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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended April 30, 2015

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 under Section 12(b) of the Act:	None
Securities registered under 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, 2014: $131,433,460.

As of July 28, 2015, the registrant had 742,610,829 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Forward-Looking Statements

This Annual Report on Form 10-K ("Report") includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). 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," "expects," "plans," "anticipates," "estimates," "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 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. 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," "PharmaCyte Biotech," "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®" This unique and patented 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.

Our treatment for pancreatic cancer involves encapsulating modified live cells capable of converting the prodrug ifosfamide into its active or "cancer-killing" form. These encapsulated live cells are placed as close to the tumor as possible to enable the delivery of the highest levels of the cancer-killing drug at the source of the cancer. Ifosfamide is then given intravenously at one third the normal dose to eliminate adverse side effects. When the ifosfamide comes in contact with the encapsulated live cells through the circulatory system, the activation of the drug takes place at or near the tumor. This "targeted chemotherapy" has proven remarkably effective and safe to use in past clinical trials. Using the same technology, we are working on improving the quality of life for patients with advanced pancreatic cancer and on treatments for other types of cancerous solid tumors.

We are also developing treatments for cancer based upon chemical constituents of the *Cannabis* plant, known as "cannabinoids." We are examining ways to exploit the benefits of Cell-in-a-Box® technology in optimizing the anticancer effectiveness of cannabinoids, while minimizing or outright eliminating the debilitating side effects usually associated with chemotherapy. This provides us with the opportunity to develop "green" approaches to fighting deadly diseases, such as cancer of the pancreas, brain and breast, which affect hundreds of thousands of individuals worldwide every year.

In addition to developing treatments for pancreatic and other solid tumor cancers, we are developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. We plan to encapsulate a human cell line which has been genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body. The encapsulation will be done using our Cell-in-a-Box® technology.

Cancer Treatment

The Cell-in-a-Box® encapsulation of genetically modified live cells capable of converting the anticancer prodrug (a prodrug requires conversion or "activation" for it to be effective) ifosfamide into its cancer-killing form will be performed at Austrianova's manufacturing facility in Bangkok, Thailand. These facilities will adhere to international current Good Manufacturing Practices ("cGMP") standards.

We have entered into a Master Services Agreement with ViruSure GmbH ("ViruSure") in Vienna, Austria, 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 will then develop a Master Cell Bank ("MCB") and, from that, a Working Cell Bank ("WCB"). The MCB is to be used as a "safe" repository of the selected clone cells. 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, and the price, fees and payment schedule depends upon the particular work being undertaken by ViruSure on our behalf.

The principal developers of the Cell-in-a-Box® cellulose-based live cell encapsulation technology are Dr. Walter H. Günzburg and Dr. Brian Salmons. Both are officers of SG Austria Pte Ltd ("SG Austria") and its wholly-owned subsidiary, Austrianova Singapore Pte Ltd ("Austrianova"). We own a 14.5% equity interest in SG Austria and have contractual relationships with 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 its live cell encapsulation technology towards the development of treatments for cancer and diabetes, payments will be made 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 marketing authorization Regulatory Agencies. Milestone payments of $50,000 are to be made after the enrollment of the first veterinary patient for each veterinary product and $300,000 after obtaining marketing authorization for each veterinary product. These milestone payments are described in more detail below.

Dr. Günzburg and Dr. Salmons are involved in all aspects of the scientific endeavors underway and being planned by us, having commenced work for us as consultants at the beginning of 2014 under an oral agreement. They currently provide their services as consultants through their consulting company, Vin-de-Bona Trading Company Pte Ltd ("Vin-de-Bona"). This arrangement was formalized as of April 1, 2014, with the execution of a Consulting Agreement between us and 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.

Commencing September 30, 2014, Dr. Günzburg was appointed as our Chief Scientific Officer. On December 22, 2014, 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 and resulting in a non-cash expense of $98,500. He will be compensated in the same way and amount for each succeeding year during which he serves as our Chief Scientific Officer.

Dr. Günzburg and Dr. Salmons are involved in our Phase 2b clinical trial in pancreatic cancer that will be conducted in Australia by one of the foremost Contract Research Organizations ("CRO") in that country, Clinical Network Services Pty Ltd ("CNS"). This Phase 2b clinical trial will compare our treatment for advanced pancreatic cancer "head to head" with the best available therapy. That therapy is currently Celgene's drug Abraxane® in combination with gemcitabine to treat advanced, inoperable pancreatic cancer.

Dr. Matthias Löhr, a renowned European oncologist and gastroenterologist, will also play a major role 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 of the combination of CapCell® (now known as Cell-in-a-Box®) with low-dose ifosfamide in patients with advanced, inoperable pancreatic cancer. Dr. Löhr is extremely familiar with the use of this combination treatment in a clinical setting. Like Dr. Günzburg and Dr. Salmons, Dr. Löhr is involved in planning much of the Phase 2b clinical trial. Dr. Löhr will also oversee how the clinical trial is conducted.

Preparations necessary for the Phase 2b clinical trial are well underway. We plan to commence the Phase 2b clinical trial the latter part of this year.

The efforts of Dr. Günzburg, Dr. Salmons and Dr. Löhr also include work associated with the preclinical studies and clinical trials we plan to conduct in the United States in the latter part of this year as well. Translational Drug Development ("TD2"), one of the leading CROs in the United States specializing in oncology, is handling the preclinical studies and clinical trials. These studies and trials involve determining the effectiveness of our pancreatic cancer treatment in: (i) ameliorating the virtually untreatable and unbearable pain associated with advanced pancreatic cancer that occurs in 20-25% of patients; and (ii) the effects of the treatment on the rate of accumulation of fluid in the abdomen, known as "malignant ascites" (malignant ascites occurs in patients with pancreatic and other solid abdominal tumors and contains cancer cells that can "seed" and form new tumors in the body).

Work is underway planning for these clinical trials. We anticipate these trials will also commence in this latter part of this year.

Cannabis to Treat Diseases

With 23 states and the District of Columbia approving the use of marijuana, commonly referred to in the scientific community as "*Cannabis*" for medicinal purposes, 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. Very few are focused on using constituents of *Cannabis* for the treatment of specific diseases. We are.

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 (skin) 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 develop treatments for two of the deadliest forms of cancer - brain and the pancreatic - rather than Kaposi's sarcoma and skin cancer. We also plan to focus initially on developing specific treatments 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, such as Δ^9-tetrahdyrocannabinol and cannabidiol, have been well-documented to have broad anti-inflammatory, antioxidant, analgesic and nerve protecting abilities. But 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 marijuana and pharmaceutical companies to develop cannabinoid-based therapies utilizing our proprietary live cell encapsulation technology as the platform.

We have 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* (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 non-cannabinoid 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.

Diabetes Treatment

Diabetes is a major health problem throughout the world. It is estimated that 387 million people worldwide have the disease and that by 2035 the number will have risen to more than 592 million. Diabetes caused 4.9 million deaths in 2014. Every seven seconds a person dies from the complications caused by diabetes. In the U.S. alone, diabetes caused $612 billion in health care expenditures in 2014. The worldwide market for diabetes treatments alone has been projected to reach $650 billion by 2020.

Diabetes is caused by insufficient availability or resistance to insulin. Insulin is produced by the islet cells of the pancreas. Its function is to assist in the transport of sugar in the blood to the inside of most types of cells in the body where it is used as a source of energy for those cells. In Type 1 diabetes, the islet cells of the pancreas have been destroyed - usually by an autoimmune reaction. Type 1 diabetics require daily insulin administration through injection or through the use of an insulin pump. Type 2 diabetes can 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 diabetes. However, over time these too may lose their effectiveness. Thus, even Type 2 diabetics may become insulin-dependent.

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. Such studies began in the late 1960s, but success was limited until 2000. That is when islet cells from human cadavers were transplanted into insulin-dependent diabetics in a clinical trial. Control of blood sugar levels was achieved. In this clinical trial, all 7 patients enrolled in the clinical trial remained insulin-independent for one year. But because of the high doses of immune-suppressive drugs that must accompany such transplantations, patients were placed at high risk of infection by opportunistic organisms and even of developing cancerous growths. These drugs have serious side effects and have required patients to cease treatment with them. Worldwide, less than 1,000 people with Type 1 diabetes 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. However, there are problems besides regulatory approval.

An attack by the body's immune system is the first and foremost problem. To protect the transplanted non-human islet cells from attack by the host's immune system, these cells 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), which allows them to survive and exchange small molecules such as glucose and insulin with their environment. These encapsulation efforts were used in an attempt to shield the transplanted islet cells from destructive attack by cells of the body's immune system.

Efforts to translate this concept into a viable treatment for Type 1 diabetes have been plagued by poor survival of the transplanted islet cells due to sub-optimal oxygen supply for the islet cells and attack on the cells by pro-inflammatory substances, such as cytokines. 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 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 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 resulting in fibrotic overgrowth and thus transplant failure.

The most extensively researched immune-protective strategy is that which employs micro-capsules. Micro-capsules are mechanically stable and have a favourable surface to volume ratio, which results in good diffusion characteristics. 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, after 18 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. Clinical trials by different groups showed similar outcomes. The clinical benefit for the patients was modest because, soon after transplantation, insulin administration had to be resumed.

We plan to develop a treatment for Type 1 diabetes that is unique among available treatments for this disease. This treatment will also be available for those who need it and who have Type 2 diabetes where traditional diabetes medications are no longer effective. We are developing a treatment that involves encapsulation of a human cell line genetically engineered to produce, store insulin and secrete insulin on demand at levels in proportion to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box® technology.

We have obtained from the University of Technology Sydney ("UTS") in Australia the worldwide license to use a line of insulin-producing genetically modified cells developed by Prof. Ann Simpson and her colleagues at UTS for the development of a treatment for insulin-dependent diabetes ("Melligen Cell License Agreement"). These cells, named "Melligen," have already been tested and shown to produce insulin in direct proportion to the amount of glucose in their surroundings. In fact, when Melligen cells were transplanted into diabetic mice whose immune systems were essentially not functioning, the blood glucose levels of the mice became normal. This observation illustrates that Melligen cells can reverse the diabetic condition. Our partner, Austrianova, has already successfully encapsulated Melligen cells using the Cell-in-a-Box® technology.

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. 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.

Encapsulating the Melligen cells using 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. Furthermore, these capsules and the cells inside them do not give rise to any immune or inflammatory responses like those seen with alginate-encapsulated cells. Recently, a scientific review article discussed the advantages of the Cell-in-a-Box® encapsulation technology over alginate-based encapsulation for use in the development of a treatment for insulin-dependent diabetes.

We believe that the combination of the Melligen cells and the Cell-in-a-Box ® encapsulation technology could lead to a break-through treatment for insulin-dependent diabetes using these genetically modified insulin-producing cells that will overcome all of the past problems in developing a true bio-artificial pancreas.

We have established an international Diabetes Consortium that consists of world-renowned physicians and scientists from several countries, all of whom share the same goal of developing a treatment for insulin-dependent diabetes. We have research agreements in place with the University of Veterinary Medicine Vienna ("UVMV") in Vienna, Austria, UTS in Sydney, Australia, the Vorarlberg Institute for Vascular Investigation and Treatment ("VIVIT") in Feldkirch, Austria, the University of Barcelona ("UOB") in Barcelona, Spain and the University of Copenhagen ("UOC") in Denmark. A research agreement is in the process of being finalized with the Ludwig-Maximillian University ("LMU") in Munich, Germany.

In addition to our Chief Executive Officer and Chief Operating Officer, the Diabetes Consortium is made up of well-known scientists from the universities and institutions identified above and from the Karolinska Institute in Stockholm, Sweden, and the biotech company Austrianova in Singapore.

Dr. Eva Maria Brandtner leads the Diabetes Consortium and is our Director of Diabetes Program Development. Dr. Brandtner, who is also a consultant for us, previously served as the Chief Scientist with Austrianova. In that role, she conducted preclinical studies with the Melligen cells. As mentioned above, Prof. Simpson and her colleagues at UTS developed the Melligen cell line. Prof. Simpson is also a member of the Diabetes Consortium and serves as a consultant under a Consulting Agreement with UTS.

In addition to our key personnel, Dr. Brandtner and Prof. Simpson, the Diabetes Consortium includes Dr. Gunzburg, our Chief Scientific Officer and the Chief Technical Officer of Austrianova, and Dr. Salmons, the Chief Executive Officer of Austrianova and a member of our Scientific Advisory Board. It also includes Dr. Constantine Konstantoulas from UVMV who coordinates the daily activities of the Diabetes Consortium and works on many of the preclinical studies being done to develop our treatment for insulin-dependent diabetes. The research scientists, Prof. Dr. Eckhard Wolf and Prof. Dr. Rüdiger Wanke from LMU, are also key members of the Diabetes Consortium. These professors, together with their colleagues at LMU, have developed unique animal models for insulin-dependent diabetes. The other key members of the Diabetes Consortium include Prof. Dr. Thomas Stratmann of the UOB and Prof. Dr. Axel Kornerup Hanson of UOC.

Finally, Dr. Löhr is playing a major role in the development our diabetes program. Because he is an expert in diseases of the pancreas, Dr. Löhr is an expert in both pancreatic cancer and diabetes and has already had extensive experience in the clinic using the Cell-in-a-Box® technology, having served as Principal Investigator for the early-phase clinical trials pancreatic cancer that involved the combination of that technology and the cancer prodrug ifosfamide.

Our Business

We operate independently and through four wholly-owned subsidiaries: (i) Bio Blue Bird AG ("Bio Blue Bird"); (ii) Nuvilex Europe Limited (soon to be renamed PharmaCyte Biotech Europe Limited); (iii) Nuvilex Australia Limited (soon to be renamed PharmaCyte Biotech Australia Private Limited); and (iv) Viridis Biotech, Inc. ("Viridis Biotech").

In 2013, we restructured our operations in an effort to focus on biotechnology, having been primarily a nutraceutical products company in the recent past. The restructuring resulted in us focusing all of our efforts on the Cell-in-a-Box® technology for the development of unique, effective and safe ways to treat cancer and diabetes.

Effective June 25, 2013, we entered into a Third Addendum ("Third Addendum") to an Asset Purchase Agreement with SG Austria previously entered into dated July 26 2011 ("SG Austria APA"). The Third Addendum resulted in us acquiring 100% of the equity interests in a subsidiary of SG Austria, Bio Blue Bird, and receiving a 14.5% equity interest in SG Austria.

Our acquisition of a 14.5% equity interest in SG Austria and a 100% interest in Bio Blue Bird were the first acquisitions related to our biotechnology company. The acquisition of Bio Blue Bird provided us with exclusive, worldwide licenses to use the Cell-in-a-Box® technology for the development of treatments for all forms of cancer using certain types of cells. The licenses are pursuant to patents licensed from Bavarian Nordic A/S and GSF-Forschungszentrum fur Umwelt u. Gesundeit GmbH. They enable us to carry out the research and development of cancer treatments using the Cell-in-a-Box® technology.

In July 2013, we acquired from Austrianova the 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 for this technology ("Diabetes Licensing Agreement"). We made our first $1,000,000 payment to secure the Diabetes Licensing Agreement on October 30, 2013. The second and final payment of $1,000,000 was made on February 25, 2014.

In December 2014, we also 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 a result of the Cannabis Licensing Agreement, we are developing treatments for cancer using the chemical constituents of the *Cannabis* plant in combination with the Cell-in-a-Box® technology. As of April 30, 2015, we paid Austrianova $1.0 million of the $2.0 million "Upfront Payment" required by us to be made by for this license. As of the date of this Report, we have paid $1.3 million of the Upfront Payment. The parties have agreed to an amendment to the Cannabis Licensing Agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented.

Management Goal and Strategy

Our goal is to become an industry-leading biotechnology company using the Cell-in-a-Box® live cell encapsulation technology as a platform upon which treatments for cancer and diabetes can be developed.

Our initial strategy is to build upon and advance the success of the previous Phase 1/2 and Phase 2 pancreatic cancer clinical trials. Our acquisition of Bio Blue Bird was the first step in this strategy. This acquisition enabled us to advance as a biotechnology company. We believe we are positioned to move forward and become a significant biotech company predicated upon the Cell-in-a-Box® technology.

We will seek to raise capital to fund growth opportunities and provide for our working capital needs as our strategy is executed. Our strategy to achieve financial stability and to enable us to reach our goal consists of the following:

- The completion of the preparations for the Phase 2b clinical trial in advanced, inoperable pancreatic cancer to be conducted by CNS in Australia;
- The completion of the preparations for the clinical trials that will examine the effectiveness of our pancreatic cancer treatment in ameliorating the pain and accumulation of malignant ascites fluid in the abdomen that are characteristic of pancreatic cancer. These clinical trials will be conducted by TD2 in the United States;
- The completion of preclinical studies that involve the encapsulation of a human cell line genetically engineered to produce, store and secrete insulin on demand at levels in proportion to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box® technology;
- The enhancement of our ability to expand into the biotechnology arena through further research and partnering agreements;
- The acquisition of new 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 live cell encapsulation technology for use in oncology with certain types of live cells. The 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. 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 intend to use our cellulose-based live cell encapsulation technology for creating treatments for patients suffering from cancers and insulin-dependent diabetes. Initially, focus will be placed on the preparations for a Phase 2b clinical trial in advanced 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 ("CYP2B1") 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 modified so that they could 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 aim is for production of genetically modified encapsulated cells that are capable of being placed inside the body of a person or an animal in precisely the right location to target the disease being treated**.** 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.

The two areas we are currently developing for live cell encapsulation-based treatments are cancer and diabetes. The field of diabetes cell therapy development is competitive. There are a number of companies developing cell based therapies for diabetes. These competitors include Living Cell Technologies, Viacyte, Cellmed, Microislet Sciences, Cerco Medical and BetaCell, among others. Although competition exists, we believe these other companies are developing encapsulation-based treatments 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 our Cell-in-a-Box capsules.
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 active 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.

Market Opportunity and the Competitive Landscape

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 typically operable in approximately only 10% of patients after being diagnosed. Therefore, we believe the potential market for our product equates to approximately 68% of the incidence in industrialized countries or about 338,000 new patients per year in 2012. Due to the "unmet medical need" status of pancreatic cancer, the biotechnology and pharmaceutical sectors have been working to discover a treatment for this disease and have invested significant levels of funding required for clinical discovery. We believe there is no treatment comparable to our Cell-in-a-Box® plus low dose of ifosfamide combination treatment when survival rates and a patient's quality of life are compared, increasing the potential that our product candidate will be of value to the oncology community and to pancreatic cancer patients in particular. Further, we believe that our treatment will become the "treatment choice" for patients with advanced pancreatic cancer because it results in no meaningful side-affects.

There is, however, intense competition for the use of the product candidates being developed by us for treating 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 gemcitabine and Abraxane®. This is the primary FDA-approved combination of drugs for treating 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. The same is true of our diabetes cell therapy. 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.

Earlier Clinical Trials Using Live Cell Encapsulation

The two earlier clinical trials referred to above 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 studies have appeared in the peer-reviewed scientific literature and are summarized as follows:

Phase 1/2 Clinical Trial

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

Identity of Trial Sponsors*:* The trial was sponsored by Bavarian Nordic GmbH ("Bavarian Nordic").

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

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, 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 uroprotector MESNA 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 treatments with ifosfamide were given.

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

Effects of the treatment on tumor size were measured by CAT scans. Control CAT scans were scheduled for weeks 10 and 20, respectively. During the final visit a control angiography was performed. On the initial CAT 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. CAT scans were evaluated by two unrelated radiologists, one of whom was not involved in the study. After formally finishing the study, patients were followed on an ambulatory basis with three-monthly visits.

Toxicity was measured based on WHO/NCI guidelines on common toxicity criteria. The World Health Organization ("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 United States. Most clinical trials carried out in the United States 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 the CapCell® (now known as Cell-in-a-Box®) plus low-dose ifosfamide combination in pancreatic cancer patients, the study investigators noted 11 serious adverse events 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 CapCell® 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 analgesic and 25, 50 and 100 indicated administration of non-steroidal anti-inflammatory drugs or opiates several times per year, per month or per week, respectively.

The primary tumor did not grow in any of the 14 patients. Two patients had a partial response (more than 50% reduction in tumor volume); 12 patients exhibited stable disease (tumor size in the range of 50% to 125% of initial size); and two patients showed a minor response (tumor reduction of between 25% and 50%).

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 being detected in any of the 14 patients; thus, there were no obvious treatment-related risks.

Eleven serious adverse events ("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.

Implantation of 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.

Only one adverse event (increased lipase activity on day 15 after installation of the capsules) "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 experienced such a benefit. For 7 of the patients, this was confirmed by their analgesic consumption. None of these "benefited" patients registered an increase analgesic usage both 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 study and no week 20 weight was obtained). Two patients showed stable body weights at week 10, one of whom dropped out of the study 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, an Eli Lilly drug first approved by the FDA in 1996.

An examination of the prescribing information for gemcitabine reflects that the median survival seen in the pivotal (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 pivotal (Phase 3) clinical trial of Celgene's Abraxane® plus gemcitabine combination that was approved by the FDA in September 2013 for the treatment of patients with advanced inoperable pancreatic cancer, 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 CapCell® (now known as 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 CapCell® 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 trial's investigators only, in the Phase 1/2 clinical trial the use of the combination of CapCell® (now known as 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 CapCell® (now known as Cell-in-a-Box®) plus low-dose ifosfamide combination is safe and effective for the purposes of granting marketing approval.

In the Phase1/2 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 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 United States, 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 the cancer treatment were approved by the Regulatory Agencies (defined below under "Government Regulations for Drug Development"), 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, 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 cancer after preclinical studies and clinical trials have been completed.

Phase 2 Clinical Trial

Location of Trial*:* The trial was opened on November 16, 1999 and closed on December 1, 2000. This trial was carried out at four centers in two countries in Europe; these were in Berne, Switzerland, and in Rostock, Munich and Berlin in 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 (by CT scan) and determination of tumor sizes 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 in this Phase 2 clinical trial. 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 AEs 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 National Cancer Institute'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 stating ifosfamide treatment and at weeks 10 and 20 post-treatment. No partial remissions were observed, but 4 patients exhibited tumor size reductions, 4 patients showed tumor growth and the remaining 5 patients had stable disease 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.

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 MCB and WCB for our future clinical trials. There are approximately $195,000 in future milestone payments relating to testing to be completed.

We have entered into a Manufacturing Framework Agreement with Austrianova pursuant to which it will encapsulate the genetically modified cells that will be used for our cancer treatment. We also have contracted with Austrianova to provide encapsulated insulin-producing cells for our preclinical studies in diabetes. For the pancreatic cancer studies, we anticipate incurring approximately $112,000 in costs associated with the encapsulation of the cells. At the appropriate time, we will enter into a similar Manufacturing Framework Agreement with Austrianova for the encapsulated cells we will need for our clinical trial in diabetes.

Government Regulations for Drug Development

The United States' Food and Drug Administration ("FDA"), Europe's European Medicines Agency ("EMA"), Australia's Therapeutic Goods Administration ("TGA") and other country-specific regulatory agencies around the world (collectively, "Regulatory Agencies") ensure the safety of the entire community through their regulations pertaining to new drugs. Regulation by governmental authorities plays a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. Our therapeutic products require regulatory approval by the Regulatory Agencies. Human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing and post-marketing approval requirements of the Regulatory Agencies. In the United States, various federal and, in some cases, state statutes and regulations also govern or impact the manufacturing, testing for safety and effectiveness, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. 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, 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 products and our ability to receive product revenue, license revenue or profit sharing payments. For more information, see Item 1A. "Risk Factors."

Clinical Development

Before a product may be administered to human subjects, 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. The results of these studies must be submitted to the Regulatory Agencies as part of an Investigational New Drug ("IND") application which must be reviewed by the Regulatory Agencies for safety and other considerations before clinical trials in humans can begin.

Typically, clinical trials in humans involve 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 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 many years and significant cost. 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 drug or product candidate.

Phase 1 Clinical Trials: Phase 1 clinical trials begin when Regulatory Agencies allow initiation of clinical investigation of a new drug or product candidate. The clinical trials study a drug's safety profile and may include a preliminary determination of a drug or 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 Trials: Phase 2 clinical trials are conducted on a limited number of subjects with the targeted disease. An initial evaluation of the drug's effectiveness on subjects is performed and additional information on the drug's safety and dosage range is obtained. For many diseases, Phase 2 clinical trials normally include up to several hundred subjects.

Phase 3 Clinical Trials: Phase 3 clinical trials are typically controlled multi-center trials that involve a larger target patient population that can consist of from several hundred to thousands of subjects to ensure that study results are statistically significant. During Phase 3 clinical trials, physicians monitor subjects to determine efficacy and to gather further information on safety. These trials are designed to generate all of the clinical data necessary to submit an application for marketing approval to Regulatory Agencies.

Regulatory Review: If a product candidate successfully completes Phase 3 clinical trials and is submitted to Regulatory Agencies, such as the FDA in the United States 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 a New Drug Application ("NDA"), a Marketing Authorization Application ("MAA") or a Biologics License Application ("BLA"). The Regulatory Agencies require monitoring of all aspects of clinical trials and reports of all adverse events must be made. The Regulatory Agencies may also require the conduct of pediatric studies for the drug and indication either before or after submission of a NDA or a BLA.

Review and Approval by Regulatory Agencies

The results of the preclinical testing, production parameters and clinical trials are submitted to the Regulatory Agencies 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 Agencies may grant marketing approval, deny approval or request additional information.

Expedited Programs for Serious Conditions

Regulatory Agencies have developed distinct approaches to make new drugs 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 drug, 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 as confirmatory trials. Approval of a drug 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 drug.

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 drug is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug 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 products 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 the Regulatory Agencies, a sponsor may request that the Regulatory Agencies designate a drug intended to treat a "Rare Disease or Condition" as an "Orphan Drug." For example, in the United States, a "Rare Disease or Condition" is defined as one which affects less than 200,000 people in the United States, 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 United States. Upon the approval of the first NDA or BLA for a drug 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 United States 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, and in Australia it is 5 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. Orphan drugs may also be eligible for federal income tax credits for costs associated with such as the disease state, 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.

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 products 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; (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 products, 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 a License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules ("Bavarian Nordic/GSF License"). The licensors are Bavarian Nordic and GSF – Forschungszentrum fur Umwelt u. Gesundheit GmbH. The licensee is Bio Blue Bird, our wholly owned subsidiary. The 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 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 cells for a variety of indications;

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

- We have an exclusive license world-wide to use the Cell-in-a-Box® technology with genetically modified or non-modified non-stem cell lines and induced pluripotent stem (iPS) cells, with the right to sublicense, designed to produce insulin or other critical components for the treatment of diabetes. We must enter into a research program involving European academic research partners providing a total funding of at least US$400,000 within three years of June 25, 2013 and must enter clinical trials within 7 years of June 25, 2013 to retain the exclusive world-wide license;

- We have an exclusive license world-wide 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, with the right to sublicense, to develop therapies involving Cannabis, including the activation of cannabinoids. We must enter into a research program involving the scope of the Cannabis Licensing Agreement within three years of December 1, 2014 and must enter clinical trials within 7 years of December 1, 2014 to retain the exclusive world-wide license. We must also pay the Upfront Payment of $2,000,000 in full by December 31, 2015; and

- We have a License Agreement with UTC pursuant to which we acquired the exclusive license world-wide to use genetically modified cells, named Melligen, that have been modified to comprise pancreatic islet cell glucokinase for use in developing a treatment for insulin-dependent diabetes.

We have assumed Bio Blue Bird's responsibilities under the Bavarian Nordic/GSF License, 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 Phase 3 clinical trials, 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 United States, 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. The patents expire starting in 2016 through 2017.

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 a cell expressing cytochrome P450 and treatment methods using same.
- There are no contested proceedings or third party claims known to us.
- All major countries provide for patent term extension.
- 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.
- All major countries provide for patent term extension.
- 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

On May 26, 2011, we entered into the SG Austria APA. As a result, Austrianova and Bio Blue Bird 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 and for us to receive 100,000 shares of Austrianova's common stock and nine Bio Blue Bird bearer shares evidencing ownership of Bio Blue Bird.

In June 2011, we and SG Austria entered into a First Addendum to the SG Austria APA to extend the due date for the sums to be paid to SG Austria. In June 2012, we and SG Austria entered into the Second Addendum to the SG Austria APA for the same purpose. In June 2013, we and SG Austria entered into the Third Addendum.

Under the terms of the Third Addendum, the transaction contemplated by the SG Austria APA was materially changed. The Third Addendum provided that we were to acquire 100% of the equity interests in Bio Blue Bird and receive a 14.5% equity interest in SG Austria. In addition, we received nine bearer shares of Bio Blue Bird representing 100% ownership. Under the Third Addendum, we paid: (i) $500,000 to retire all outstanding debt of Bio Blue Bird; and (ii) $1.0 million to SG Austria. We acquired a 14.5% interest in SG Austria for $1,572,193 in cash previously paid to SG Austria to maintain SG Austria from the date of the SG Austria APA until the closing of the Third Addendum. The Third Addendum returned the original 100,000,000 shares of common stock to our treasury and returned to SG Austria the 100,000 Austrianova shares we had received under the SG Austria APA.

The acquisition of Bio Blue Bird provided us with exclusive, worldwide licenses to use a proprietary cellulose-based live cell encapsulation technology for the development of treatments for all forms of cancer with a right to sublicense. These licenses enable us to carry out the research and development of cancer treatments that are based upon the Cell-in-a-Box® technology. The license relates in general terms to encapsulation of cells that: (i) produce viral particles; (ii) express biomolecules; or (iii) convert molecules from one form to another pursuant to a License Agreement from Bavarian Nordic/GSF as the licensor and Bio Blue Bird as the licensee, as amended.

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.

The Third Addendum requires us to pay SG Austria, pursuant to a manufacturing agreement between the parties, a one-time manufacturing setup fee in the amount of $633,144.05, of which 50% is required to be paid on the signing of the manufacturing agreement and 50% is required to be paid three months later. In addition, the Third Addendum requires us 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.

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

Pursuant to the Diabetes Licensing Agreement, we acquired from Austrianova the exclusive license worldwide 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 with a right to sublicense. The licensed rights pertain to genetically modified or non-modified non-stem cell lines and certain stem cells specifically designed to produce insulin or other critical components for the treatment of diabetes.

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 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 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.

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:

- If we do not enter into a research program with technology in the scope of the license involving European academic university partners providing a total funding equal to or greater than $400,000 within three years of 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.

Melligen Cell License Agreement

Pursuant to the Melligen Cell License Agreement, we acquired the exclusive license world-wide to use genetically modified cells that have been modified to produce, store and then release insulin "on demand" in developing a treatment for insulin-dependent diabetes. In addition, we obtained the non-exclusive worldwide rights to "know-how" associated with the Melligen cells. These cells have been shown to be able to produce, store and secrete insulin "on demand" in response to changing levels of blood sugar in the cells' surroundings. We intend to use the Melligen cells, after they have been encapsulated using our Cell-in-a-Box® technology, as a treatment for insulin-dependent diabetes.

The Melligen Cell License Agreement does not require any "up-front" payment to UTS. We are required to pay to UTS a Patent Administration Fee equal to 15% of all amounts paid by UTS to prosecute and maintain patents related to the licensed property.

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 license world-wide 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, 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. As of the date of this Report, we have paid Austrianova $1.3 million of the Upfront Payment. The parties have agreed to an amendment to the Cannabis Licensing Agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented.

The Cannabis Licensing Agreement requires us 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. In addition, the Cannabis Licensing Agreement requires us 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.

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 due 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 the effective date of the Diabetes Licensing Agreement;
- If we do not enter into a clinical trial or its equivalent for a product within 7 years of the effective date of the Diabetes Licensing Agreement; and
- We do not pay the Upfront Payment of $2,000,000 in full by December 31, 2015.

Sources and Availability of Raw Materials

The entire encapsulation process relating to the encapsulation and 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.

Employees

As of April 30, 2015, we had four full-time employees. We primarily use consulting scientists, physicians, academics and other professionals for the work in which we are engaged.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, as well as other documents we file with the SEC, are available free of charge through the Investor Relations section of our web site (http://client.irwebkit.com/PharmaCyteBiotech) as soon as reasonably practicable after such material is electronically filed with or furnished to the Commission. The public can obtain documents that we file with the SEC at www.sec.gov. 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 Form 10-K, 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.

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 an Early Stage Company and May Not Achieve Profitability.

We are an early stage, 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 products. Furthermore, the present products may not receive sufficient interest to generate revenues or achieve profitability.

We 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 the level of sales and marketing activities for our products. 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 Entry into a Significant Licensing Agreement Could Adversely Affect our Liquidity and our Ability to Execute our Research and Development Strategy.

On November 24, 2014, we entered into the Cannabis Licensing Agreement. The use of our existing capital resources to make payments under the Cannabis Licensing Agreement will accelerate our need for additional capital to continue our operations. Failure to obtain such capital or generate such operating revenues would have an adverse impact on our financial position, operations and ability to continue as a going concern unless we are able to extend the payment provisions of the Cannabis Licensing Agreement. The payment terms of the Cannabis Licensing Agreement taken in conjunction with any difficulty or failure to successfully obtain additional funding may jeopardize our ability to continue our business and 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.

Development of Brand Awareness is Critical to Our Success.

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

Any Weakness in Our Internal Controls Could Have a Material Adverse Effect on Us.

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

Our Success Depends on Additional States Legalizing Medical Cannabis.

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

Cannabis Remains Illegal under Federal Law.

Cannabis remains illegal under federal law. It is a Schedule 1 controlled substance. Even in those jurisdictions in which the use of medical Cannabis has been legalized at the state level, its prescription is a violation of federal law. The United States Supreme Court has ruled in *United States v. Oakland Cannabis Buyers' Coop*. and *Gonzales v. Raich* that it is the federal government that has the right to regulate and criminalize Cannabis, even for medical purposes. Therefore, federal law criminalizing the use of Cannabis trumps state laws that legalize its use for medicinal purposes. The Obama administration has made a policy decision not to prosecute anyone operating in accordance with applicable state law, but a new administration could introduce a less favorable policy. Changes in federal policy could adversely affect our business.

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 United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the United States Department of Health and Human Services. 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 United States and have not been approved for reimbursement in certain European countries. Outside the United States, 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 United States. 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 United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and 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.

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.

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 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 CROs 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 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, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

We Intend to Conduct Clinical Trials for Certain of Our Product Candidates at Sites Outside of the United States, and the United States Regulatory Agencies May Not Accept Data from Trials Conducted in Such Locations.

We intend to conduct one or more of our clinical trials outside of the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the Regulatory Agencies outside of the United States. 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 United States population and medical practice in the United States in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. 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 United States laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, 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 United States 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 United States without obtaining marketing approval from the FDA. Comparable Regulatory Agencies outside of the United States, 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 a NDA, a BLA or a MAA to Regulatory Agencies for any of our product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if: (i) we are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we contemplate; (ii) we are unable to successfully complete 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.

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 institutional review boards 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 failing 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 institutional review boards 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 and we may 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 encapsulated live cell/ifosfamide product or any other 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.

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. Also, interim results during a clinical trial 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.

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, Would 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. The 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, the 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 a NDA, a BLA or a 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 the 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. The 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 Exclusivity 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 the 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 United States, 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 United States 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.

Orphan Drug Exclusivity may be lost if the Regulatory Agencies determine 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 Agencies 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 the Regulatory Agencies, even if Granted for any of the 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 is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The 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 the Regulatory Agencies 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 the Regulatory Agencies. In addition, the Regulatory Agencies may withdraw Fast Track designation if they believe that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track designation have failed to obtain drug approval.

A Breakthrough Therapy Designation by the Regulatory Agencies, 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. A "Breakthrough Therapy" is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the Regulatory Agencies and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of the Regulatory Agencies. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the Regulatory Agencies 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 considered for approval under conventional procedures of the Regulatory Agencies and does not assure their ultimate approval. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the Regulatory Agencies 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 products in Europe and many other jurisdictions outside the United States, 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 United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, 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 approvals from Regulatory Agencies outside the United States on a timely basis, if at all. Approval by FDA does not ensure approval by Regulatory Agencies in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by Regulatory Agencies in other countries or jurisdictions or by FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products 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 the Regulatory Agencies. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the Regulatory Agencies, requirements regarding the distribution of samples to physicians and recordkeeping.

In addition, the 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. The 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 products 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 products, 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 products;
- 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, Civil Penalties, Contractual Damages, Reputational Harm and Diminished Profits and Future Earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable 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 Federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing 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 Federal 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

- The Federal Health Insurance Portability and Accountability Act of 1996 ("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 the Health Information Technology for Economic and Clinical Health Act 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 products 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 United States 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 the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "PPACA"), 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 PPACA 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 PPACA 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 PPACA, 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 United States Congress of FDA's approval process may significantly delay or prevent marketing approval in the United States, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States 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 products 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 institutional review board or Regulatory Agencies 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 the Regulatory Agencies. 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.

We have never commercialized a drug product. Even if our encapsulated live cell plus ifosfamide product candidate or any of our other product candidates is approved by the one or more of the Regulatory Agencies 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 Drug is Less Effective than Previously Believed or Causes Undesirable Side Effects that Were Not Previously Identified, Our Ability to Market the Drug 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:

- Regulatory Agencies may withdraw their 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;
- Regulatory Agencies 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 a 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 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 United States 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 United States 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 United States. 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 party CROs to conduct our clinical trials. We expect to continue to rely heavily on third parties, such as CROs, clinical data management organizations, medical institutions and 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, the Regulatory Agencies require us to comply with current cGCP 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 the 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 the Regulatory Agencies 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 the Universities and Institutions is Important to Our Business. If We Are Unable to Maintain this Collaboration, or if this Collaboration is Not Successful, Our Business Could be Adversely Affected.

We rely on UVMV, UTS, UOB, UOC, UNC, LMU, VIVIT and Vin-de-Bona for a substantial portion of our preclinical capabilities, 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 a new research and collaboration partner for our preclinical and clinical development. If we are unsuccessful or significantly delayed in identifying a 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 intimately involved in all of our scientific endeavors underway and being planned by us. These endeavors include preclinical and clinical studies to be conducted in the United States on our behalf. These studies are designed to determine the effectiveness of the our pancreatic cancer treatment in ameliorating the unbearable pain that is associated with advanced pancreatic cancer and the effects of the treatment on the rate of accumulation of malignant ascites that occurs in patients with this disease. Also in the cancer area, Dr. Günzburg, Dr. Salmons and Dr. Löhr will be involved in every aspect of our Phase 2b clinical trial that will be conducted in Australia. In addition, they will be assisting us in the development of a treatment for diabetes that will employ the Cell-in-a-Box® cellulose-based live cell encapsulation technology. Dr. Günzburg, Dr. Salmons and Dr. Löhr are fulfilling a prominent role in the international Diabetes Consortium. They provide professional consulting services to us through their respective consulting agreements with us. The consulting agreements may be terminated for any reason at any time upon one party giving the other a written notice 30 days 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 products.

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.

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 products. 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 cGMP standards or the requirements of the Regulatory Agencies. 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 products.

Delays in the construction and certification of Austrianova's cGMP manufacturing facilities in Bangkok, Thailand could affect Austrianova's ability to manufacture encapsulated live cells on a timely basis and could adversely affect supplies of our product candidates.

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

In addition, we expect to rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain 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 United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States 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 and Austrianova.

The patent prosecution and/or patent maintenance process is expensive and time-consuming, and 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 United States. 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 United States 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 United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any patent applications and the enforcement or defense of our 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 United States. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office (“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 patent applications and the enforcement or defense of our 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 United States 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, and 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 United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-United States 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 United States. 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 products 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 United States 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.

Risk Factors Related to Our Stock

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.

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.

To date, the market closing price of our common stock in 2015 has ranged from $0.10 to $0.16 per share, and it may continue to experience significant volatility from time to time. Factors that may affect the market price of our common stock 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.

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 for Various Reasons in the Future.

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 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.

The Price of Our Common Stock is Volatile, Which Substantially Increases the Risk that the 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.

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 the Our Ability to Retain these Officers and other Key Executives 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, 2015, 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 its 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 CROs, collaborators and third-parties 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 collaborators. While we and, to our knowledge, our third-party collaborators 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 collaborators, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

As of May 1, 2015, we no longer qualified as a smaller reporting company. However, because we are permitted to satisfy our obligations under this Report by complying with the requirements applicable to a smaller reporting company, we are not required to include information called for by this item.

ITEM 2. PROPERTIES

Our principal office is located at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. This office is leased and consists of approximately 1,900 square feet. The lease ends July 31, 2016.

ITEM 3. LEGAL PROCEEDINGS

There is no material litigation currently pending or threatened against us or, to our knowledge, any of our officers or directors in their capacity as such.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

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 OTCQB (www.otcmarkets.com) 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 prices for our shares for each quarter during the two fiscal years ended April 30, 2015 and 2014. The prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and are not intended to represent actual transactions.

Date	**Bid Price**	
FY 2015	HIGH	LOW
First Quarter	$ 0.34	0.21
Second Quarter	$ 0.30	0.17
Third Quarter	$ 0.26	0.10
Fourth Quarter	$ 0.26	0.10
FY 2014		
First Quarter	$ 0.22	0.09
Second Quarter	$ 0.18	0.10
Third Quarter	$ 0.23	0.10
Fourth Quarter	$ 0.62	0.15

At April 30, 2015, the market price of our common stock was $0.16 per share.

As of April 30, 2015, there were 732,760,536 issued and outstanding shares of common stock. We were informed these shares are held by 1,600 shareholders of record.

Dividend Policy

We have not paid and does not plan to pay cash dividends at this time. Our Board of Directors ("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, 2015.

Securities Authorized for Issuance under Equity Compensation Plans

The information in the following table is as of April 30, 2015:

Name	Number of shares or units of stock that have not vested(#)	Market value of shares or units of stock that have not vested($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested(#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Kenneth L. Waggoner	(1) 1,800,000	(2) $ 279,180	(3) 2,200,000	(4) $ 177,550
Gerald W. Crabtree	(5) 900,000	(6) $ 139,590	(7) 2,200,000	(8) $ 177,550
Carlos Trujillo	(9) 900,000	(10) $ 139,590	(11) 2,200,000	(12) $ 177,550

(1) Represents the number of securities to be issued to Kenneth L. Waggoner during fiscal year 2015 in order to issue him 100,000 shares of common stock per month under his oral employment agreement that was in effect during the period May 1, 2014 to December 31, 2014 and 200,000 shares of common stock per month under his Executive Compensation Agreement that was in effect during the period January 1, 2015 through April 30, 2015. These shares were issued as compensation for his services as our Chairman of the Board, Chief Executive Officer, President and General Counsel and the Chief Executive Officer and General Counsel of Viridis Biotech.

(2) Represents the value of the securities to be issued to Kenneth L. Waggoner at the closing price of our common stock on April 30, 2015 of $279,180.

(3) Represents the number of unvested stock option shares granted to Kenneth L. Waggoner under the terms of the Second Stock Option Agreement dated March 10, 2015 which provided for 2,400,000 share option vesting at a rate of 200,000 shares per month subject to his Executive Compensation Agreement.

(4) Represents the unvested value of the stock options using the Black Scholes method granted to Kenneth L. Waggoner.

(5) Represents the number of securities to be issued to Gerald W. Crabtree during the fiscal year 2015 in order to issue him 100,000 shares of common stock per month under his an operative Board resolution that was in effect during the period May 1, 2014 to December 31, 2014 and 100,000 shares of common stock per month under his Executive Compensation Agreement that was in effect during the period January 1, 2015 through April 30, 2015. These shares were issued as compensation for his services as a director and our Chief Operating Officer and the Chief Operating Officer of Viridis Biotech.

(6) Represents the value of the securities to be issued to Gerald W. Crabtree at the closing price of our common stock on April 30, 2015 of $139,590.

(7) Represents the number of unvested stock option shares granted to Gerald W. Crabtree under the terms of the Second Stock Option Agreement dated March 10, 2015 which provided for 2,400,000 share option vesting at a rate of 200,000 shares per month subject to his Executive Compensation Agreement.

(8) Represents the unvested value of the stock options using the Black Scholes method granted to Gerald W. Crabtree.

(9) Represents the number of securities to be issued to Carlos Trujillo at 100,000 shares of common stock per month under his Employment Agreement that was in effect during the period January 1, 2015 through April 30, 2015. These shares were issued as compensation for his services.

(10) Represents the value of the securities to be issued to Carlos Trujillo at the closing price of our common stock as of April 30, 2015 of $139,590.

(11) Represents the number of unvested stock option shares granted to Carlos Trujillo under the terms of the Option Agreement dated March 10, 2015 which provides for 2,400,000 share option vesting at a rate of 200,000 shares per month subject to his Employment Agreement.

(12) Represents the unvested value of the stock options using the Black Scholes method granted to Carlos Trujillo.

Recent Issuance of Unregistered Securities

During the year ended April 30, 2015, we issued an aggregate of 5,500,000 shares of common stock to two consultants. The first issuance was for 5,000,000 shares at approximately $0.10, which was valued at the date of issuance. The second issuance was for 500,000 shares at approximately $0.18, which was valued at the date of issuance. The non-cash expense for these share issuances totaled $604,500.

During the year ended April 30, 2015, we issued 3,600,000 shares of common stock to officers as part of their Executive Compensation Agreements. These shares vest on a quarterly basis over a twelve month period. The 900,000 shares that vested were valued at the date of vesting and resulted in a non-cash compensation expense of $125,460.

During the year ended April 30, 2015, we issued 1,200,000 shares of common stock to an employee as part of his Employee Agreement. These shares vest on a quarterly basis over a twelve month period. The 300,000 shares that vested were valued at the date of vesting and resulted in a non-cash expense of $41,820.

All shares were issued without registration under the Securities Act in reliance upon the exemption afforded by Section 4(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

As of May 1, 2015, we no longer qualified as a smaller reporting company. However, because we are permitted to satisfy our obligations under this Report by complying with the requirements applicable to a smaller reporting company, we are not required to include information called for by this item.

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. 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."

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 clinical trials for the treatment of pancreatic cancer and its symptoms using encapsulated live cells similar to those used in the previous Phase 1/2 and Phase 2 clinical trials discussed above. We are also involved in preclinical studies to development treatment for insulin dependent diabetes.

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 cGMP produced encapsulated cells 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 clinical trials. 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 31 July	Quarter Ended 31 Oct	Quarter Ended 31 Jan	Quarter Ended 30 April
2015				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,583,160	6,200,845	1,456,554	4,454,930
Other income (expenses), net	(1,664)	3,336,402	(1,496)	(492,262)
Net loss	$ (1,584,824)	$ (2,864,443)	$ (1,458,050)	$ (4,947,192)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.01)	$ (0.00)	$ (0.00)

	Quarter Ended 31 July	Quarter Ended 31 Oct	Quarter Ended 31 Jan	Quarter Ended 30 April
2014				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,400,691	448,570	681,080	16,448,801
Other income (expenses), net	(3,265,676)	(5,209,500)	222,308	(22,010)
Net loss	$ (4,666,367)	$ (5,658,070)	$ (458,772)	$ (16,470,811)
Net loss per common share, Basic and Diluted	$ (0.01)	$ (0.01)	$ (0.00)	$ (0.03)

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, 2015 was $79,554,636. We expect to incur substantial and increasing losses in future periods.

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, 2015, combined with the sales of our common stock described below, will provide us with the ability to fund our operations through the end of 2016. However, there can be no assurance in this regard. Such actions primarily include raising additional capital from existing investors or securing additional financing.

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. The principal source of our cash is the sale our common stock as part of our S-3 Registration Statement.

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 investors, consultants, officers and directors of us will potentially have 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 investors, consultants, officers and directors of us. We rely solely on working capital as our liquidity indicator since we do not presently have any open credit lines, although we may try to obtain credit lines in the future. Further, as has often been a part of our mechanism(s) 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 February 14, 2014, we entered into a purchase agreement (“Lincoln Park Purchase Agreement”) and a registration rights agreement with Lincoln Park Capital Fund, LLC pursuant to which Lincoln Park purchased $2,000,000 of our common stock. Under the Lincoln Park Purchase Agreement, we have the right to sell to Lincoln Park up to $25,000,000 in shares of additional common stock, subject to certain limitations.

On May 28, 2014, we and Lincoln Park entered into a Mutual Termination and Release Agreement (“Lincoln Park Termination Agreement”) terminating the Lincoln Park Purchase Agreement. The Lincoln Park Termination Agreement provides that: (i) the representations and warranties of Lincoln Park and us contained in the Lincoln Park Purchase Agreement; (ii) the covenants regarding “Variable Rate Transactions” (as defined in the Lincoln Park Purchase Agreement) contained in the Lincoln Park Purchase Agreement (“Variable Rate Covenants”); (iii) the indemnification provisions set forth in Section 9 of the Lincoln Park Purchase Agreement; (iv) the agreements and covenants set forth in the Lincoln Park Purchase Agreement regarding notice, governing law and certain other related administrative provisions; and (v) the obligations of us to register for resale all 14,125,000 shares of common stock then owned by Lincoln Park each survive such termination and continue in full force and effect indefinitely, and provided further that the Variable Rate Covenants will terminate upon the earlier of the one year anniversary of the effectiveness of the registration referred to in the preceding clause (v) (“Effective Date”) and the date on which Lincoln Park has sold all of its shares of common stock.

In addition, Lincoln Park consented to us entering into the Chardan Agreement (as defined below), so long as there are no provisions within the Chardan Agreement that in any manner, directly or indirectly, limit Lincoln Park's ability to carry out or effect the sale of shares of common stock pursuant to a registration statement or otherwise, or in any manner, directly or indirectly, conflict with the surviving obligations under the Lincoln Park Termination Agreement. We issued 1,062,500 shares of our common stock to Lincoln Park in connection with the Lincoln Park Termination Agreement.

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.

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 "at-the-market" sale of our shares will provide sufficient capital to fund our operations through July 31, 2016. Our current cash expenditures are approximately $250,000 per month. As of July 27, 2015, we had approximately $3,025,000 in cash.

Year ended April 30, 2015 compared to years ended April 30, 2014 and 2013

Revenue

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

Operating Expenses

The total operating expenses during the year ended April 30, 2015 decreased by $5,283,653 to $13,695,489 from $18,979,142 in the year ended April 30, 2014. The decrease is attributable to a reduction in compensation expense as we awarded less stock based compensation in 2015 than in 2014. For the year ended April 30, 2014, there was an increase in operating expenses of $17,292,241 to $18,979,142 from $1,686,901 in the year ended April 30, 2013. The increase was attributable to an increase in stock based compensation in 2014. The table below provides additional details relating to our operating expenses.

Operating expenses:	Year ended April 30, 2015	Change - Increase (Decrease) and Percent	Year ended April 30, 2014	Change - Increase (Decrease) and Percent	Year ended April 30, 2013
Research and development	$ 3,476,912	$ 3,153,412 975%	$ 323,500	$ 323,500 100%	$ –
Compensation expense	$ 6,489,334	$ (7,120,661) -52%	$ 13,609,995	$ 12,931,288 1905%	$ 678,707
Director fees	$ 18,000	$ (750,000) -98%	$ 768,000	$ 768,000 100%	$ –
General and administrative, legal and sales and marketing	$ 3,711,243	$ (566,404) -13%	$ 4,277,647	$ 3,269,453 324%	$ 1,008,194

Loss from operations:

Loss from operations during the year ended April 30, 2015 decreased by $5,283,653 from $18,979,142 in the year ended April 30, 2014 to $13,695,489. The decrease is attributable to a reduction in compensation expense as we awarded less stock based compensation in 2015 than in 2014. For the year ended April 30, 2014, there was an increase in loss from operations of $17,294,781 to $18,979,142 from $1,684,361 in the year ended April 30, 2014. The increase was attributable to an increase in stock based compensation in 2014.

Other income (expenses), net:

Other income, net for the year ended April 30, 2015 was $2,840,980 as compared to other expense, net of $8,274,878 in the year ended April 30, 2014. Other income, net for the year ended April 30, 2015 is attributable to gain on the recovery of 15.6 million shares from officers and directors as part of three settlements and the unrealized loss on the derivative liability. Other expenses, net for the year ended April 30, 2014 was $8,274,878 as compared to other income, net of $86,259 in the year ended April 30, 2013. 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. The table below provides additional detail relating to other income (expenses), net.

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,

	Year Ended April 30, 2015	Year Ended April 30, 2014	Year Ended April 30, 2013
Net cash used in operating activites:	$ (4,560,169)	$ (1,554,708)	$ (390,426)
Net cash used in investing activities:	$ –	$ (3,559,069)	$ (646,750)
Net cash provided by financing activities:	$ 3,641,974	$ 8,530,944	$ 1,220,756
Effect of currency rate exchange	$ 1,462	$ –	$ –
Increase (decrease) in cash	$ (916,733)	$ 3,417,167	$ 183,580

Operating Activities:

The cash used in operating activities for the years ended April 30, 2015, 2014 and 2013 are a result of our net losses offset by securities issued for services and compensation, changes to prepaid expenses, accounts payable and accrued expenses for 2015 and 2013 and 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 for 2014.

Investing Activities:

The cash used in investing activities is mainly attributable to the purchase of licenses.

Financing Activities:

The cash provided from financing activities is mainly attributable to the proceeds from the sale of our common stock.

Off-Balance Sheet Arrangements

Except as described below, we have no off-balance sheet arrangements that could have a material current effect or that are reasonably likely to have a material 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 will be made 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.

Critical Accounting Estimates and Policies

Our consolidated financial statements are prepared in accordance with 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 125,419,908, 57,665,600 and 59,433,600 shares at April 30, 2015, 2014 and 2013, 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

As of May 1, 2015, we no longer qualified as a smaller reporting company. However, because we are permitted to satisfy our obligations under this Report by complying with the requirements applicable to a smaller reporting company, we are not required to include information called for by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and schedule and consolidated notes thereto as of April 30, 2015, 2014 and 2013, and for each of the three years in the period ended April 30, 2015, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-28 of this Report.

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

The Company's principal certifying accountants, Robison Hill & Co., notified us of their election to cease representing public companies. On May 26, 2015, the Board approved the engagement of our new auditors, Farber, Hass Hurley LLP and the dismissal of Robinson Hill & Co. There were no disagreements and there was no dissatisfaction with the prior auditors over the past three years.

ITEM 9A. CONTROLS AND PROCEDURES

Our management, including our Chief Executive Officer, President and General Counsel, as its principal executive officer ("Principal Executive and Accounting 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, 2015, 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.*

Although our management, including the Principal Executive Officer and the Vice President of Finance, believes that our disclosure controls and internal controls currently provide reasonable assurance that our desired control objectives have been met, management does not expect that our disclosure controls or internal controls will prevent all error and all fraud. 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 its internal control over financial reporting as of April 30, 2015 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.

Because of these material weaknesses, the Principal Executive Officer and the Vice President of Finance concluded that, as of April 30, 2015, our internal control over financial reporting was not effective based on the criteria outlined in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). We have undertaken the process of implementing new procedures and controls in fiscal year 2016 and to review further our procedures and controls in 2015. In addition, we expect to make additional 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.

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 Accounting 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, 2015 has been audited by Farber Hass Hurley LLP, an 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, 2015. Their reports appear on page F-2 of this Report.

Changes in Internal Control over Financial Reporting

There were no changes, other than those detailed above under Management Report on Internal Control over Financial Reporting, 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 of Pharmacyte Biotech, Inc., formerly known as Nuvilex, Inc.

We have audited 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). Pharmacyte Biotech, Inc.'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 2015 consolidated financial statements, and this report does not affect our report dated July 28, 2015, on those consolidated financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Pharmacyte Biotech, Inc., formerly known as Nuvilex, Inc. has not maintained effective 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).

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 consolidated statements of operations, comprehensive loss, stockholders' equity (Deficiency), and of cash flows of Pharmacyte Biotech, Inc., formerly known as Nuvilex, Inc., and our report dated July 28, 2015, expressed an unqualified opinion.

/s/ Farber Hass Hurley LLP

Chatsworth, California

July 28, 2015

ITEM 9B. OTHER INFORMATION

None.

PART II

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and executive officers as of July 28, 2015, 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	74	Director and Chief Operating Officer
Richard Goldfarb, MD, FACS	61	Director
Thomas Liquard	43	Director

Kenneth L. Waggoner, JD

Kenneth L. Waggoner commenced employment with us on September 1, 2013. He became our Chief Executive Officer and President on November 25, 2013. Shortly thereafter, Mr. Waggoner assumed the additional position of General Counsel. 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 2005, he was a senior partner with Brobeck, Phleger and Harrison, where he was the Managing Partner of Brobeck's Los Angeles office. Brobeck was named one of the top two law firms worldwide that provided services to biotechnology clients including Chiron, Amgen, Biogen Idec, Sangamo, Ligand, DepoTech and many others. While at Brobeck, Mr. Waggoner served as a member of the Executive Committee for almost ten years and on the Policy Committee for numerous years managing Brobeck's worldwide operations with annual revenues in excess of $750,000,000. 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 2005 to 2007, 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 2007 until 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 ("COO") since February 2011 and is a member of the Board. 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, he 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 CEO. 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.

Richard Goldfarb, MD, FACS

Dr. Richard M. Goldfarb has served on the Board since September 2005 when he was President of MedElite, Inc., a subsidiary of eFoodSafety.com.Inc., a predecessor of PharmaCyte Biotech. In that capacity, Dr. Goldfarb brought Talsyn™ CI/bid scar cream into MedElite, Inc.'s product portfolio. Since 2006, Dr. Goldfarb has been the owner and CEO of the Center for SmartLipo & Plastic Surgery and is also Medical Director of Viora, a provider of aesthetic medical solutions. Dr. Goldfarb is the Medical Director of R&D at the FDA-approved Bucks County Clinical research center in Pennsylvania. Dr. Goldfarb is also the medical director of Silhouette Lift and Selphyl. Dr. Goldfarb has 20 years of surgical experience, including liposuction, and has been performing SmartLipo since its inception. He was the first in Pennsylvania to receive the SmartLipo technology and has performed the most procedures in this area. In view of his skill in performing this SmartLipo procedure, Cynosure has commissioned Dr. Goldfarb to travel throughout the country teaching and training other physicians the SmartLipo surgical procedure.

Dr. Goldfarb obtained his M.D. degree from the University of Health Sciences/Finch University, the Chicago Medical School, with honors in surgery. He completed his surgical training at Northeastern Ohio College of Medicine. Dr. Goldfarb obtained additional training in cosmetic surgery at the University of Pennsylvania, Department of Plastic Surgery. He also trained at Yale University and is a Member of the American Academy of Cosmetic Surgeons. Dr. Goldfarb is Board Certified and a Fellow of the American College of Surgeons, the American Medical Association, the Ohio State Medical Association and the Pennsylvania Medical Society. He is also a member of the American Academy of Cosmetic Physicians.

During his tenure on the Board, Dr. Goldfarb has seen us transition from a nutraceutical company to its present position as a biotechnology company. In addition to his proficiency as a surgeon, Dr. Goldfarb has significant interest and experience with all forms of cancer and its treatments. Based upon his education, training, experience, we appointed Dr. Goldfarb to the Board.

Thomas Liquard

Thomas Liquard was appointed to the Board on April 27, 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 COO then CEO of Alchemia Limited (Alchemia), a major 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 CEO, 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, facilitated multiple competitive planning sessions in the United States, 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 big pharma 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, 2015, 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, 2015 includes Board meetings which are run by the Board, with Kenneth L. Waggoner as Chairman of the Board and Secretary leading the meetings. Directors include Mr. Waggoner, Dr. Crabtree, Dr. Goldfarb 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

On September 19, 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.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information about all cash and non-cash compensation awarded to, earned by, or paid to: (i) all persons serving as our principal executive officer during the last two fiscal years; (ii) all persons serving as our principal financial officer during the last two fiscal years; (iii) our three most highly compensated executive officers (other than principal executive officer and principal financial officer) serving as such at the end of the last two fiscal years; and (iv) up to two additional persons for whom disclosure would have been provided pursuant to clause (iii) above but for the fact that the person was not serving as our executive officer at the end of the last fiscal year, and each current director during fiscal years ended April 30, 2015 , 2014 and 2013. There were no other 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 in the Summary Officer Compensation Table below.

Summary Officer Compensation Table

Officers:

Name	Principal Position	Fiscal Year Ended April 30,	Salary ($)	Stock Awards Shares	Stock Value ($)	Option Awards ($)	Total ($)
Kenneth L. Waggoner	Chief Executive Officer,	2015	$ 150,000	2,200,000	$ 450,150	$ 778,172	$1,378,322
	President and	2014	$ 50,000	10,000,000	$3,180,000		$3,230,000
	General Counsel	2013					$ –
Patricia Gruden	Former Chief	2015	$ 72,000				$ 72,000
	Financial Officer	2014	$ 34,000	10,000,000	$3,180,000		$3,214,000
		2013		150,000	$ 4,200		$ 4,200
Gerald W. Crabtree, PhD	Chief Operating Officer	2015	$ 140,000	1,100,000	$ 242,860	$ 778,172	$1,161,032
		2014	$ 59,830	10,800,000	$3,338,380		$3,398,210
		2013	$ 17,500	240,000	$ 13,900		$ 31,400
Timothy Matula	Former President of	2015	$ 87,000				$ 87,000
	Viridis Biotech	2014		10,000,000	$3,180,000		$3,180,000
		2013					$ –
Robert R. Ryan, PhD	Former Chief Scientific	2015					$ –
	Officer Former Chief	2014	$ 35,000	800,000	$ 102,080		$ 137,080
	Executive Officer and President	2013		7,780,000	$ 360,544		$ 360,544

On March 24, 2014, our Board granted Mr. Waggoner 10,000,000 shares of our common stock for his extraordinary efforts and time commitment related to the successful growth and development of the Company and Viridis Biotech since he joined us. The stock grant was provided on the condition that Mr. Waggoner enter into an Executive Compensation Agreement ("Waggoner Compensation Agreement") requiring him to: (i) stay employed by us on a full-time basis in his current positions of Chief Executive Officer, President and General Counsel; (ii) assume the new positions of Chief Executive Officer and General Counsel of Viridis Biotech; and (iii) become our director, unless extenuating circumstances require that he withdraw from these full-time positions, at which time Mr. Waggoner will be obligated to remain our consultant for the duration of the term of the Waggoner Compensation Agreement. Among other provisions, the Waggoner Compensation Agreement is to have a term of two years and contain an appropriate "anti-dilution" provision with respect to the shares granted to Mr. Waggoner. The specific terms and conditions of the Waggoner Compensation Agreement are to be negotiated, documented and approved by the Board.

On March 24, 2014, our Board granted Mrs. Gruden 10,000,000 shares of our common stock for her extraordinary efforts and time commitment since 2011 and anticipated contribution to our success in the future. The stock grant was provided on the condition that Mrs. Gruden enter into an Executive Compensation Agreement ("Gruden Compensation Agreement") requiring that she stay employed by us on a full-time basis in her current positions of Chairman of the Board and Chief Financial Officer, unless extenuating circumstances require that she withdraw from full-time employment, at which time she will be obligated to remain as our consultant for the duration of the term of the Gruden Compensation Agreement. Among other provisions, the Gruden Compensation Agreement will have a term of two years and contain an appropriate "anti-dilution" provision with respect to the shares granted to Mrs. Gruden. The specific terms and conditions of the Gruden Compensation Agreement are to be negotiated, documented and approved by the Board.

On March 24, 2014, our Board granted Dr. Crabtree 10,000,000 shares of our common stock for his extraordinary efforts and time commitment related to the successful growth and development of the Company and Viridis Biotech since he joined us. The stock grant was provided on the condition that Dr. Crabtree enter into an Executive Compensation Agreement ("Crabtree Compensation Agreement") requiring that he stay employed by us on a full-time basis in his current positions as the Chief Operating Officers and Viridis Biotech and as our director, unless extenuating circumstances require that he withdraw from these full-time positions, at which time Dr. Crabtree will be obligated to remain our consultant for the duration of the term of the Crabtree Compensation Agreement. Among other provisions, the Crabtree Compensation Agreement will have a term of two years and contain an appropriate "anti-dilution" provision with respect to the shares granted to Dr. Crabtree. The specific terms and conditions of the Crabtree Compensation Agreement are to be negotiated, documented and approved by the Board.

On March 24, 2014, our Board granted Mr. Matula 10,000,000 shares of our common stock for his extraordinary efforts and time commitment since 2011 and anticipated contribution to the our success in the future. The stock grant was provided on the condition that Mr. Matula enter into an Executive Compensation Agreement ("Matula Compensation Agreement") requiring that he stay employed by us on a full-time basis in his current position as President of Viridis Biotech, remain our director and assume the new position of Chief Strategist, unless extenuating circumstances require that he withdraw from full-time employment for us, at which time he will be obligated to remain as our consultant for the duration of the term of the Matula Compensation Agreement. Among other provisions, the Matula Compensation Agreement will have a term of two years and will contain an appropriate "anti-dilution" provision with respect to the shares granted to Mr. Matula. The specific terms and conditions of the Matula Compensation Agreement are to be negotiated, documented and approved by the Board.

We did not pay or accrue any other compensation, in the form of bonus, stock awards, option awards, 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, 2015 and 2014; neither were there any prerequisites or other personal benefits. We do not have any option plan, equity incentive plan or retirement plan at the present time.

Employment Arrangements

Dr. Robert F. Ryan

The following sets forth a summary of an oral agreement, a Memorandum of Understanding ("MOU"), an employment agreement ("Employment Agreement") our Board resolutions with respect to the employment of Dr. Ryan.

In January of 2011, we employed Dr. Ryan as our President and Chief Executive Officer. We agreed to pay an indeterminate amount of compensation based upon the availability of funds from the efforts of Dr. Ryan to raise $5.0 million he committed to raise when he became employed. That compensation was to include the issuance of shares of our common stock based upon Dr. Ryan's performance. It was agreed between the parties to defer developing the factors necessary to determine the amount of cash and share compensation until sufficient funds had been raised by Dr. Ryan. This agreement was oral.

Commencing February 1, 2011 and ending January 31, 2012, Dr. Ryan served as our President and Chief Executive Officer. There is a MOU with Dr. Ryan, dated January 31, 2011. Under the MOU compensation was composed of two parts: Part 1. For joining us, Dr. Ryan was issued 6,000,000 shares of restricted stock and 500,000 shares on a monthly basis earned on the first day of each respective month with us; Part 2. In lieu of a standard salary, Dr. Ryan was paid 250,000 restricted shares on a monthly basis earned on the last day of each respective month on a monthly basis from February through May 2011 and 415,000 shares each month starting June 1, 2011 through the end of the term of the MOU. There was no cash component of his salary. In addition, we provided four incentives: Part 1. We offered Dr. Ryan the following performance-based incentives as a supplement to his income: 3,000,000 restricted shares of common stock upon completion of the acquisition of SG Austria or a related entity by us; Part 2. 2,000,000 restricted shares of common stock upon completion of the acquisition of another comparable company earned at the Closing of the acquisition; Part 3. 1,000,000 restricted shares of common stock upon completion of the acquisition of a third comparable company or through the arrangement of a distribution channel where sales are imminent or sales to any entity where the sales are anticipated to be greater than $50,000; Part 4. 1,000,000 restricted shares of common stock for the commercialization of Oraphyte, Citroxin, or another of the company's products from the existing product line or addition of any other entity to us. These shares are deemed to have been earned at either the sale of the product to a third party, or through the arrangement of a distribution channel where sales are imminent or sales to any entity where the sales are anticipated to be greater than $50,000; Part 4: 1,000,000 restricted shares for the completion of any major event, such as, but not limited to, the following: an IND filing and issuance, clinical trial initiation or completion, a NDA filing, a NDA approval, commercialization or monetization of any new product or acquisition of additional products or companies.

On January 9, 2012, Dr. Ryan assumed the position of Chief Financial Officer upon the receipt of the resignation from Patricia Gruden, our then Chief Financial Officer. There was no Board approval for Dr. Ryan assuming this position.

There is an Employment Agreement with Dr. Ryan dated January 31, 2012. Pursuant to the provisions of the Employment Agreement: (i) the term was from February 1, 2012 through January 31, 2016; (ii) Dr. Ryan will continue to receive 415,000 shares of restricted common stock per month as temporary salary as President and CEO with no cash component through the compensation term; (iii) in lieu of a standard salary as CFO, if there is no new person to take on the position of CFO by July 31, 2012, commencing on August 1, 2012, Dr. Ryan would receive 350,000 restricted shares of common stock each month; (iv) performance incentives shall remain as provided previously unless changed by the Board; (v) a permanent salary of $120,000 shall be provided starting upon completion of the acquisition of Austrianova or another entity plus 2,980,000 shares stock per year; (v) an annual bonus based on performance shall be given in conjunction with achievement of objectives set by us and Dr. Ryan; (vi) a failure to renew the agreement at the end of the term regardless of reason shall be treated as a termination by us without cause; (vii) upon our termination of Dr. Ryan's employment without cause or by Dr. Ryan with good reason, we are to pay Dr. Ryan his base salary for one year following the termination plus the previous year's annual bonus payment; (viii) in the event we terminate Dr. Ryan's employment with cause or Dr. Ryan resigns, we are to pay Dr. Ryan his then current base salary for one year; and (ix) in the event that the agreement is terminated pursuant to a change in control, Dr. Ryan shall receive a severance payment equal to 24 months of benefits and bonuses to be calculated at the time of termination.

On February 12, 2012, our Board elected Dr. Robert F. Ryan to be a member of the Board.

On May 1, 2013, by Unanimous Written Consent of our Board ("May 1, 2013 BOD Consent"), our Board resolved that, commencing July 1, 2013 and continuing until April 30, 2017 or until it reconvenes and establishes new compensation terms, we will pay Dr. Ryan: (i) a salary of $60,000 per year at the rate of $5,000 per month; (ii) 2,400,000 restricted shares of our common stock per year payable in the amount of 200,000 shares per month; and (iii) an increase in his monthly salary to $10,000 per month for an annual salary of $120,000 upon the commencement of clinical trials of our "Cell-in-a-Box®" technology.

During May of 2014, a dispute arose between us and Dr. Ryan relating to: (i) the validity, authenticity and approval of the MOU and the Employment Agreement; (ii) the circumstances surrounding our issuance of stock and compensation to Dr. Ryan; and (iii) Dr. Ryan's entitlement to the compensation previously paid and described in the various purported agreements. Shortly thereafter, we placed Dr. Ryan on a leave of absence with pay pending the completion of our investigation. We undertook an investigation into the facts relating to these issues.

On May 14, 2014, our Board adopted a resolution to eliminate any further accrual of Dr. Ryan's shares pursuant to a Board resolution and continued his leave of absence with pay pending the completion of our review into Dr. Ryan's activities.

Effective as of September 19, 2014, Dr. Ryan resigned from our Board and from his position as our Chief Scientific Officer. In connection with his departure, we entered into the Settlement Agreement pursuant to which we agreed to pay Dr. Ryan $183,000 in settlement of certain loans and expenses, transfer certain assets to Dr. Ryan under the terms of the Asset Purchase Agreement and allow Dr. Ryan to retain 26,036,800 shares of our common stock earned and purchased. Under the Settlement Agreement, Dr. Ryan agreed to surrender certain share certificates of us and of Bio Blue Bird AG, resign from all of his positions with us, return all our property and data in his possession and release us from all claims of any type or description. In addition, Dr. Ryan agreed to abide by certain limitations on the transfer of his shares of our common stock. Upon the execution of the Settlement Agreement, Dr. Ryan may sell up to 1,250,000 shares, except that he may not sell any shares for a price that is more than $0.02 less than the closing price of the shares on the previous trading day. Apart from these 1,250,000 shares of his common stock, on any given day Dr. Ryan may not sell any more than 30,000 shares plus an additional 15,000 shares for each 1,000,000 shares reported traded (rounded down to the nearest million) on the immediately previous trading day. The Asset Purchase Agreement provides for the sale of listed nutraceutical assets to Dr. Ryan in exchange for his execution of the Settlement Agreement and his assumption of certain obligations.

Kenneth L. Waggoner, JD

In September of 2013, we employed Mr. Waggoner as an employee and agreed to commence paying him an annual salary of $60,000, payable in the amount of $5,000 per month. In addition, we agreed to pay Mr. Waggoner 1,200,000 restricted shares of our common stock annually, payable at the rate of 100,000 shares per month as additional compensation subject to review and increase at our discretion. On April 1, 2014, we increased Mr. Waggoner's annual salary to $120,000, payable in the amount of $10,000 per month. On July 1, 2014, we increased Mr. Waggoner's annual salary to $156,000, payable in the amount of $13,000 per month.

On March 11, 2015, effective as of January 1, 2015, we entered into the Waggoner Compensation Agreement. The Waggoner Compensation Agreement is for a term of two years with annual extensions thereof 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.

As discussed above, subject to Mr. Waggoner entering into the Waggoner Compensation Agreement, in March of 2014, our Board granted Mr. Waggoner 10,000,000 shares of our common stock. On March 11, 2015, Mr. Waggoner was granted 2,400,000 additional shares of our common stock vesting at the rate of 600,000 shares per quarter with an identical grant to be made on January 1, 2016. Further, and as previously disclosed and subject to Mr. Waggoner entering into the Waggoner Compensation Agreement, on March 11, 2015, Mr. Waggoner was granted a stock option to purchase up to 10,000,000 shares of common stock at a price of $0.11 per share, the fair market value on the date of grant, and on March 11, 2015, was granted a second stock option to purchase up to 2,400,000 shares at a price of $0.11 per share, the fair market value on the date of grant, with vesting at the rate of 200,000 shares per month. On January 1, 2016, Mr. Waggoner will be granted another stock option to purchase up to 2,400,000 shares at the fair market value on the date of grant with the same vesting schedule.

Dr. Gerald W. Crabtree

In February of 2011, we employed Dr. Crabtree as our Chief Operating Officer. We agreed to pay an indeterminate amount of compensation based upon the availability of funds from the efforts of Dr. Ryan to raise $5.0 million he committed to raise when he became employed. That compensation was to include the issuance of shares of our common stock based upon Dr. Crabtree's performance. It was agreed between the parties to defer developing the factors necessary to determine the amount of cash and share compensation until sufficient funds has been raised by Dr. Ryan. This agreement was oral.

Pursuant to the May 1, 2013 BOD Consent, our Board resolved that, commencing September 1, 2013 and continuing until April 30, 2017 or until it reconvenes and establishes new compensation terms, we will pay Dr. Crabtree: (i) a salary of $60,000 per year at the rate of $5,000 per month; (ii) 1,200,000 shares of our restricted common stock per year payable in the amount of 100,000 shares per month; and (iii) an increase in his monthly salary to $7,500 per month for an annual salary of $90,000 upon the commencement of clinical trials of our "Cell-in-a-Box®" technology.

On April 1, 2014, we increased Dr. Crabtree's annual salary to $120,000, payable in the amount of $10,000 per month. On July 1, 2014, we increased Dr. Crabtree's annual salary to $156,000, payable in the amount of $13,000 per month.

On March 11, 2015, effective as of January 1, 2015, we entered into the Crabtree Compensation Agreement. The Crabtree Compensation Agreement is for a term of two years with annual extensions thereof 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.

As discussed above, subject to Dr. Crabtree entering into the Crabtree Compensation Agreement, in March of 2014, our Board granted Dr. Crabtree 10,000,000 shares of our common stock. On March 11, 2015, Dr. Crabtree was granted an additional 1,200,000 shares of our common stock vesting at the rate of 300,000 shares per quarter with an identical grant to be made on January 1, 2016. Further, as previously disclosed and subject to Dr. Crabtree entering into the Crabtree Compensation Agreement, on March 11, 2015, Dr. Crabtree was granted a stock option to purchase up to 10,000,000 shares of Common Stock at a price of $0.11 per share, the fair market value on the date of grant, and on March 11, 2015, was granted a second stock option to purchase up to 2,400,000 shares at a price of $0.11 per share, the fair market value on the date of grant, with vesting at the rate of 200,000 shares per month. On January 1, 2016, Dr. Crabtree will be granted another stock option to purchase up to 2,400,000 shares at the fair market value on the date of grant with the same vesting schedule.

Patricia Gruden

Prior to April 1, 2014, Mrs. Gruden was not employed by us even though she periodically worked as our Chief Financial Officer. Mrs. Gruden did not work for us in accordance with an agreement that specified the terms of her employment. She was, however, compensated as the Chairman and member of our Board. Her compensation was set in accordance with our policy in compensating all of our directors at the time. As described above, previously our Board did not set a fixed compensation fee for directors; instead, it reviewed individual director performance on an annual basis. Compensation was earned on a merit-system based upon a review of the preceding year's performance.

On April 1, 2014, we employed Mrs. Gruden as an employee at an annual salary annual salary to $120,000, payable in the amount of $10,000 per month. On July 1, 2014, we increased Mrs. Gruden's annual salary to $156,000, payable in the amount of $13,000 per month.

Effective October 1, 2014, Mrs. Gruden resigned as our Chief Financial Officer, Treasurer, Secretary, Board member and employee.

Tim Matula

Prior to April 1, 2014, Tim Matua was not employed by us even though he periodically worked for Viridis Biotech, then known as Medical Marijuana Sciences. He was, however, compensated as a member of our Board. His compensation was set in accordance with our policy in compensating all of our directors at the time. As described above, the Board previously did not set a fixed compensation fee for directors; instead, it reviewed individual director performance on an annual basis. Compensation was earned on a merit-system based upon a review of the preceding year's performance.

On April 1, 2014, we employed Mr. Matula as an employee at an annual salary annual salary to $120,000, payable in the amount of $10,000 per month. On July 1, 2014, we increased Mr. Matula's annual salary to $156,000, payable in the amount of $13,000 per month.

Effective October 1, 2014, Mr. Matula resigned as the President of Medical Marijuana Sciences, Inc., Board member and employee of us.

Director Compensation

The following table sets forth certain information concerning compensation paid or accrued to our directors during the year ended April 30, 2015.

Summary Compensation Table

Directors:

Name	Principal Position	Fiscal Year Ended April 30,	Salary ($)	Stock Awards Shares	Stock Value ($)	Option Awards ($)	Total ($)
Kenneth L. Waggoner	Chairman of the Board	2015					$ –
		2014					$ –
		2013					$ –
Patricia Gruden	Former Chairman of the Board	2015	$ 30,000			$1,451,893	$1,481,893
		2014		1,500,000	$ 144,000		$ 144,000
		2013					$ –
Gerald W. Crabtree, PhD	Director	2015					$ –
		2014		500,000	$ 48,000		$ 48,000
		2013					$ –
Robert Bowker	Former Director	2015					$ –
		2014		500,000	$ 48,000		$ 48,000
		2013	$ 90,000	3,500,000	$ 98,000		$ 188,000
Richard Goldfarb, MD	Director	2015	$ 9,000			$ 725,946	$ –
		2014		500,000	$ 48,000		$ 48,000
		2013					$ –
Timothy Matula	Former Director	2015	$ 10,000			$1,451,893	$1,461,893
		2014	$ 20,000	4,500,000	$ 432,000		$ 452,000
		2013					$ –
Robert R. Ryan, PhD	Former Director	2015					$ –
		2014		500,000	$ 48,000		$ 48,000
		2013					$ –
Thomas Liquard	Director	2015	$ 9,000			$ 34,685	$ 43,685
		2014					$ –
		2013					$ –

Members of our Board were previously compensated for performance of their duties as directed by the Chairman of the Board. Until April 27, 2015, the Board had not set a fixed compensation plan for directors, but chose to review Board and individual director performance on an annual basis with Board compensation being earned on a merit-system. Effective April 27, 2015, the Board approved a compensation plan for directors Mr. Liquard and Dr. Goldfarb. The plan commenced April 1, 2015 and continues until resignation or removal or until a success 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 is to receive 9,000 per quarter on a pro-rated basis for period of less than a quarter. Board compensation for Mr. Waggoner and Dr. Crabtree are included in their Executive Compensation Agreement.

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

The following table sets forth as of April 30, 2015, 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	13,500,000	1.84%
Patricia Gruden, Former Chairman of the Board and Chief Financial Officer	(2)	
Gerald W. Crabtree, PhD, Chief Operating Officer and Board Member	12,600,000	1.72%
Robert Bowker, Board Member	(3)	
Richard Goldfarb, MD, FACS, Board Member	15,920,000	2.17%
Timothy Matula, Former President of Viridis Biotech and Board Member	(4)	
Robert F. Ryan, PhD, Former Chief Scientific Officer and Board Member	(5)	
All directors and executive officers as a group (7 persons)	42,020,000	5.73%

(1) Percentages based on 732,760,536 shares of common stock issued and outstanding as of April 30, 2015.

(2) Effective October 1, 2014, Mrs. Gruden resigned. We believe that Mrs. Gruden has sold some of the shares she was awarded during her tenure with us. We have no information as to the number of shares she has sold.

(3) Effective October 1, 2014, Mr. Bowker resigned. We believe that Mr. Bowker 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.

(4) Effective October 1, 2014, Mr. Matula resigned. We believe that Mr. Matula 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.

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

We had the following related party transactions:

As of April 30, 2015, 2014 and 2013, we owed Berkshire Capital $0, $0 and $393,158, 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, 2013 and 2014 were $393,158 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, 2013, we did not make any payments on these loans. 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.

As of April 30, 2015, 2014 and 2013, we owed our Chief Financial Officer and Chairman of the Board, Patricia Gruden, $0, $0 and $23,200 in principal and $2,740 in interest, for a total of $25,940; respectively, for a loan she made to us in 2011. The loan bears interest at 8% and is due on demand. The highest amount outstanding during the fiscal year ended April 30, 2013 was $25,940. During the year ended April 30, 2014, we paid the outstanding principal balance of $23,200 and accrued interest of $4,117.

As of April 30, 2013, we owed Dr. Robert F. Ryan, our former Chief Scientific Officer and former Chief Executive 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. The highest amount outstanding occurred during the fiscal year ended April 30, 2013 and totaled $283,743. During the year ended April 30, 2013, we made principal payments totaling $95,600 and no interest payments in respect of this loan. During the year ended April 30, 2014, we 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. Subsequent to April 30, 2014, we repaid an additional $20,000 of principal. Effective as of September 19, 2014, Dr. Ryan resigned from the Board and from his position as our Chief Scientific Officer. In connection with his departure, we entered into the Settlement Agreement pursuant to which we paid Dr. Ryan $183,000 in settlement of the full amount of his loan.

During the year ended April 30, 2015, we issued stock options to directors and officers (see Note 8 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 Marketplace Rules. 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 auditor, Robison, Hill & Company, PC for professional services rendered for fiscal year ended April 30, 2014 and through the period ended January 30, 2015, is set forth below. A summary of the fees billed by the our current independent auditor, Farber Hass Hurley LLP, for professional services rendered for fiscal year ended April 30, 2015, is also set forth below.

Service	2015	2014
Audit Fees	$ 40,000	$ 31,500
Quarterly Review Fees	$ 23,750	$ 20,165
Tax Fees	$ 6,500	$ 5,500
All Other Fees	$ –	$ –
Total	$ 70,250	$ 57,165

Our Chief Executive Officer and our Vice President of Finance pre-approve all services to be performed by our independent auditor. All of the services listed above have been pre-approved by them.

ITEM 15. EXHIBITS

Except as so indicated in Exhibits 32.1 and 32.2, the following exhibits are filed as part of, or incorporated by reference, the Report.

Exhibit No.	Description	Location
2.1	Asset Purchase Agreement, dated August 24, 2005, between the Company and Mark Taggatz.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the 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	Share Exchange Agreement, dated May 26, 2011 between the Company and SG Austria Private Limited.	Incorporated by reference from the Company's Current Report on Form 10-Q filed with the SEC on September 14, 2011.
2.6	Third Addendum, dated June 25, 2013 between the Company and SG Austria Private Limited.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 17, 2013.
2.7	Licensing Agreement, dated June 25, 2013 between the Company and Austrianova Singapore Private Limited.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 17, 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.
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 Registrant.	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 Singapore Pte. Ltd. and Registrant 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 Singapore dated June 25, 2013.	Incorporated by reference from the Company's 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 Registrant 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 Registrant 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 registrant 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 Australia Pty Ltd 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	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.
10.15	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
10.16	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.
10.17	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.
10.18	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.
10.19	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.
10.20	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.
10.21	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.
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.
15a(2)	Schedule II - Valuation and Qualifying Accounts for the Years Ended 2015, 2014 and 2013.	Incorporated by reference to page F-28 of the financial statements included herewith.
21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of Farber Hass Hurley LLP	Filed herewith.
23.2	Consent of Robison, Hill & Co.	Filed herewith.
31.1	Certification of Chief Executive and Financial 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 and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.	Filed herewith.
101	Interactive Data Files for PharmaCyte Biotech, Inc. Form 10-K for the period ended April 30, 2015	Filed 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.

**Financial Statements Schedule:

The following financial statement schedule is set forth on page F-28 of this Report:

Schedule II — Valuation and Qualifying Accounts for the years ended April 30, 2015, 2014 and 2013.

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 the Exchange Act, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMACYTE BIOTECH, INC.

July 29, 2015 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer and acting Principal Financial and 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, 2015 By: /s/ Richard Goldfarb
Richard Goldfarb, MD, FACS, Director

July 29, 2015 By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, PhD, Director

July 29, 2015 By: /s/ Thomas Liquard
Thomas Liquard, Director

ITEM 8. SELECTED FINANCIAL DATA

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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.

/s/ Farber Hass Hurley LLP

Chatsworth, California
July 28, 2015

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 balance sheet of Nuvilex, Inc., now known as PharmaCyte Biotech, Inc., and Subsidiaries ("Company") as of April 30, 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficiency) and cash flows for the years ended April 30, 2014 and 2013. Our audits 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 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. 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 years ended April 30, 2014 and 2013, 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.
CONSOLIDATED BALANCE SHEETS

	April 30, 2015	April 30, 2014
ASSETS		
Current assets:		
Cash	$ 2,699,737	$ 3,616,470
Prepaid expenses and other current assets	119,257	570,106
Total current assets	2,818,994	4,186,576
Other assets:		
Intangibles	3,549,427	3,549,427
Investment in S G Austria	1,572,193	1,572,193
Other assets	7,854	7,854
Total other assets	5,129,474	5,129,474
Total Assets	$ 7,948,468	$ 9,316,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 496,699	$ 188,044
Accrued expenses	23,667	41,763
Derivative liability	492,049	–
License agreement obligation	1,000,000	–
Due to officer	–	143,859
Total current liabilities	2,012,415	373,666
Total Liabilities	2,012,415	373,666
Commitments and Contingencies (Notes 10 and 12)		
Preferred stock, authorized 10,000,000 shares, $0.0001 par value, 0 shares issued and outstanding, respectively	–	–
Stockholders' equity:		
Common stock, authorized 1,490,000,000 shares, $0.0001 par value, 732,760,536 and 690,615,714 shares issued and outstanding as of April 30, 2015 and 2014, respectively	73,273	69,063
Additional paid in capital	85,415,954	75,998,588
Common stock to be issued	–	1,574,860
Accumulated deficit	(79,554,636)	(68,700,127)
Accumulated other comprehensive income	1,462	–
Total stockholders' equity	5,936,053	8,942,384
Total Liabilities and Stockholders' Equity	$ 7,948,468	$ 9,316,050

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30,		
	2015	**2014**	**2013**
Revenues:			
Product sales	$ –	$ –	$ 12,160
Total revenue	–	–	12,160
Cost of revenue	–	–	9,620
Gross margin	–	–	2,540
Operating Expenses:			
Sales and marketing	230,500	872,200	106,413
Research and development costs	3,476,912	323,500	–
Compensation expense	6,489,334	13,609,995	678,707
Director fees	18,000	768,000	–
Legal and professional	884,346	1,487,668	284,510
General and administrative	2,596,397	1,917,779	617,271
Total operating expenses	13,695,489	18,979,142	1,686,901
Loss from operations	(13,695,489)	(18,979,142)	(1,684,361)
Other income (expense):			
Gain on forgiveness of debt	–	1,633,380	277,085
Loss on conversion of preferred stock	–	(5,895,000)	
Loss on settlement of debt	–	(3,993,295)	(39,000)
Unrealized loss on change in derivative	(492,049)	–	–
Gain on settlements	3,337,967	–	–
Other income	–	–	2,590
Interest expense, net	(4,938)	(19,963)	(154,416)
Total other income (expense), net	2,840,980	(8,274,878)	86,259
Net loss	$ (10,854,509)	$ (27,254,020)	$ (1,598,102)
Basic and diluted loss per share	$ (0.02)	$ (0.05)	$ (0.00)
Weighted average shares outstanding basic and diluted	704,327,656	583,219,665	440,954,850

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended April 30,		
	2015	**2014**	**2013**
Net Loss	$ (10,854,509)	$ (27,254,020)	$ (1,598,102)
Other comprehensive income:			
Foreign currency translation adjustment	1,462	–	–
Other comprehensive income	1,462	–	–
Comprehensive loss	$ (10,853,047)	$ (27,254,020)	$ (1,598,102)

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)
YEARS ENDED APRIL 30, 2015, 2014 AND 2013

	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, 2012	**416,293,195**	**$ 41,631**	**$ 37,526,524**	**$ –**	**$(39,848,005)**	**$ –**	**(2,279,850)**
Shares issued for compensation	13,326,668	1,332	652,364	–	–	–	653,696
Shares issued for services	8,771,429	877	330,123	–	–	–	331,000
Shares issued for settlement of debt	3,592,656	359	143,237	–	–	–	143,596
Shares issued for PPM	39,622,400	3,962	1,234,242	–	–	–	1,238,204
Shares issued for cash	500,000	50	9,950	–	–	–	10,000
Net loss	–	–	–	–	(1,598,102)	–	(1,598,102)
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	–	–	231,490	–	–	–	231,490
Foreign currency translation adjustment	–	–	–	–	–	1,462	1,462
Net loss	–	–	–	–	(10,854,509)	–	(10,854,509)
Balance, April 30, 2015	**732,760,536**	**$ 73,273**	**$ 85,415,954**	**$ –**	**$(79,554,636)**	**$ 1,462**	**$ 5,936,053**

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30,		
	2015	**2014**	**2013**
Cash flows from operating activities:			
Net loss	$ (10,854,509)	$ (27,254,020)	$ (1,598,102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock issued for services	1,269,707	17,928,309	984,696
Stock issued for compensation	735,189	–	–
Stock based compensation - options	5,236,901	–	–
Stock based compensation - warrants	231,490	–	–
Gain on settlements	(3,337,967)	–	–
Gain on recovery of stock issued for services	(74,436)	–	–
Loss on derivative liability	492,049	–	–
Loss on settlement of debt	–	3,993,295	39,000
Loss on conversion of preferred stock	–	5,895,000	–
Gain of forgiveness of debt	–	(1,633,380)	(277,085)
Stock issued for interest expense	–	–	102,203
Amortization of discount premium	–	–	(5,695)
Change in assets and liabilities, net of effect of acquisition of business:			
Decrease in accounts receivable	–	–	2,581
Decrease in inventories	–	–	6,846
(Increase) / decrease in prepaid expenses and current assets	450,849	(442,236)	62,667
Increase / (decrease) in accounts payable	308,654	(59,191)	97,708
Increase / (decrease) in accrued expenses	(18,096)	17,515	194,755
Increase in license agreement obligation	1,000,000	–	–
Net cash used in operating activities	(4,560,169)	(1,554,708)	(390,426)
Cash flows from investing activities:			
Purchase of intangibles	–	(3,500,000)	(646,750)
Payment towards lease deposit	–	(7,854)	–
Payments towards acquisition	–	(51,215)	–
Net cash used in investing activities	–	(3,559,069)	(646,750)
Cash flows from financing activities:			
Proceeds from sale of common stock	3,785,833	8,510,880	1,146,000
Proceeds from borrowings, related party	–	81,586	149,756
Repayment of debt, related party	(143,859)	(61,522)	(75,000)
Net cash provided by financing activities	3,641,974	8,530,944	1,220,756
Effect of currency rate exchange on cash	1,462	–	–
	–	–	–
Net increase (decrease) in cash	(916,733)	3,417,167	183,580
Cash at beginning of the year	3,616,470	199,303	15,723
Cash at end of the year	$ 2,699,737	$ 3,616,470	$ 199,303
Supplemental disclosures of cash flows information:			
Cash paid during the years for interest	$ 45,141	$ 4,117	$ –
Non cash investing and financing activities:			
Common stock issued in settlement of debt	$ –	$ 765,981	$ 143,596

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, PharmaCyte Biotech, Inc. ("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 unique and patented technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer and its symptoms, 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 Singapore Private Limited ("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.

The acquisition of Bio Blue Bird provided the Company with exclusive, worldwide licenses to use a proprietary cellulose-based live cell encapsulation technology for the development of treatments for all forms of cancer using certain types of human cells. The licenses are pursuant to patents licensed from Bavarian Nordic A/S and GSF-Forschungszentrum fur Umwelt u. Gesundeit GmbH. These licenses enable the Company to carry out the research and development of cancer treatments that are based upon the "Cell-in-a-Box® technology."

In June 2013, the Company 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. 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, 2015, the Company paid Austrianova $1.0 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 $1.3 million of the Upfront Payment. The parties have agreed in principle to an amendment to the license agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented.

NOTE 2 – CAPITALIZATION AND MANAGEMENT PLANS

Capitalization

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America ("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, 2015, the Company has an accumulated deficit of $79,554,636 and incurred a net loss for year ended April 30, 2015 of $10,854,509.

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. The Company continues 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" 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 it is not without doubt that it will be successful in generating revenues in the future in this sector. The Company believes that cash as of April 30, 2015 and the proceeds from the additional sale of registered shares will raise sufficient capital to meet its capital requirements. From May 1, 2015 through July 13, 2015; the Company raised additional capital of approximately $1,220,000 in "at-the-market" transactions. The Company believes that the "at-the-market" sale of its shares will provide sufficient capital to fund its operations through July 31, 2016.

If the Company is not able to raise substantial additional capital in a timely manner, the Company may not be able to complete its required clinical trials and may be forced to cease operations.

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 Goals and Strategy

The Company's goal is to have the Company become an industry-leading biotechnology company using the Cell-in-a-Box® live cell encapsulation technology as a platform upon which treatments for cancer and diabetes can be built.

The Company's initial strategy is to build upon and advance the success of previous Phase 1/2 and Phase 2 pancreatic cancer clinical trials. The Company's acquisition of Bio Blue Bird was the first step in this strategy.

The Company will seek to raise capital to fund growth opportunities and provide for its working capital needs as its strategy is executed. The Company's strategy to achieve its goals consists of the following:

- The completion of the preparations for the Phase 2b clinical trial in advanced, inoperable pancreatic cancer to be conducted by CNS in Australia;
- The completion of the preparations for the clinical trials that will examine the effectiveness of its pancreatic cancer treatment in ameliorating the pain and accumulation of malignant ascites fluid in the abdomen that are characteristic of pancreatic cancer. These clinical trials will be conducted by TD2 in the United States;
- The completion of preclinical studies that involve the encapsulation of a human cell line genetically engineered to produce, store and secrete insulin on demand at levels in proportion to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box® technology;
- The enhancement of the Company's ability to expand into the biotechnology arena through further research and partnering agreements;
- The acquisition of new 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.

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 AG ("Bio Blue Bird"); (ii) Nuvilex Europe Limited (soon to be renamed PharmaCyte Biotech Europe Limited); (iii) Nuvilex Australia Limited (soon to be renamed PharmaCyte Biotech Australia Private Limited); and (iv) Viridis Biotech, Inc. ("Viridis Biotech") and are prepared in accordance with United States generally accepted accounting principles ("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. 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.

Goodwill and Intangible Assets

The Company records the excess of purchase price over the fair value of the identifiable net assets acquired as goodwill and other indefinite-lived intangibles. 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.

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 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, 2015, 2014 and 2013.

Earnings per Share

Basic earnings (loss) per share are computed by dividing earnings available to common stockholders by the weighted average number of outstanding common shares during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares outstanding during the period increased to include the number of additional shares of common stock that would have been outstanding if the potentially dilutive securities had been issued. During April 30, 2015, 2014 and 2013, the Company incurred losses; therefore the effect of any common stock equivalent would be anti-dilutive during these periods.

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 receivables and current liabilities each 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 ("ASC 820-10") and Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10"), 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 balance sheets, approximate fair value because of the short-term maturity of these instruments.

Derivative Instruments

The Company issued cashless warrants that are accounted for as a derivative instruments which prevents them from being considered indexed to the Company's common stock and qualified for an exception to derivative accounting.

The Company recognized the derivative instruments as either assets or liabilities on the accompanying consolidated balance sheets at fair value. The Company records changes in the fair value (i.e. gains or losses) of the derivatives in the accompanying consolidated statements of operations.

Revenue Recognition

Sales of products and related costs of products sold are recognized when: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured. These terms are typically met upon the prepayment or invoicing and shipment of products.

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 United States 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 our 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 our 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, 2015. As of April 30, 2015, the Company has paid Austrianova $1 million of the Upfront Payment. The parties have agreed to an amendment to the Cannabis Licensing Agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented. The $2 million cost of the license has been recorded as research and development costs.

Stock-Based Compensation

The Company's stock-based employee compensation awards are described in Note 9. The Company has adopted the provisions of ASC 718, which requires the fair value measurement and recognition of compensation expense for all stock-based awards made to directors, executives and employees.

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 $2,450,000 at April 30, 2015. 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 income and are included in other comprehensive loss. Gains and losses on short-term intercompany foreign currency transactions are recognized as incurred.

Reclassification

Certain prior year balances have been reclassified to conform to the 2015 presentation, with no changes in net loss for prior periods presented.

Recent Accounting Pronouncements

In May 2014, the FASB issued 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 June 2014, the FASB issued ASU No. 2014-12, *"Compensation - Stock Compensation* (Topic 718)," which makes amendments to the codification topic 718, "*Accounting for Share-Based Payments*," when the terms of an award provide that a performance target could be achieved after the requisite service period. The new guidance becomes effective for annual reporting periods beginning after December 15, 2015; early adoption is permitted. The Company is currently evaluating the impact this guidance will have on its consolidated financial position and results of operations.

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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.

NOTE 4 – BUSINESS ACQUISITION

Effective as of June 25, 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, 2015 and 2014 are summarized below:

	2015	2014
Accrued interest	$ –	$ 33,960
Deferred rent	1,480	–
Payroll related costs	19,539	–
Other	2,648	7,803
Total	$ 23,667	$ 41,763

NOTE 6 – DEBT

In November, 2013, the Company settled its obligation to pay $400,000 in licensing fees, for a licensing agreement terminated in 2009 with the issuance of 2,000,000 shares of common stock. The shares were valued at $226,000 using the closing share price of the common stock on the day of issuance resulting in a gain on settlement of debt of $174,000.

In February, 2014, the Company settled its obligation to pay $20,000 plus $6,000 of accrued interest to a note holder with the issuance of 250,000 shares of common stock. The shares were valued $45,500 using the closing share price of the common stock on the day of issuance resulting in a loss on settlement of debt of $19,500.

In December 2014, the Company entered into a licensing agreement for a license to use the Cell-in-a-Box® technology to develop therapies involving Cannabis. As of the date of this Report, the Company has paid $1,000,000 of a required $2,000,000 payment for the license.

NOTE 7 – COMMON STOCK TRANSACTIONS

During the year ended April 30, 2013, 8,771,429 shares of common stock were issued for various services. The shares were valued using the closing stock price on the day of issuance for a total expense of $331,000.

During the year ended April 30, 2013, 3,592,656 shares of common stock were issued to settle various debts. The shares were valued using the closing stock price on the day of issuance for a total expense of $143,596.

During the year ended April 30, 2013, 13,326,668 shares of common stock were issued to officers of the Company for compensation. The shares were valued using the closing stock price on the day of issuance for a total expense of $653,696.

During the year ended April 30, 2013, 500,000 shares of common stock were issued for $10,000 cash.

During the year ended April 30, 2013 the Company issued 39,622,400 shares of common stock for proceeds of $1,136,000, which were sold through the Company's Private Placement Memorandum at approximately $0.03 per share.

In May 2013, 75,000 shares of common stock were issued to settle debt of $32,392. The shares were valued using the closing share price of the common stock of the day of issuance, resulting in a gain on settlement of $21,142.

During the year ended April 30, 2014, a shareholder converted 8,500 shares of the Company’s Series E Preferred Stock (see Note 8) 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.

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 had committed to issue 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, the Company issued options to purchase 25 million shares to officers and directors. The options vested immediately and expire on September 30, 2019 and are exercisable at $0.19 per share. The grant of these options resulted in a current period expense of $4,307,822 and is included as a compensation expense in the consolidated statements of operations.

During the year ended April 30, 2015, the Company issued 600,000 shares of common stock to an officer as part of his compensation agreement in effect as of April 30, 2014. The non-cash expense for this share issuance was accrued in previous periods and totals $133,440. In addition, the Company issued 2,400,000 shares of common stock to officers as part of their compensation 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 $567,550.

During the year ended April 30, 2015, the Company issued 7,284,150 shares of common stock to consultants. The non-cash expense for these share issuances total $972,206.

During the year ended April 30, 2015, the Company issued 3,600,000 shares of common stock to officers as part of their compensation agreements. These shares vest on quarterly basis over a twelve-month period. The 900,000 shares that vested were valued at the date of vesting and resulted in a non-cash compensation expense of $125,460.

During the year ended April 30, 2015, the Company issued 1,200,000 shares of common stock to an employee as part of an employee agreement. These shares vest on quarterly basis over a twelve-month period. The 300,000 shares that vested were valued at the date of vesting and resulted in a non-cash expense of $41,820.

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 Act.

On October 24, 2014, the Company completed a $50 million underwritten public offering. During the year ended April 30, 2015 the Company sold and issued approximately 24.2 million shares of common stock at prices ranging from $0.10 to $0.24 per share. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately $3.7 million.

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 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. Thus, the full value for the convertible Series E Preferred Stock was recorded outside of stockholders' equity in the accompanying consolidated financial statements.

NOTE 9 – STOCK OPTIONS AND WARRANTS

Stock Options

The Company granted stock options to its directors, officers and an employee during the year ended April 30, 2015, 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 option-pricing model, based on the following assumptions:

	April 30,		
	2015	**2014**	**2013**
Risk-free interest rate	2%	–	–
Expected volatility	145%	–	–
Expected lives (years)	2.7	–	–
Expected dividend yield	0.00%	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, 2015, 2014 and 2013, 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. Based on historical experience, for the year ended April 30, 2015, the Company has estimated an annualized forfeiture rate of 5% for stock options granted to its employees, 5% for stock options granted to officers and 5% for stock options granted to directors. Compensation costs will be adjusted for future changes in estimated forfeitures. The Company will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated. No amounts relating to employee stock-based compensation have been capitalized.

At April 30, 2015, there remained approximately $533,000 of unrecognized compensation expense related to unvested stock options granted to current and former employees and directors, to be recognized as expense over a weighted-average period of one year.

Presented below is the Company's stock option activity for employees and directors:

The weighted average fair value of stock options granted during the years ended April 30, 2015, 2014 and 2013 are $0.10, $0.00 and $0.00, respectively.

A summary of the activity for unvested employee stock options during the three years ended April 30, 2015 is presented below:

	Options Outstanding	Weighted Average Grant Date Fair Value per Share
Nonvested, April 30, 2012	–	$ –
Granted	–	
Vested	–	
Forfeited	–	
Nonvested, April 30, 2013	–	–
Granted	–	–
Vested	–	–
Forfeited	–	–
Nonvested, April 30, 2014	–	
Granted	47,200,000	$ 0.14
Vested	40,600,000	0.15
Forfeited	–	–
Nonvested, April 30, 2015	6,600,000	$ 0.10

The Company recorded approximately $5,237,000, $0 and $0 of non-cash charges related to the issuance of stock options to certain directors and employees in exchange for services during the years ended April 30, 2015, 2014 and 2013, respectively.

At April 30, 2015, there remained approximately $558,000 (subject to change in the future based on vesting date fair value) of unrecognized compensation expense related to unvested employee stock options to be recognized as expense over a weighted-average period of one year.

Presented below is the Company's employee stock option activity during the three years ended April 30, 2015:

	Options Outstanding	Weighted Average Grant Date Fair Value per Share
Nonvested, April 30, 2012	–	$ –
Granted	–	
Vested	–	
Forfeited	–	
Nonvested, April 30, 2013	–	–
Granted	–	–
Vested	–	–
Forfeited	–	
Nonvested, April 30, 2014	–	
Granted	5,250,000	$ 0.19
Vested	5,250,000	0.19
Forfeited	–	–
Nonvested, April 30, 2015	–	$ –

The following table summarizes ranges of outstanding stock options at April 30, 2015:

	Exercise Prices		
Range of Exercise Price	$ 0.19	$ 0.11	$ 0.18
Number of Options	25,000,000	27,200,000	250,000
Weighted Average Remaining Contractual Life (years)	4.42	4.67	4.98
Weighted Average Stock Price	$ 0.19	$ 0.10	$ 0.18
Number of Options Exercisable	25,000,000	27,200,000	250,000
Weighted Average Contractual Life (years)	5	5	5
Weighted Average Exercise Price	$ 0.19	$ 0.10	$ 0.18

The aggregate intrinsic value of outstanding options as of April 30, 2015 was approximately $1,360,000. This represents options whose exercise price was less than the closing fair market value of the Company's common stock on April 30, 2015 of $0.16 per share.

Warrants

Warrants issued in connection with a consulting agreement are classified as liabilities as opposed to equity due to their settlement terms (see Note15). The other 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.

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, 2015, 18,755,200 Class A warrants were 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, 2015, 2,318,000 Class B warrants were 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.

On March 23, 2015, the Company granted 5,000,000 warrants to purchase common stock at an exercise price of $0.11 per share, which expire on December 31, 2015.

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.

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.

A summary of the Company's warrant activity and related information for the three years ended April 30, 2015 are shown below:

	Warrants	Weighted Average Price	Weighted Average Fair Value
Outstanding, April 30, 2012	–	$ –	$ –
Issued	59,433,600	0.125	0.064
Exercised	–	–	–
Outstanding, April 30, 2013	59,433,600	0.125	0.064
Issued	–	–	–
Exercised	(1,768,000)	–	–
Outstanding, April 30, 2014	57,665,600	0.18	0.065
Issued	15,854,308	–	–
Exercised	(550,000)	–	–
Outstanding, April 30, 2015	72,969,908	–	–
Exercisable, April 30, 2015	72,969,908	$ 0.17	$ 0.075

There were no cashless exercises of warrants on April 30, 2015 and 2014.

The following table summarizes additional information concerning warrants outstanding and exercisable at April 30, 2015:

Range of Exercise Prices	Number of Warrant Shares Exercisable at 04/30/2015	Weighted Average Remaining Contractual Life	Exercisable Weighted Average Exercise Price
$0.075, $0.11, $0.12, $0.18 and $0.25	72,969,908	2.86	0.17
Five Year Term - $0.075	1,056,000	2.45	
Five Year Term - $0.12	18,347,508	2.75	
Five Year Term - $0.18	19,811,200	2.67	
Five Year Term - $0.25	18,755,200	2.68	
Five Year Term - $0.11	10,000,000	4.90	
Nine Month Term - $0.11	5,000,000	0.67	
	72,969,908		

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 follows:

The Settlement Agreement with Cornerstone Bank, entered into on or about May 7, 2012, concluded a prior material legal proceeding. The settlement with Cornerstone Bank was fully satisfied with cash proceeds of $702,061 received by Cornerstone Bank through the sale of 6,374,977 of the 14,605,614 total shares of stock collateral that was held by them. Collateral held by Cornerstone in the form of 8,230,637 shares of common stock was returned to the Company. These shares were transferred to a third party as compensation for professional fees to be provided. The shares were valued at the closing price of the stock on the date of the final settlement agreement for total non-cash expense of $1,160,520. All obligations to Cornerstone have been satisfied. As a result of writing off the liability due to Cornerstone totaling $2,341,106 and the building asset and the accumulated depreciation totaling $1,028,778, the Company recognized a gain on settlement of debt of $1,312,328.

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 claim 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, Freedon-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, Inc. 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, Inc., 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, Inc. and Brown University are parties to an Intellectual Property License Agreement dated May 16, 2009. Brown University asserted a claim against the Company and Freedom-2, Inc. for $400,000 under the Property License Agreement. Although the Company and Freedom-2, Inc. 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 University, the Company and Freedom-2, Inc. pursuant to which the parties released each other for all claims relating to the Property License Agreement. In addition, the Company agreed to issue 2,000,000 shares of common stock to Brown University 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, 2015, 2014 and 2013, the Company owed Berkshire Capital $0, $0 and $393,158, 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, 2013 and 2014 were $393,158 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, 2013, the Company did not make any payments on these loans. 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, 2015, 2014 and 2013, the Company owed the Company's former Chief Financial Officer and Chairman of the Board, Patricia Gruden, $0, $0 and $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. The highest amount outstanding during the fiscal year ended April 30, 2013 was $25,940. 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 Dr. Robert F. Ryan, our former Chief Scientific Officer and former Chief Executive 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. The highest amount outstanding occurred during the fiscal year ended April 30, 2013 and totaled $283,743. During the year ended April 30, 2013, the Company made principal payments totaling $95,600 and no interest payments in respect of this loan. 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, Dr. 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 the Settlement Agreement pursuant to which the Company paid Dr. 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 $63,000.

Effective April 1, 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. Dr. 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, 2015 is approximately $97,000. In addition, the Company has issued 500,000 shares of common stock in connection with Dr. Gunzburg's services as the Chief Scientific Officer of the Company and 250,000 shares to Dr. Salmons for his services on the Company's 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, the Upfront Payments must be paid in full by no later than June 30, 2015. As of April 30, 2015, the Company has paid Austrianova $1 million of the Upfront Payment. The parties have agreed to an amendment to the Cannabis Licensing Agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented. The $2 million cost of the license has been recorded as research and development costs.

During the year ended April 30, 2015, the Company issued stock options to directors and officers (see Note 9).

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, 2015, 2014 and 2013 were $49,250, $49,085 and $56,763, respectively.

April 30, Year ending,	Amount
2016	$ 51,117
2017	12,873
	$ 63,990

Licensing Agreements

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.

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 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.

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, the Upfront Payments must be paid in full by no later than June 30, 2015. As of the April 30, 2015, the Company has paid Austrianova $1 million of the Upfront Payment. The parties have agreed to an amendment to the Cannabis Licensing Agreement pursuant to which the balance of the Upfront Payment will be due by December 31, 2015. That amendment is in the process of being documented.

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. 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.

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 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.

Consulting Agreement

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 MCB and WCB for our future clinical trials. There are approximately $195,000 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 agreement has a term of two years. The Company also entered into compensation agreements with two Board members in April 2015 which continue in effect until the member is no longer on the Board.

NOTE 13 - INCOME TAXES

At April 30, 2015, the Company had federal and state net operating loss carryforwards of $33,257,000 and $33,257,000, respectively, available to offset against future taxable income, which expire in 2019 through 2033.

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,	
	2015	**2014**
Deferred tax assets:		
Net operating loss carryforwards	$ 13,118,046	$ 21,328,813
Forgiveness of debt	–	555,349
Derivative liability	194,089	–
Other	8,291	–
Total deferred tax assets	13,320,426	21,884,162
Deferred tax liabilities:		
Shares issued for services	–	5,701,048
Conversion of preferred stock	–	2,004,300
Conversion of debt	–	1,357,720
Total deferred tax liabilities	–	9,063,068
Net deferred tax assets	13,320,426	12,821,094
Valuation allowance	(13,320,426)	(12,821,094)
	$ –	$ –

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, 2015 and 2014 were increases of $499,332 and $364,071, 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,		
	2015	2014	2013
Federal benefit at statutory rate	$ (3,690,533)	$ (8,871,790)	$ (543,355)
State income taxes, net of Federal taxes	(591,028)	(1,420,791)	(87,017)
Permanent differences	1,605,247	644,287	109,296
Provision related to change in valuation allowance	499,332	364,071	256,694
Return to provision	2,339,028	9,063,069	348,057
Other, net	(162,046)	221,154	(83,675)
	$ –	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended April 30, 2015.

The Company files income tax return in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2015, the tax returns for 2009 through 2014 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, 2015, 2014 and 2013, the Company had accrued no interest or penalties related to uncertain tax positions.

NOTE 14 – EARNINGS PER SHARE

Basic earnings per share are based on the weighted average number of shares outstanding for a period. Diluted earnings per share are based upon the weighted average number of shares and potentially dilutive common shares outstanding. Potential common shares outstanding principally include stock options, under our stock plan and warrants. During April 30, 2015, 2014 and 2013, 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,		
	2015	2014	2013
Net loss	$ (10,854,509)	$ (27,254,020)	$ (1,598,102)
Basic weighted average number of shares outstanding	704,327,656	583,219,665	440,954,850
Diluted weighted average number of shares outstanding	704,327,656	583,219,665	440,954,850
Basic and diluted loss per share	$ (0.02)	$ (0.05)	$ (0.00)

NOTE 15 – DERIVATIVE LIABILITY

A cashless warrant issued in connection with a marketing and consulting agreement is classified as a derivative liability as opposed to equity. This cashless warrant is a non-cash liability, and the Company is not required to expend any cash to settle this liability. The fair value of this cashless warrant is recorded on the balance sheets at issuance. The cashless warrant was marked to fair value at each financial reporting period, with changes in the fair value recorded as a gain or loss in the consolidated statements of operations. The fair value of the cashless warrants is determined using the Black-Scholes option pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. The following reflects the weighted-average assumptions for each of the periods indicated:

	Years Ended April 30,		
	2015	2014	2013
Risk-free interest rate	143%	–	–
Expected dividend yield	0%	–	–
Expected lives	5	–	–
Expected volatility	142%	–	–
Number of warrants classified as liability	3,487,271	–	–
Loss on warrant liability	$ 492,049	–	–

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. The expected lives are based on the remaining contractual lives of the related warrants at the valuation date. The Company's computation of expected volatility is based on the historical daily volatility of its publicly traded stock.

The derivative liability level within the fair value hierarchy is a Level 3 - Significant Unobservable Input.

The change in the fair value for Level 3 derivative liability for the year ended April 30, 2015, is as follows:

Beginning balance as of March 23, 2015	$ –
Change in unrealized loss	492,049
Ending balance as of April 30, 2015	$ 492,049

NOTE 16 – QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

	Quarter Ended 31 July	Quarter Ended 31 Oct	Quarter Ended 31 Jan	Quarter Ended 30 April
2015				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,583,160	6,200,845	1,456,554	4,454,930
Other income (expenses), net	(1,664)	3,336,402	(1,496)	(492,262)
Net loss	$ (1,584,824)	$ (2,864,443)	$ (1,458,050)	$ (4,947,192)
Net loss per common share, Basic and Diluted	$ (0.00)	$ (0.01)	$ (0.00)	$ (0.01)

	Quarter Ended 31 July	Quarter Ended 31 Oct	Quarter Ended 31 Jan	Quarter Ended 30 April
2014				
Net revenue	$ –	$ –	$ –	$ –
Cost of revenue	–	–	–	–
Gross profit	–	–	–	–
Operating expenses	1,400,691	448,570	681,080	16,448,801
Other income (expenses), net	(3,265,676)	(5,209,500)	222,308	(22.010)
Net loss	$ (4,666,367)	$ (5,658,070)	$ (458,772)	$ (16,470,811)
Net loss per common share, Basic and Diluted	$ (0.01)	$ (0.01)	$ (0.00)	$ (0.03)

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 17 – SUBSEQUENT EVENTS

From May 1, 2015 to July 16, 2015, the Company issued 9,328,713 shares of common stock under the S-3 Registration Statement. The issuance of the shares provided the Company approximately $1,220,000. The Company currently has $2,900,000 in cash as a result of the sales of common stock under the S-3 Registration Statement.

On May 19, 2015, the Company made a payment of $300,000 to Austrianova pursuant to the Licensing Agreement that was entered into in December 2014.

PHARMACYTE BIOTECH, INC. (FORMERLY NUVILEX, INC.)
SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS
Years Ended April 30, 2015, 2014 and 2013

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, 2015	$ 12,821,094	$ –	$ 499,332	$ –	$ 13,320,426
Year ended April 30, 2014	$ 12,457,023	$ –	$ 364,071	$ –	$ 12,821,094
Year ended April 30, 2013	$ 12,200,329	$ –	$ 256,694	$ –	$ 12,457,023

Exhibit 21.1

List of Subsidiaries

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

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. (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 and the effectiveness of the Company's internal control over financial reporting as of April 30, 2015, which appears in this Form 10-K.

/s/ Farber Hass Hurley LLP

Chatsworth, California
July 28, 2015

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PharmaCyte Biotech, Inc.
(Formerly Nuvilex, Inc.)
Silver Spring, Maryland 20904

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 years ended April 30, 2014 and 2013, which appears in this Form 10-K.

/s/ Robison, Hill & Co.
Certified Public Accountants
Salt Lake City, Utah
July 28, 2015

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, certify that:

1. I have reviewed this Annual Report on Form 10-K of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2015;

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 in the United States;

(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;

(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, 2015

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer and President
(Principal Executive Officer and acting Principal Financial and Accounting Officer on behalf of Registrant)

EXHIBIT 32.1

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

In connection with Annual Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-K for the year ended April 30, 2015 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, 2015

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer
(Principal Executive Officer and acting Principal Financial and 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.