first clinical trial for each product; $300,000 due 30 days after enrollment of the first human patient in the first Phase 3 clinical trial for each product; and $800,000 due 60 days after having a marketing application approved by the applicable regulatory authority 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 marketing application approved by the applicable regulatory authority for each veterinary product.

In addition, the parties to the Third Addendum entered into a Manufacturing Framework Agreement pursuant to which the Company is required 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.

Diabetes Licensing Agreement

The Diabetes Licensing Agreement requires the Company to pay a fee for producing the final encapsulated cell product of $633.14 per vial of 300 capsules after production with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product (subject to adjustment for inflation per the terms of the Diabetes Licensing Agreement).

The Diabetes Licensing Agreement requires the Company to make future royalty and milestone payments as follows: (i) ten percent royalty of the gross sale of all products the Company sells; (ii) twenty percent royalty of the amount actually received by the Company from sub-licensees on sub-licensees' gross sales; (iii) milestone payments of $100,000 within 30 days of beginning the first pre-clinical experiments using the encapsulated cells; (iv) $500,000 within 30 days after enrollment of the first human patient in the first clinical trial; (v) $800,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial; and (vi) $1,000,000 due 60 days after having a marketing application approved by the applicable regulatory authority for each product.

Melligen Cell License Agreement

The Melligen Cell License Agreement does not require any "up-front" payment to UTS. The Company is required to pay to UTS a patent administration fee amounting to 15% on all amounts paid by UTS to prosecute and maintain patents related to the licensed property.

The Melligen Cell License Agreement requires that the Company pay royalty payments to UTS of (i) six percent gross exploitation revenue on product sales; and (ii) twenty-five percent of gross revenues if the product is sub-licensed by the Company. In addition, the Company is required to pay milestone payments of: (iii) AU$ 50,000 at the successful conclusion of clinical studies; (iv) AU$ 100,000 at the successful conclusion of Phase 1 clinical trials; (v) AU$ 450,000 at the successful conclusion of Phase 2 clinical trials; and (vi) AU$ 3,000,000 at the conclusion of Phase 3 clinical trials.

Cannabis Licensing Agreement

Under the Cannabis Licensing Agreement, the Company is required to pay Austrianova an Upfront Payment of $2,000,000. The Company has 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, as amended, the Upfront Payments must be paid in full by no later than June 30, 2016. As of the April 30, 2016, the Company has paid Austrianova $1.85 million of the Upfront Payment (see Note 7).

The Cannabis Licensing Agreement requires the Company to pay Austrianova, pursuant to a manufacturing agreement 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. As of April 30, 2016, the manufacturing agreement remains unsigned. In addition, the Cannabis Licensing Agreement requires the Company to pay a fee 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 (subject to adjustment for inflation per the terms of the Cannabis Licensing Agreement).

The Cannabis Licensing Agreement requires the Company to make future royalty and milestone payments as follows: (i) ten percent royalty of the gross sale of all products sold by the Company; (ii) twenty percent royalty of the amount actually received by the Company from sub-licensees on sub-licensees' gross sales value; (iii) a milestone payment of $100,000 within 30 days of beginning the first pre-clinical experiments using the encapsulated cells; (iv) a milestone payment of $500,000 within 30 days after enrollment of the first human patient in the first clinical trial; (v) a milestone payment of $800,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial; and (vi) a milestone payment of $1,000,000 due 90 days after having a marketing application approved by the applicable regulatory authority for each product.

Consulting Agreement with ViruSure

We have engaged ViruSure, a professional cell growing and adventitious agent testing company that has had extensive experience with the CYP2B1-expressing cells that will be needed for our pancreatic cancer treatment. We did so in order to recover them from frozen stocks of similar cells and regenerate new stocks for use by us in our preclinical studies and clinical trials. ViruSure is in the process of cloning new cells from a selected clone. Those clones will be grown to populate a Master Cell Band and a Working Cell Bank for our future clinical trials. There are approximately $171,000 in future milestone payments relating to testing to be completed.

Compensation Agreements

The Company entered into executive compensation agreements with its two executive officers and an employment agreement with one of its employees in March 2015, each of which was amended in December 2015. Each agreement has a term of two years. The Company also entered into a compensation agreement with a Board member in April 2015 which continues in effect until the member is no longer on the Board.

NOTE 13 - INCOME TAXES

At April 30, 2016, the Company had federal and state net operating loss carryforwards of $36,170,000 and $36,170,000, respectively, available to offset against future taxable income, which expire in 2019 through 2034.

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. As a result, 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, both current and long-term, are as follows:

	April 30,	
	2016	2015 (As Restated)
Deferred tax assets:		
Net operating loss carryforwards	$ 14,267,224	$ 13,118,046
Stock compensation	2,376,826	–
Other	29,682	8,291
Total deferred tax assets	16,673,732	13,126,337
Total deferred tax liabilities	–	–
Net deferred tax assets	16,673,732	13,126,337
Valuation allowance	(16,673,732)	(13,126,337)
	$ –	$ –

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, 2016 and 2015 were increases of $3,547,395 and $305,243, 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,		
	2016	2015 (As Restated)	2014
Federal benefit at statutory rate	$ (2,061,687)	$ (3,375,420)	$ (8,871,790)
State income taxes, net of Federal taxes	(330,173)	(540,564)	(1,420,791)
Permanent differences	711,316	1,433,758	644,287
Provision related to change in valuation allowance	3,547,395	305,243	364,071
Stock compensation	(2,065,695)	–	–
Return to provision	195,211	2,339,028	9,063,069
Other, net	3,633	(162,045)	221,154
	$ –	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended April 30, 2016.

The Company files income tax return in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2016, the tax returns for 2010 through 2015 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, 2016, 2015 and 2014, the Company had accrued no interest or penalties related to uncertain tax positions.

NOTE 14 – 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, 2016, 2015 and 2014, 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,		
	2016	2015 (As Restated)	2014
Net loss	$ (6,063,784)	$ (9,927,706)	$ (27,254,020)
Basic weighted average number of shares outstanding	752,403,049	704,327,656	583,219,665
Diluted weighted average number of shares outstanding	752,403,049	704,327,656	583,219,665
Basic and diluted loss per share	$ (0.01)	$ (0.01)	$ (0.05)

The table below sets forth these potentially dilutive securities:

	Years Ended April 30,		
	2016	2015	2014
Excluded options	68,050,000	52,450,000	0
Excluded warrants	84,969,908	72,969,908	57,665,600
Total excluded options and warrants	153,019,908	125,419,908	57,665,600

NOTE 15 – QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

	Quarter Ended July 31	Quarter Ended Oct 31	Quarter Ended Jan 31	Quarter Ended April 30
2016				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,514,311	1,635,818	1,792,151	1,130,853
Other income (expenses), net	(727)	236	1,054	8,786
Net loss	$ (1,515,038)	$ (1,635,582)	$ (1,791,097)	$ (1,122,067)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.00)	$ (0.00)	$ (0.00)

	Quarter Ended July 31	Quarter Ended Oct 31	Quarter Ended Jan 31	Quarter Ended April 30
2015				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,583,160	6,200,845	1,456,554	4,020,176
Other income (expenses), net	(1,664)	3,336,402	(1,496)	(213)
Net loss	$ (1,584,824)	$ (2,864,443)	$ (1,458,050)	$ (4,020,389)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.01)	$ (0.00)	$ (0.01)

Quarterly and year-to-date loss per share amounts are computed independently of each other. Therefore, the sum of the per share amounts for the quarters may not agree to the per share amounts for the year.

NOTE 16 – SUBSEQUENT EVENTS

From May 1, 2016 to July 29, 2016, the Company issued 66,821,327 shares of common stock under the S-3 Registration Statement. The issuance of the shares provided the Company approximately $1.33 million.

During May and June 2016, the Company made three payments of $50,000 to Austrianova pursuant to the Licensing Agreement that was entered into in December 2014. These payments settled the remaining Upfront Payment obligation under the licensing agreement in full.

PHARMACYTE BIOTECH, INC.
(FORMERLY NUVILEX, INC.)
SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS
Years Ended April 30, 2016, 2015 and 2014

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, 2016	$ 13,126,337	$ –	$ 3,547,395	$ –	$ 16,673,732
Year ended April 30, 2015 (As Restated)	$ 12,821,094	$ –	$ 305,243	$ –	$ 13,126,337
Year ended April 30, 2014	$ 12,457,023	$ –	$ 364,071	$ –	$ 12,821,094

EXHIBIT 10.30

First Amendment to Licensing Agreement

This First Amendment to Licensing Agreement ("First Amendment") is to memorialize the agreement between PharmaCyte Biotech, Inc., formerly Nuvilex, Inc. ("Licensee") and Austrianova Singapore Pte Ltd ("Licensor") to amend, effective as of June 30, 2015, the Licensing Agreement between the parties dated as of 1 December 2014 ("Licensing Agreement") as follows. The defined terms in the Licensing Agreement have the same meaning as the terms in this First Amendment.

A. The Parties entered into the Licensing Agreement to, among other things provide Licensee with an exclusive worldwide license to use the Cell-in-a-Box® Trademark and its Associated Technology with genetically modified non-stem cell lines specifically designed to activate members of the Cannabinoid family of molecules to: (i) conduct research; (ii) have made by Licensor; (iii) use in preclinical studies and clinical trials; (iv) obtain marketing approval; (v) and market and sell products and treatments utilizing the Cell-in-a-Box® Trademark and its Associated Technology world-wide;

B. The Licensing Agreement provides Licensee shall pay Licensor an initial payment ("Upfront Payment") of Two Million Dollars US (USD $2,000,000 .00. It further provides that Licensee shall 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; provided, however the Upfront Payment shall be paid in full by no later than June 30, 2015.; and

C. The Parties desire to extend the date by which the Upfront Payment must be made by Licensee.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties, the Research Agreement is hereby amended as follows:

1. Section 2.2 of the Licensing Agreement shall be deleted and the following inserted in its place: "Subject to the terms of this Agreement , Licensee shall pay Licensor an initial payment ("Upfront Payment") of Two Million Dollars US (USD $2,000,000.00). Licensee shall 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: provided, however, the Upfront Payment shall be paid in full by no later than December 31, 2015."

2. Section 8.1.2. of the Licensing Agreement shall be deleted and the following inserted in its place: "Similarly, the License may be terminated and all rights shall revert to Licensor if any of the following events do not occur within the timeframe set forth in this Agreement provided that Licensor gives Licensee thirty (30) days' notice prior to the effective date of termination and Licensee fails to cure the following events during the thirty (30) day period: (i) if Licensee fails to pay in full the Upfront Payment by December 31, 2015; (ii) if Licensee does not enter into a research program involving the Scope of the Agreement within three (3) years of the Effective Date; or (iii) if Licensee does not enter clinical trials or their equivalent for a Product within seven (7) years from the Effective Date."

3. Except as provided in this First Amendment , all of the other provisions of the Licensing Agreement shall remain in full force and effect.

IN WITNESS WHEREOF , each Party has executed this First Amendment by its duly authorized representative as of the date first written above.

PharmaCyte Biotech, Inc.

/s/ Kenneth L. Waggoner
By: Dr. Kenneth L. Waggoner
Title: Chief Executive Officer

Austrianova Singapore Pte Ltd

/s/ Brian Salmons
By: Dr. Brian Salmons
Title: Chief Executive Officer

EXHIBIT 10.31

Second Amendment to Licensing Agreement

This Second Amendment to Licensing Agreement ("Second Amendment") is to memorialize the agreement between PharmaCyte Biotech, Inc.,formerly Nuvilex, Inc. ("Licensee"), and Austrianova Singapore Pte Ltd ("Licensor") to amend, effective as of 19 October 2015, the Licensing Agreement between the Parties dated as of 1 December 2014 ("Licensing Agreement") as set forth below . Defined terms in the Licensing Agreement have the same meaning as the terms in this Second Amendment.

A. The Parties entered into the Licensing Agreement to, among other things, provide Licensee with an exclusive worldwide license to use the Cell-in-a-Box® Trademark and its Associated Technology with genetically modified non-stem cell lines specifically designed to activate members of the Cannabinoid family of molecules to: (i) conduct research; (ii) have made by Licensor; (iii) use in preclinical studies and clinical trials; (iv) obtain marketing approval; (v) and market and sell products and treatments utilizing the Cell-in-a-Box® Trademark and its Associated Technology world-wide;

B. The Licensing Agreement provides Licensee shall pay Licensor an initial payment ("Upfront Payment") of Two Million Dollars US (USD $2,000,000.00. It further provides that Licensee shall 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; provided, however the Upfront Payment shall be paid in full by no later than 30 June 2015 ;

C. Effective as of 30 June 2015, the Parties extended the date by which the Upfront Payment must be made by Licensee to 31 December 2015; and

D. The Parties desire to further extend the date by which the Upfront Payment must be made by Licensee to 30 June 2016.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties, the Research Agreement is hereby amended as follows:

1 .. Section 2.2 of the Licensing Agreement shall be deleted and the following inserted in its place: "Subject to the terms of this Agreement, Licensee shall pay Licensor an initial payment ("Upfront Payment") of Two Million Dollars US (USD $2,000,000.00). Licensee shall 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: provided, however, the Upfront Payment shall be paid in full by no later than 30 June 2016."

2. Section 8.1.2. of the Licensing Agreement shall be deleted and the following inserted in its place: "Similarly, the License may be terminated and all rights shall revert to Licensor if any of the following events do not occur within the timeframe set forth in this Agreement provided that Licensor gives Licensee thirty (30) days' notice prior to the effective date of termination and Licensee fails to cure the following events during the thirty (30) day period: (i) if Licensee fails to pay in full the Upfront Payment by 30 June 2016; (ii) if Licensee does not enter into a research program involving the Scope of the Agreement within three (3) years of the Effective Date; or (iii) if Licensee does not enter clinical trials or their equivalent for a Product within seven (7) years from the Effective Date."

3. Except as provided in this Second Amendment, all of the other provisions of the Licensing Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, each Party has executed this First Amendment by its duly authorized representative as of the date first written above.

PharmaCyte Biotech, Inc.

/s/ Kenneth L. Waggoner
By: Dr. Kenneth L. Waggoner
Title: Chief Executive Officer

Austrianova Singapore Pte Ltd

/s/ Brian Salmons
By: Dr. Brian Salmons
Title: Chief Executive Officer

EXHIBIT 10.36

UTS
UNIVERSITY OF TECHNOLOGY SYDNEY

20 April 2016

David Robson
Director
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Kenneth L. Waggoner
Chief Executive Officer and Director
Pharmacyte Biotech Australia Pty Ltd
Level 15
300 Queen Street
Brisbane, QLD 4001
Australia
By email: kwaggoner@PharmaCyte.com

RE: VARIATION TO LICENCE AGREEMENT DATED 10 OCTOBER 2014

Dear Ken,

We refer to recent discussions regarding the need to clarify several terms and correct the named Licensee in the License Agreement between University of Technology, Sydney and Pharmacyte Biotech Australia Pyt Ltd, formerly Nuvilex Australia Pty Ltd, made on 10 October 2014 ("License Agreement").

We confirm our agreement to vary the License Agreement as follows:

1. At **Item 2** of the Reference Schedule to replace the former name of the Licensee "Nuvilex Australia Pty Ltd" with its new name "Pharmacyte Biotech Australia Pty Ltd" and including the Australian Buisness Number after the name of the Licensee and to include the Australian Business Number (ABN 89 600 316 621) after the name of the Licensee.

2. At **Item 8** of the Reference Schedule in the column next to the words "Patent Administration Fee", the new wording to replace the current wording to be, "15% on all **Patent Costs** paid by University to prosecute and maintain patents related to Licensed Intellectual Property".

3. The **"Licensee"** (page 4) replace the former name "Nuvilex Australia Pty Ltd" with the new name "Pharmacyte Biotech Australia Pty Ltd" and replace Australian Company Number (ACN 600 316 621) with the Australian Business Number (ABN 89 600 316 621).

4. Insert a new definition **"Patent Costs** means any and all official fees from any patent administering office or bureau, any and all attorney fees charged in relation to the prosecution of any Patent in any jurisdiction, and any taxes or charges incurred or included in any invoice received by the Universtiy in relation to the Licensed Intellectual Property".

5. The following wording will replace the current wording of Clause 6.4. "Subject to Clause 6.5, the Licensee will decide which patents shall be maintained and will pay the University a Patent Administration Fee (Item 8) and all Patent Costs to administer the Intellectual Property on behalf of the Licensee."

In all other respects we confirm the terms and conditions of the Licnese Agreement.

In accordance with clause 18.8 of the Licence Agreement, your signature below will constitute written confirmation of this variation to the Licence Agreement dated 13 October 2014.

Signed for the University of Technology Sydney by:	Signed for Pharmacyte Biotech Australia Pty Ltd by:
Professor Glenn Wightwick Deputy Vice-Chancellor (Research) University of Technology Sydney Date: 27/4/2016	Kenneth L.Waggoner Chief Executive Officer and Director Pharmacyte Biotech Australia Pty Ltd Date: 27 April 2016

EXHIBIT 10.37

First Amendment to Licensing Agreement

This First Amendment to Licensing Agreement ("First Amendment") is to memorialize the agreement between PharmaCyte Biotech, Inc., formerly Nuvilex, Inc. ("Licensee"), and Austrianova Singapore Pte Ltd ("Licensor") to amend, effective as of 24 June 2016, the Licensing Agreement between the parties entered into as of June 25th, 2013 ("Licensing Agreement") as follows.

A. The parties entered into the Licensing Agreement to provide Licensee with an exclusive worldwide license to use the Cell-in-a-Box® Trademark and its Associated Technology with genetically modified non-stem cell lines and IPS stem cells specifically designed to produce insulin or other critical components for the treatment of diabetes to research, have made by Licensor, use in clinical trial, obtain market approval, market and sell products and treatments utilizing the Cell-in-a-Box® Trademark and its Associated Technology world-wide;

B. Section 8.1.2.1. of the Licensing Agreement provides that if Licensee does not enter into a research program with the technology in the scope of the license granted in the Licensing Agreement involving European academic university partners providing a total funding equal to or greater than US $400,000.00 within three year of the effective date of the Licensing Agreement, Licensor has the right to terminate the Licensing Agreement on the condition that Licensor provide Licensee 30 days' notice and the opportunity to cure Licensee's failure to meet this milestone event; and

C. The Parties desire to amend the provisions of Section 8.1.2.1. to expand the scope of the research program to include countries world-wide and not require the research program be limited to academic university partners.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties, the Research Agreement is hereby amended as follows:

1. Section 8.1.2.1. of the Licensing Agreement shall be deleted and the following inserted in its place: "If LICENSEE does not enter into a research program with the technology in the scope of the License providing a total funding equal to or greater than Four Hundred Thousand Dollars US (US $400,000.00) within three (3) years of the Effective Date; or"

2. Except as provided in this First Amendment, all of the other provisions of the Licensing Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, each party to the Licensing Agreement has executed this First Amendment by its duly authorized representative as of the date first written above.

PharmaCyte Biotech, Inc.

/s/ Kenneth L. Waggoner
By: Dr. Kenneth L. Waggoner
Title: Chief Executive Officer

Austrianova Singapore Pte Ltd

/s/ Brian Salmons
By: Dr. Brian Salmons
Title: Chief Executive Officer

EXHIBIT 10.38

BINDING MEMORANDUM OF UNDERSTANDING

This Binding Memorandum of Understanding ("MOU") is effective as of 28 July 2016 ("Effective Date") and entered into by and between PharmaCyte Biotech, Inc.("PharmaCyte"), a Nevada corporation with its principal place of business at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 USA, and Austrianova Singapore Pte Ltd ("Austrianova"), a Singapore corporation, with its principal place of business at 3 Biopolis Way #05-19, Synapase, Singapore, 138668. PharmaCyte and Austrianova are referred to in this MOU each as a "Party" and collectively as the "Parties."

RECITALS

A. The Parties desire to enter into a relationship pursuant to which they will, together with one or more third parties, develop, assess in clinical trials and manufacture and market various products for the treatment of cancer ("Products") in the Field (defined below) that utilize the cytochrome P450-based Technology (defined below). Except as otherwise provided in this MOU, defined terms in the Third Addendum (defined below) and the Clarification Agreement (defined below) shall have the same meaning in this MOU;

B. The Parties desire to have the relationship described in this MOU apply only in the "Territories" (defined below);

C. Austrianova has offered to actively work to seek an investment partner or partners ("Investment Partner") who will finance clinical trials and further develop Products in the Field, including the cost of Product manufacturing and marketing approval from the country or countries in which each Product is approved in exchange for an agreed upon percentage of Product Revenue (defined below). For their contribution to the relationship, the Parties desire each Party to receive an equal share of any Product Revenue; and

D. It is the intent of the Parties that a separate binding written agreement ("Agreement") will be negotiated in good faith with regard to each Party's obligations and responsibilities to implement the intent of this MOU.

E. The Parties are signatories to a Manufacturing Framework Agreement entered into as of the 20th day of March 2014, pursuant to which the production of Phase 2 clinical trial material utilizing the P450 Technology will be supplied by Austrianova to PharmaCyte for a Phase 2 clinical trial to be conducted by PharmaCyte and which will take place in the United States with study sites in Europe. The Parties recognize the need to negotiate a new Manufacturing Framework Agreement pursuant to which the production of Phase 3 clinical trial material utilizing the P450 Technology will be supplied by Austrianova to PharmaCyte for PharmaCyte to conduct a Phase 3 clinical trial in the United States with study sites in Europe.

AGREEMENT

1. Defined Terms. The Agreement shall include, among others, the following defined terms:

(a) "Affiliate" shall mean, with respect to the Parties, any corporation or other business entity controlling, controlled by or under common control with that party. The term "controlling," with correlative meanings for the terms "controlled by" and "under common control with" as used in this definition means either: (i) possession of the direct or the indirect ownership of more than fifty percent (50%) of the voting or income interest of the applicable corporation or other business entity; or (ii) the ability, by contract or otherwise, to control the management of the applicable corporation or other business entity.

(b) "Active Pharmaceutical Ingredient" shall mean the genetically modified HEK293 cells overexpressing the cytochrome P450 2B1 gene that have been produced according to cGMP standards.

(c) "Associated Technology" shall mean technologies owned by SG Austria or an Affiliate of Austrianova and marketed by Austrianova under the Cell-in-a-Box® registered trademark which enables encapsulation of live eukaryotic cells placed in a polymer where one constituent of the encapsulation material is cellulose sulphate or a derivative thereof and shall include any derivative or further development of these technologies.

(d) "Cell-in-a-Box® Trademark and its Associated Technology" refers to United States registered trademark No. 85307295 that is owned by SG Austria and the Associated Technology.

(e) "Confidential Information" shall mean any and all technical or commercial information that is provided by one Party or its Affiliate to the other Party or its Affiliate after the Effective Date that is of a confidential nature or is received in circumstances in which the receiving Party knows or should know that the information is confidential, including, without limitation, data, know-how, formulae, processes, designs, photographs, drawings, specifications, software programs and samples of any other material bearing or incorporating information relating to the business of either Party, whether or not such information is marked as "Confidential."

(f) "Field" shall mean the use of the P450 Technology specifically designed for the treatment of cancer.

(g) "P450 Technology" shall mean the Active Pharmaceutical Ingredient encapsulated using the Cell-in-a-Box® Trademark and its Associated Technology.

(h) "Product Revenue" shall mean any net revenue generated from the sale of any Products in the Field and within the Territories (defined below). In calculating "Product Revenue," any royalty or other fees PharmaCyte is currently contractually obligated to pay Bavarian Nordic A/S and GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH ("Bavarian Nordic/GSF") under PharmaCyte's License Agreement with Bavarian Nordic/GSF, as amended, will be taken into account in calculating Product Revenue.

(i) "Territories" shall mean countries in which there is no patent protection arising from granted or pending patents, or extensions thereof, based on the family of patents originating from the applications WO 1997001357 A1 and WO 1997035994 A3 filed by Bavarian Nordic/GSF.

2. Grant of License by PharmaCyte; Active Pharmaceutical Ingredient. PharmaCyte will grant an exclusive royalty-free sub-license to the parties to the Third Party Agreement (defined below) under the license PharmaCyte obtained from Bavarian Nordic/GSF or otherwise to use and commercialize the Active Pharmaceutical Ingredient to carry out the provisions of the Third Party Agreement. PharmaCyte will also provide the Active Pharmaceutical Ingredient free of charge in the form of vials of a Working Cell Bank to the extent necessary to produce a Product in the Field. The grant of this royalty-free sub-license and the free use of the Active Pharmaceutical Ingredient by PharmaCyte shall in no way conflict with the licensed rights of PharmaCyte to use the "Associated Technology" and the "Cell-in-a-Box® Trademark and its Associated Technology" for use in the Field, as set forth the Third Addendum to Asset Purchase Agreement between SG Austria and PharmaCyte effective as of June 25, 2013 ("Third Addendum"), as amended by the Clarification Agreement to Third Addendum to Asset Purchase Agreement between SG Austria and PharmaCyte effective as of June 25, 2013 ("Clarification Agreement"). Nor shall a sublicense fee or any other fee or royalty be charged by SG Austria for the grant of such a sub-license or the sale of any Product in the Territories under the Third Addendum and the Clarification Agreement.

3. Grant of License by Austrianova. Austrianova shall grant the parties to the Third Party Agreement (defined below) an exclusive royalty-free license to use the Cell-in-a-Box® Trademark and its Associated Technology for Products in the Field sold within the Territories.

4. Joint Venture/Framework/Revenue Sharing/Cooperation Agreement. The Parties and the Investment Partner or Partners shall enter into a Joint Venture, Framework, Revenue Sharing or Cooperation Agreement ("Third Party Agreement") to carry out the purposes of this MOU with respect to the sale of Products in the Field within the Territories, with terms and conditions that are reasonable and customary in an agreement of this kind. For their respective contributions to the Third Party Agreement, the Parties will work with each Investment Partner with the goal that the Parties and the Investment Partner will each receive 33.3% of any Product Revenue; provided, however, any other Product Revenue sharing percentage agreed to by the Parties in order to consummate a transaction with an Investment Partner will be acceptable.

5. Efforts to Secure Partner. Austrianova will actively seek an Investment Partner who will become a party to the Third Party Agreement and who will finance clinical trials and further develop of Products in the Field for sale within the Territories, as determined by the Parties, including the cost of Product manufacturing and marketing approval from the country or countries in which each Product is approved.

6. Clinical Trials and Disclosure of Results of Clinical Trials. Except as otherwise required by law, the commencement of any clinical trial or any public disclosure thereof pursuant to the Agreement shall not take place without the prior written consent of Austrianova and PharmaCyte. Except as otherwise required by law, the results of any clinical trial shall not be made public or reported to any regulatory agency without the prior written consent of Austrianova and PharmaCyte.

7. Manufacture Set-Up Fee for Phase 1 and Phase 2 Clinical Trials. The manufacture set-up fee for Phase 1 and Phase 2 clinical trials, if any, shall be the responsibility of Austrianova to the extent it is not paid for by the Investment Partner.

8. New Manufacturing Framework Agreement for Phase 3 Material. During the third quarter of 2016 the Parties agree to commence negotiating in good faith a new Manufacturing Framework Agreement pursuant to which Austrianova will provide PharmaCyte with Phase 3 clinical material utilizing the P450 Technology to conduct a Phase 3 clinical trial in the United States with study sites in Europe.

9. Joint Development Committee. The Parties and the Investment Partner will establish a Joint Development Committee ("JDC") that will oversee the strategy for and coordinate and implement: (i) conducting any clinical trials of the Product needed to obtain regulatory approvals of the Product in the Field in the Territory; (ii) filing applications for and maintaining such regulatory approvals in the Territory; and (iii) conducting any clinical trials of the Product in the Field needed to maintain regulatory approval in the Territory as well as any other clinical trials of the Product in the Field (including investigator initiated trials) conducted for a purpose other than to maintain regulatory approvals in the Territory. Additional details about the composition of the JDC, frequency of meetings and scope of responsibility will be described in the Third Party Agreement.

10. Conditions to the MOU. The consummation of the transactions contemplated by this MOU shall be subject to satisfaction of various customary conditions, including, without limitation, the following by each of the Parties:

(a) approve this MOU by the Board of Directors or other authorized management of the Parties;

(b) maintain their respective business operations in the ordinary course and prevent any material adverse change in the physical or operational condition of their business operations subsequent to the execution of this MOU; and

(c) secure any required governmental or third-party approvals, waivers or consents to consummate the transactions contemplated by this MOU.

11. Miscellaneous.

(a) **Conduct and Legal Compliance**. The Parties shall comply with all United States and other country laws and regulations applicable to the performance of their obligations under this MOU and the Agreement, including, but not limited to, the provisions of the United States Foreign Corrupt Practices Act. Neither Party shall pay, promise to pay or authorize the payment of money or anything of value, directly or indirectly, to any person (whether a governmental official or a private individual) for the purpose of illegally or improperly inducing or attempting to induce any foreign official or political party or official thereof to make a buying decision or illegally or improperly assist either Party in obtaining or retaining business, or to take any other action favorable to the Parties in connection with any proposed transaction between the Parties or a third party.

(b) **Choice of Laws**. This MOU shall be construed according to the laws of England.

(c) **Mediation**. In the event of any dispute arising between the Parties arising out of or related to the MOU ("Dispute"), the Parties shall use their best endeavours to settle amicably such Dispute by consultation and negotiation. In the event the Parties are not able to resolve any Dispute, the Parties shall first to try in good faith to settle the Dispute by mediation, the cost of which shall be assumed equally by both Parties. Either Party may initiate the mediation by providing a written request to the other Party.

(d) **Arbitration**. Any Dispute which cannot be resolved by consultation, negotiation and mediation between the Parties shall, within ninety (90) days of commencement of the discussions under Section 10. (c), be referred to and finally resolved by arbitration in London, England in accordance with the Arbitration Rules of the London International Arbitration Centre for which rules are deemed to be incorporated by reference to this Section 10 (d). The language of the arbitration shall be English. Any award made under this Section 10. (d) shall be final and binding upon the Parties. Judgment on such award may be entered by any court or tribunal having jurisdiction thereof.

(e) **Binding Agreement; Modification**. This MOU constitutes a binding agreement between the Parties, subject to further negotiations of the final terms and conditions that will be incorporated into the Agreement. The Parties agree to negotiate in good faith to carry out the purpose and intent of this MOU. No amendment or modification or waiver of any provisions of this MOU shall be effective unless made in writing and signed by a duly authorized officer of each Party.

(f) Successors and Assigns. This MOU shall be binding upon the successors and assigns of the Parties. Austrianova shall undertake to impose the obligations under this MOU upon its legal successors and assigns. PharmaCyte shall undertake to impose the obligations under this MOU upon its legal successors or assigns. Except as otherwise expressly provided for in this MOU, neither Party shall be entitled to assign this MOU or any rights hereunder to any third party without the prior written consent of the other Party, except that a Party may assign this MOU to its successor in interest pursuant to a merger, acquisition or sale of all or substantially all of its assets.

(g) Force Majeure. Both Parties shall be excused from the performance of their obligations under this MOU to the extent that such performance is prevented by *force majeure* and the non-performing Party promptly provides notice of the *force majeure* event to the other Party. If the *force majeure* in question continues for a period in excess of three (3) months, the Parties shall enter into *bona fide* discussion with a view to agreeing upon such alternative arrangements as may be fair and reasonable. If the Parties cannot agree such alternative arrangement, then either Party shall be entitled to terminate this MOU by thirty (30) days' "Notice" to the other Party prior to the effective date of the termination.

(h) Notice. No notice or other communication from one Party to the other ("Notice") shall have any validity unless made in writing by or on behalf of the Party concerned. Any Notice that is to be given by either Party to the other may be given by letter, facsimile transmission or electronic mail. Such letters shall be delivered by hand or sent prepaid by certified mail, addressed to the other Party at the address given above as the registered address of each Party, with receipted recorded delivery. Notice shall be considered received upon receipt of any such letter, facsimile transmission or electronic mail.

(i) Press Releases and Media Statements. No press or media statement may be released by either Party to this MOU with regard to the existence of this MOU or the subject of this MOU without the express prior consent of the other Party as to content and as to the nature and extent of the press or media statement.

(j) No Drafting Inference. This MOU has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this MOU shall not be construed against any Party regardless of which Party may be deemed to have authored the ambiguous provision.

(k) Invalidity of Certain Provisions. If any one or more of the provisions of this MOU are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provisions shall be considered severed from this MOU and shall not serve to invalidate any remaining provisions of the MOU. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable provision such that the objectives contemplated by the Parties when entering this MOU may be realized.

(l) Enforcement or Waiver. Any delay in enforcing a Party's right under this MOU or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's right to the future enforcement of its rights under the MOU, except only as to an express written and signed waiver as to a particular matter for particular period of time.

(m) No Authority to Bind a Party. Nothing in this MOU shall be construed to give either Party the power or authority to act for, bind or commit the other Party in any way. Nothing in this MOU shall be construed to create a partnership between the Parties, principle-agent relationship or any other form of relationship between the Parties expects as specifically set forth in the Agreement.

(n) Confidentiality of MOU. The Parties agree that, without the prior written consent of the other Party, which may be withheld in such Party's sole discretion, neither Party shall disclose any provision of this MOU, or its existence, to any third party (subject to the other terms set forth herein).

(o) Fees and Costs of MOU and Agreement. Each Party shall pay its own attorney's fees, costs and expenses incurred in connection with this MOU and the Agreement.

(p) Section Headings. Section headings are used in this MOU for convenience only and are not to be considered in construing or interpreting this MOU.

(q) Counterpart Signatures. The Third Addendum may be executed in two counterparts, each of which shall be an original and all of which shall constitute together the same document.

IN WITNESS WHEREOF, the Parties have executed this MOU as of the Effective Date.

/s/ Dr. Brian Salmons	/s/ Dr. Kenneth L. Waggoner
Dr. Brian Salmons	Dr. Kenneth L. Waggoner
Chief Executive Officer	Chief Executive Officer
SG Austria Pte Ltd	PharmaCyte Biotech, Inc.

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
Nuvilex Europe Limited	Ireland
Freedom-2, Inc.	Delaware

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PharmaCyte Biotech, Inc.
(Formerly Nuvilex, Inc.)
Silver Spring, Maryland

We hereby consent to the incorporation by reference in the Registration Statement on Amendment No. 1 to Form S-3 (No. 333-199440) of PharmaCyte Biotech, Inc., formerly Nuvilex, Inc. ("Company"), relating to the consolidated financial statements and schedule as of April 30, 2016 for the year ended April 30, 2016, which appears in this Form 10-K.

/s/ Armanino LLP
Certified Public Accountants
San Ramon, California
July 29, 2016

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PharmaCyte Biotech, Inc.
(Formerly Nuvilex, Inc.)
Silver Spring, Maryland

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-199440), as amended, of PharmaCyte Biotech, Inc., formerly Nuvilex, Inc. (the "Company"), of our reports dated July 28, 2015, relating to the consolidated financial statements and schedule as of April 30, 2015 and for the year then ended (as updated, with respect to Note 1A to such consolidated financial statements, on January 19, 2016).

/s/ Farber Hass Hurley LLP

Chatsworth, California
July 29, 2016

EXHIBIT 23.3

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PharmaCyte Biotech, Inc.
(Formerly Nuvilex, Inc.)
Silver Spring, Maryland

We hereby consent to the incorporation by reference in the Registration Statement on Amendment No. 1 to Form S-3 (No. 333-199440) of PharmaCyte Biotech, Inc., formerly Nuvilex, Inc. ("Company"), relating to the consolidated financial statements and schedule as of April 30, 2014 for the year ended April 30, 2014, which appears in this Form 10-K.

/s/ Robison, Hill & Co.
Certified Public Accountants
Salt Lake City, Utah
July 29, 2016

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, 2016;
790

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: July 29, 2016

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer (Principal Executive Officer and acting 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, 2016 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: July 29, 2016

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer (Principal Executive Officer and acting Principal Financial and Acting 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 but is instead furnished as provided by applicable rules of the SEC.